Structural Heart 8 (2024) 100323

Articles and Issues Available at ScienceDirect

Structural Heart

journal homepage: www.structuralheartjournal.org

Research Correspondence

National Trends, In-Hospital Mortality, and Outcomes of Atrial Septal Defect/Patent Foramen Ovale Closure Procedure: An Analysis From the National Inpatient Sample

Kunal N. Patel, MD, MPH [a], Vidit Majmundar, MD [b], Monil Majmundar, MD [c], Harshvardhan Zala, MD [d], Rajkumar Doshi, MD, MPH [e], Vyoma Patel, MBBS [f], Sourbha S. Dani, MD, MSc [g], Irfan Zeb, MD [a], Brijesh Patel, DO [a], Ankur Kalra, MD [h,i,j,*]

[a] Department of Cardiology, West Virginia University Hospital, Morgantown, West Virginia
[b] Department of Internal Medicine, Saint Vincent Hospital, Worcester, Massachusetts
[c] Department of Cardiovascular Medicine, University of Kansas Medical Center, Kansas City, Kansas
[d] Department of Cardiology, Indiana University, Indianapolis, Indiana
[e] Department of Cardiology, St. Joseph's University Medical Center, Paterson, New Jersey
[f] Department of Internal Medicine, Maimonides Medical Center, Brooklyn, New York
[g] Department of Cardiology, Lahey Hospital & Medical Center, Burlington, Massachusetts
[h] Franciscan Health, Lafayette, Indiana
[i] Krannert Cardiovascular Research Center, Indianapolis, Indiana
[j] Indiana University School of Medicine, West Lafayette, Indiana

ARTICLE INFO

Article history:
Submitted 10 September 2023
Revised 17 April 2024
Accepted 25 April 2024
Available online 22 May 2024

Keywords:
atrial septal defect
bleeding
mortality
patent foramen ovale
stroke
trends

Introduction

Limited data exist on temporal trends of in-hospital mortality and complications after transcatheter and surgical atrial septal defect/patent foramen ovale (ASD/PFO) closure. We aimed to analyze trends of transcatheter and isolated surgical ASD/PFO closure procedures and in-hospital mortality and their complications.

Methods

The National Inpatient Sample database was queried for all who underwent transcatheter or surgical atrial septal repair or closure from 2016-2019. Due to the limitations of International Classification of Diseases-10 coding in distinguishing between PFO and ASD, this study collectively analyzed and described them together when adjunctive echocardiographic information was not available to differentiate between the two conditions. To obtain an isolated surgical ASD/PFO repair group, patients simultaneously undergoing other cardiac surgeries such as coronary artery bypass graft and valve (aortic, mitral, tricuspid, and pulmonary) surgeries were excluded. Biannual trends of transcatheter and surgical ASD/PFO closure procedures, in-hospital mortality, stroke, major bleeding requiring transfusion, and length of stay were studied from 2016-2019. We used the Jonckheere-Terpstra and Cochran-Armitage trend tests to analyze trends.

Results

A total of 19,005 adults with ASD/PFO closure were included, out of which 7785 (41%) had an isolated surgical approach and 11,220 (59%)

Abbreviations: ASD/PFO, atrial septal defect/patent foramen ovale; CLOSE, patent foramen ovale closure or anticoagulants versus antiplatelet therapy to prevent stroke recurrence; DEFENSE-PFO, device closure versus medical therapy for cryptogenic stroke patients with high-risk patent foramen ovale; REDUCE, Gore HELEX septal occluder and antiplatelet medical management for reduction of recurrent stroke or imaging-confirmed transient ischemic attack in patients with patent foramen ovale; RESPECT, randomized evaluation of recurrent stroke comparing PFO closure to established current standard of care treatment.

* Address correspondence to: Ankur Kalra, MD, Franciscan Health, 3900 St. Francis Way, Ste 200, Lafayette, IN 47905.
E-mail address: akalra@alumni.harvard.edu (A. Kalra).

https://doi.org/10.1016/j.shj.2024.100323

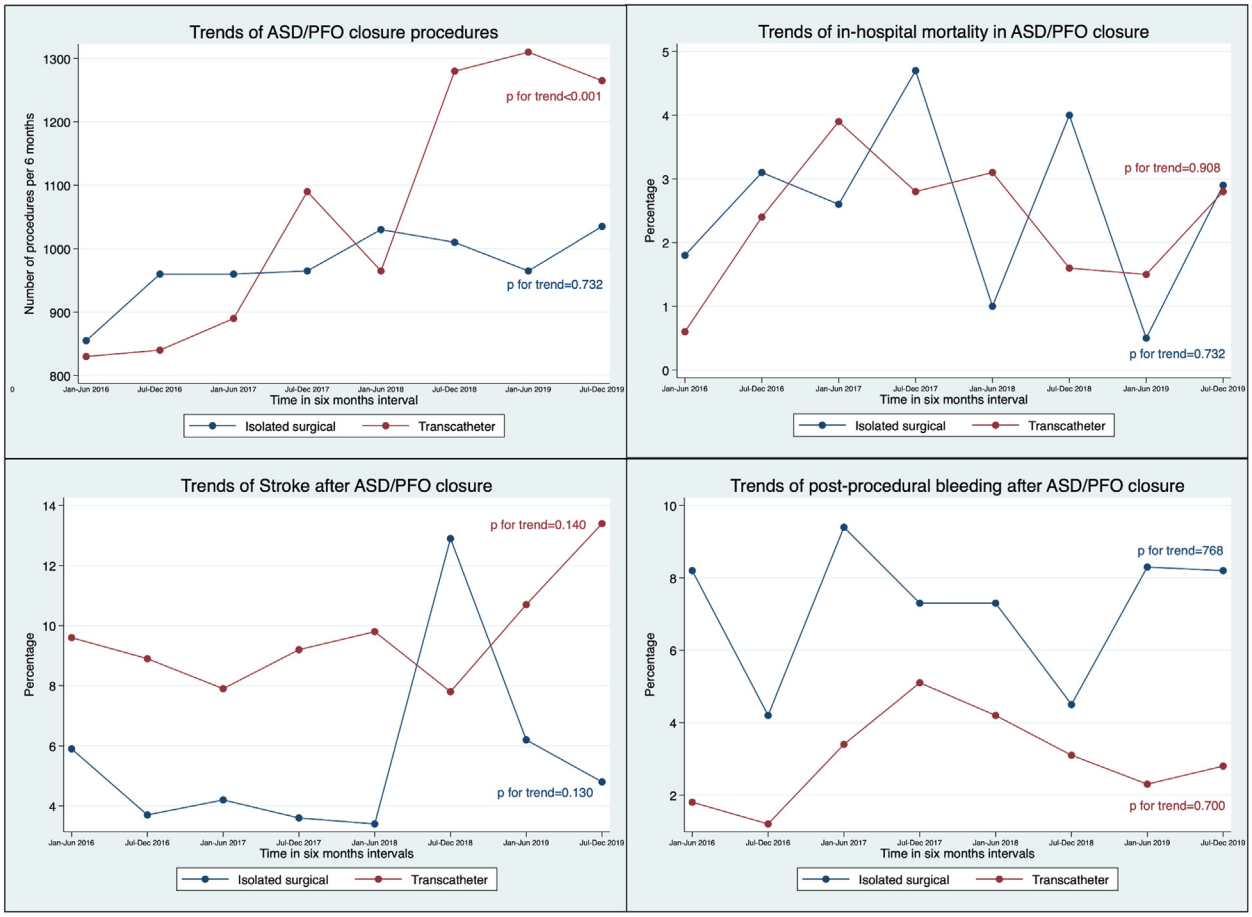

Figure 1. Trends of ASD/PFO closure procedures, in-hospital mortality, stroke, and postprocedural bleeding from 2016-2019. Trend of transcatheter ASD/PFO closure increased, while trend of isolated surgical closure did not change from 2016-2019. Trends of in-hospital mortality, stroke, and postprocedural bleeding did not change for both groups during the study period
Abbreviation: ASD/PFO, atrial septal defect/patent foramen ovale.

had transcatheter approach from 2016-2019. Overall, 530 (2.79%) patients died (200 [2.57%] in surgical group and 330 [2.94%] in transcatheter group). Trend of transcatheter closure increased significantly (p for trend < 0.001), while trend of surgical closure remained unchanged (p for trend $= 0.732$) from 2016-2019. Trends of in-hospital mortality, stroke, and major bleeding remained unchanged over time in both groups. Median length of stay decreased in the transcatheter group (3 days in 2016 to 2 days in 2019, $p = 0.04$), while it remained unchanged in the surgical group (7 days; Figure 1).

Discussion

Surgical ASD/PFO closure was first performed in the 1960s as open-heart surgery. A small case series in the 1980s and 1990s suggested that it was effective for stroke prevention. Surgical ASD/PFO closure predated transcatheter closure techniques but was not widely adopted prior to 2000 due to the inherent risks of open-heart surgery. The introduction of transcatheter ASD/PFO closure in the early 2000s led to a steady decline in surgical closure rates, while catheter-based procedures simultaneously increased, especially after positive trial data. Transcatheter closure has accelerated rapidly over the past decade, given its minimally invasive approach and favorable safety profile compared with surgery. Current estimates indicate an increase in the ASD/PFO closure rate from 4.66 per 100,000 person-years in 2006 to 6.43 per 100,000 person-years in 2019.[1] Our study concurs with the current data showing a significant increase in the use of transcatheter ASD/PFO closure compared with the surgical ASD/PFO closure procedure.

Several randomized controlled trials have directly compared outcomes between medical therapy and ASD/PFO closure, following which the Society of Cardiovascular Angiography and Interventions has developed an Expert Consensus Statement for managing ASD/PFO.[2,3] Closure of ASD/PFO is recommended mostly in patients aged <60 years with very high/high risk from the PFO-associated stroke causal likelihood classification and Risk of Paradoxical Embolism Score.[3] Transcatheter-based therapies are preferred over surgical interventions due to lower complication rates, shorter hospital stays, and faster recovery times. One potential tradeoff noted in comparative studies was a slightly higher rate of residual shunting after transcatheter closure.[4,5] Nevertheless, given the favorable safety profile and similar efficacy, current evidence from these direct comparative studies supports transcatheter ASD/PFO closure as the first-line treatment choice for most patients requiring ASD/PFO closure. Surgical closure is reserved for patients who are not candidates for the transcatheter procedure. In our study, we noticed no change in the trends of in-hospital mortality, stroke, and device-related complications between these two approaches. However, we showed an increased trend of major adverse event in the surgical group, reinforcing the fact that the transcatheter method is preferred.

In a meta-analysis by Butera et al.,[4] including 1270 surgical and 1812 percutaneous ASD/PFO closures, it was noted that patients with surgical ASD/PFO closure had 3.8 times higher odds of complications than percutaneous closure ($p < 0.01$). Bleeding, atrial arrhythmias, heart block, and pericardial effusion were significantly higher in the surgical arm. Our study did not perform any comparative analysis, but did find a higher percentage of complications or major adverse events in the surgical group

than in the transcatheter group. Interestingly, the trend of increased complications was also noted to be significant in the surgical group.

Several landmark clinical trials have helped demonstrate the safety and efficacy of transcatheter ASD/PFO closure compared with medical therapy alone for secondary stroke prevention in cryptogenic stroke patients with ASD/PFO. These include the Percutaneous Closure Trial showing noninferiority of transcatheter closure vs. surgery, RESPECT (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment) trial demonstrating fewer recurrent strokes with PFO closure compared with medical therapy, CLOSE (Patent Foramen Ovale Closure or Anticoagulants Versus Antiplatelet Therapy to Prevent Stroke Recurrence) trial supporting the superiority of closure over antiplatelet therapy alone, and Gore REDUCE (Gore HELEX Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent Stroke or Imaging-Confirmed Transient Ischemic Attack in Patients with Patent Foramen Ovale) trial leading to Food and Drug Administration approval of a closure device.[2] Some of the notable device-related complications included serious bleeding complications, device dislocation, device-related thrombosis, aortic dissection, and pulmonary embolism. However, these adverse events were reported to be insignificant compared with the control arm in the above trials. The incidence of atrial fibrillation/flutter was noted to be clinically significant in the PFO closure arm compared with antiplatelet therapy alone ($p < 0.001$) in the Gore REDUCE trial. The major limitations of the RESPECT, Gore REDUCE, and CLOSE trials include long-term monitoring for detecting atrial fibrillation. Ongoing trials like DEFENSE-PFO (Device Closure Versus Medical Therapy for Cryptogenic Stroke Patients with High-Risk Patent Foramen Ovale) and CLOSE-2 continue to study optimal PFO closure patient selection and techniques. In aggregate, the growing body of evidence from these pivotal trials has supported the adoption of transcatheter ASD/PFO closure as a standard therapy for selected cryptogenic stroke patients found to have ASD/PFO.

Use of this administrative database has its limitations, including the lack of outpatient data, probable coding mistakes, a lack of clinical granularity, a distinction between ASD and PFO, a shifting hospital sample over time, and a failure to capture global trends. Additionally, patient variables, clinician biases, ability to identify postdischarge stroke rates, and other confounders could affect the discovered patterns.

In conclusion, national trends show a steady increase in the number of transcatheter ASD/PFO closure procedures from 2016-2019. However, trends of in-hospital mortality, stroke, and postprocedural major bleeding did not change for both groups from 2016-2019 in the United States.

ORCIDs

Kunal N. Patel https://orcid.org/0000-0003-2712-0670
Vidit Majmundar https://orcid.org/0000-0002-4572-8957
Rajkumar Doshi https://orcid.org/0000-0002-5618-2750
Ankur Kalra https://orcid.org/0000-0003-0080-1660

Ethics Statement

The research reported has adhered to the relevant ethical guidelines.

Funding

This study was funded by makeadent.org, Ram and Sanjita Kalra Aavishqaar Fund.

Disclosure Statement

A. Kalra is the Chief Executive Officer and Creative Director of makeadent.org. The other authors had no conflicts to declare.

References

1 Goldsweig AM, Deng Y, Yao X, et al. Approval, evidence, and "Off-Label" device Utilization: the patent foramen ovale closure story. *Circ Cardiovasc Qual Outcomes*. 2024;17(1):e010200.
2 Giacoppo D, Caronna N, Frangieh AH, et al. Long-term effectiveness and safety of transcatheter closure of patent foramen ovale compared with antithrombotic therapy alone: a meta-analysis of six randomised clinical trials and 3,560 patients with reconstructed time-to-event data. *EuroIntervention*. 2018;14(8):857-867.
3 Kavinsky CJ, Szerlip M, Goldsweig AM, et al. SCAI Guidelines for the Management of patent foramen ovale. *Catheter Cardiovasc Interv*. 2022;1(4):100039.
4 Butera G, Biondi-Zoccai G, Sangiorgi G, et al. Percutaneous versus surgical closure of secundum atrial septal defects: a systematic review and meta-analysis of currently available clinical evidence. *EuroIntervention*. 2011;7(3):377-385.
5 Kotowycz MA, Therrien J, Ionescu-Ittu R, et al. Long-term outcomes after surgical versus transcatheter closure of atrial septal defects in adults. *JACC Cardiovasc Interv*. 2013;6(5):497-503.