 ● Koşuyolu Heart J 2023;26(1):14-19 • DOI: 10.51645/khj.20239903

# Clinical Characteristics and in-Hospital Outcomes of Patients Undergoing Left Atrial Appendage Closure

**Gönül Zeren[1](İD), Fatma Can[1](İD), Mustafa Azmi Sungur[1](İD), Şahin Yılmaz[2](İD), Can Yücel Karabay[1](İD)**

[1] Clinic of Cardiology, Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, İstanbul, Türkiye
[2] Clinic of Anaesthesiology, Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, İstanbul, Türkiye

## ABSTRACT

**Introduction:** Percutaneous left atrial appendage closure (LAAC) is considered in patients with non-valvular atrial fibrillation (AF) who cannot receive long-term anticoagulant therapy or who experience thromboembolism despite anticoagulant therapy. The structural feature of the left atrial appendage (LAA) and high variability of the clinical features of the patients endorse the difficulty of the procedure. In this study, it was aimed to present our single-center LAAC experience and in-hospital follow-up results of the patients.

**Patients and Methods:** Patients who had undergone LAAC in our cardiology clinic between 2017 and 2022 were included in the study retrospectively. All clinical, laboratory and imaging characteristics of the patients and in-hospital follow-up results were evaluated.

**Results:** Median age of 29 patients included in the study was 78 years (65-82, IQR= 25-75) and 17 were males (58.6%). Median score of $CHA_2DS_2$-VASc was 4 (4-6, IQR= 25-75). In addition, median value of the HAS-BLED score was 3 (3-4, IQR= 25-75). The rate of complete closure, minor bleeding during the procedure, and pericardial tamponade were 27 (93.1%), 1 (3.4%), and 1 (3.4%) respectively, and the device was dislocated immediately after the procedure in one patient (3.4%). The most common type of LAA appendix was chicken wings 15 (51.7%).

**Conclusion:** Success rate of the LAAC procedure was high in this single-center study conducted in our country with a relatively high number of patients.

**Key Words:** Atrial fibrillation; anticoagulant drugs; thromboembolism

## Sol Atriyal Apendiks Kapatma Yapılan Hastaların Klinik Özellikleri ve Hastane İçi Sonlanımları

## ÖZET

**Giriş:** Non-valvüler atriyal fibrilasyonu (AF) olan, uzun süreli antikoagülan tedavi alamayan ya da antikoagülan tedaviye rağmen tromboemboli geçiren olgularda, perkütan sol atriyal apendiks kapatma (SAAK) düşünülmektedir. Sol atriyal apendiksin (SAA) yapısal özelliği ile hastaların klinik özelliklerinin yüksek değişkenliği, prosedürün zorluğunu desteklemektedir. Biz bu çalışmada, tek merkezli SAAK deneyimimizi ve hastaların hastane içi takip sonuçlarını vermeyi amaçladık.

**Hastalar ve Yöntem:** Çalışmamıza kardiyoloji kliniğimizde 2017-2022 yılları arasında SAAK yapılan hastalar retrospektif olarak alındı. Hastaların tüm klinik, laboratuvar ve görüntüleme özellikleri ve hastane içi takip sonuçları değerlendirildi.

**Bulgular:** Çalışmaya dahil edilen toplam 29 hastanın yaş ortalaması 78 (65-82, IQR= 25-75) ve çoğunluğu erkek (%58.6) idi. $CHA_2DS_2$-VASc'nin medyan skoru 4 (4-6, IQR= 25-75) idi. Ayrıca HAS-BLED skorunun ortanca değeri 3 (3-4, IQR= 25-75) idi. İşlem sırasında tam kapanma, küçük kanama ve perikardiyal tamponad oranı sırasıyla 27 (%93.1), 1 (%3.4) ve 1 (%3.4) idi ve bir hastada işlemden hemen sonra cihaz yerinden çıktı (%3.4). SAA'nin en sık görülen tipi tavuk kanadı idi (%51.7).

**Sonuç:** Ülkemizde yapılan, tek merkezli, nispeten yüksek hasta sayısına sahip bu çalışmada, LAAK işleminin başarı oranı yüksektir.

**Anahtar Kelimeler:** Atriyal fibrilasyon; antikoagülan ilaçlar; tromboembolizm

***Cite this article as:*** *Zeren G, Can F, Sungur MA, Yılmaz Ş, Karabay CY. Clinical characteristics and in-hospital outcomes of patients undergoing left atrial appendage closure Koşuyolu Heart J 2023;26(1):14-19.*

**Correspondence**

**Gönül Zeren**

**E-mail:** gonulzeren@hotmail.com
**Submitted:** 13.10.2022
**Accepted:** 12.12.2022
**Available Online Date:** 21.03.2023

## INTRODUCTION

Atrial fibrillation (AF) is an important cause of mortality and morbidity due to increased risk of ischemic stroke. It is responsible for approximately 20-30% of all ischemic strokes[1-3]. Oral anticoagulant therapy, both vitamin K antagonist (VKA) and non-vitamin K antagonist oral anticoagulants (NOAC) are the only drugs to prevent ischemic stroke due to AF[2,4]. However, the use of anticoagulants may pose a safety risk, especially in patients who are elderly, have liver and renal dysfunction, have a high risk of bleeding due to use of other drugs and have a history of bleeding under anticoagulant therapy[5,6]. In cases where the HAS-BLED risk score, which is frequently used to evaluate individual bleeding risk, is 3 and above, the annual risk of major bleeding is around 5.8%[2].

Due to its general structure and characteristics, LAA is often the source of left atrial thromboembolism due to AF and is responsible for >90% of it[7]. For this reason, LAAC procedure has become widespread with increasing experience and technological developments in high-risk patients for whom OAC use is contraindicated or who develop thromboembolism under OAC. Short and long-term positive results have been supported by many randomized controlled studies[8-11].

In this study, it was aimed to present our LAAC experience in our single-center clinic, clinical, laboratory and imaging characteristics of our patients and in-hospital follow-up results.

## PATIENTS and METHODS

Patients who had undergone LAAC in our clinic between 2017 and 2022 were included in study retrospectively. An informed consent form was obtained from all patients before the procedure. All clinical, laboratory and imaging characteristics of the patients and in-hospital follow-up results were evaluated. Ethics committee approval for the study was obtained from Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee (Ethics Committee No: HNEAH-KAEK 2022/34).

### Procedure

Following percutaneous puncture of the femoral vein, left atrial access is gained by transseptal puncture, ideally in the infero-posterior part of the interatrial septum. Thereafter, a device-specific sheath is introduced to the LA over a stiff guidewire, which is either placed in the left upper pulmonary vein or in LA. LAA angiogram is performed through the delivery sheath or via a pigtail catheter in right anterior oblique caudal and cranial projections and, less importantly, left anterior oblique or lateral projections. LAA dimensions of the ostium, the neck, i.e., the landing-zone and depth are measured or estimated to help choose the appropriate occluder type and size. The occluder is advanced through the delivery sheath and positioned into the LAA. Its position is confirmed via fluoroscopy, transesophageal echocardiography (TEE), and a tug test is performed. Finally, the occluder is released.

In our center, closure was performed using TEE before and during the procedure, under deep sedation and general anesthesia, considering the patient's comorbidity. In all groups, intraprocedural monitoring included continuous invasive measurement of the arterial blood pressure via a radial artery catheter. Continuous ECG monitoring and pulse oximetry for transcutaneous arterial oxygen saturation were performed. All patients were followed up in the intensive care unit after procedure until they were awake and hemodynamic stability was achieved.

### Definitions

**$CHA_2DS_2$-VASc:** $CHA_2DS_2$-VASc score as previously described: 2 points each were assigned for age ≥75 years ($A_2$) and for history of stroke, TIA, or thromboembolism ($S_2$) and 1 point was assigned for each of the following items including congestive heart failure (C), hypertension (H), diabetes mellitus (D), age 65-75 years (A), vascular disease (VA) (defined as previous myocardial infarction, complex aortic plaque, carotid stenosis, and peripheral artery disease) and female sex category (Sc)[12,13].

**HAS-BLED:** HAS-BLED score as previously described: 1 point each were assigned for hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly (n> 65), and drugs/alcohol concomitantly[7].

**High bleeding risk:** A score of "≥3" according to the HAS-BLED score recognized as high bleeding risk.

**Classification of LAA morphology**: The chicken wing LAA, with an obvious bend in the proximal or middle part of the dominant lobe or folding back of the LAA anatomy on itself at some distance from the perceived LAA ostium. This type of LAA may have secondary lobes or twigs. The windsock LAA, with one dominant lobe of sufficient length as the primary structure. Variations of this LAA type arise with the location and number of secondary or even tertiary lobes arising from the dominant lobe. The cactus LAA, with a dominant central lobe with secondary lobes extending from the central lobe in both superior and inferior directions. The cauliflower LAA, with limited overall length with more complex internal characteristics. Variations of this LAA type have a more irregular shape of the LAA ostium (oval vs. round) and a variable number of lobes with lack of a dominant lobe. The "cauliflower" morphology is most often associated with an embolic event[14].

### Statistical Analysis

Continuous variables are presented as median and interquartile range (IQR). Categorical variables are presented as numbers and percentages. All statistical analyzes were performed with R version 4.0.4 (Vienna, Austria) using the "Hmisc" and "ggplot2" packages.

## RESULTS

Median age of 29 patients included in the study was 78 years (65-82, IQR= 25-75), and 17 were males (58.6%). Median score of $CHA_2DS_2$-VASc was 4 (4-6, IQR= 25-75). In addition, median value of the HAS-BLED score was 3 (3-4, IQR= 25-75). All demographic and clinical findings of the patients are summarized in Table 1. In Figure 1, the histogram of HAS-BLED and $CHA_2DS_2$-VASc scores of all patients is presented.

Eight of the patients (27.5%) had pre-implantation spontaneous echo contrast (SEC), and eight (27.6%) had pre-procedural NOAC use. The rate of complete closure, minor bleeding during the procedure, and pericardial tamponade were 27 (93.1%), one (3.4%), and one (3.4%) respectively, and the device was dislocated immediately after the procedure in one patient (3.4%). The most common type of LAA appendix was chicken wings found in 15 patients (51.7%). All procedural and imaging characteristics of the patients are given in Table 2.

## DISCUSSION

In high-risk patients who cannot receive oral anticoagulant therapy, who experience bleeding and thromboembolism during treatment, LAAC is a treatment option with a high success rate and predictable complication rate.

In the first randomized controlled PROTECT-AF trial on LAA closure devices, the Watchman (Boston Scientific Co., USA) device has been used, and it has been shown that LAA closure with the device was non-inferior to warfarin in preventing cerebrovascular events[8]. In the follow-up with another comprehensive randomized PREVAIL trial, it has also been observed that procedural safety was improved with less complication rate[9]. Five-year follow-up results of both trials have also been published; Watchman has shown that LAAC, non-inferior to warfarin, provides stroke prevention in nonvalvular atrial fibrillation and additional reductions especially in major bleeding, hemorrhagic stroke, and death[10]. In another recently published randomized controlled AMULET-IDE trial, it has been shown that for non-valvular atrial fibrillation, the Amulet (Abbott Vascular, USA) device was non-inferior to the Watchman device in terms of safety and effectiveness, and superior in terms of complete occlusion of the LAA. It has been observed that procedural complications were relatively higher in the Amulet group; however, it was decreased with operator experience. The most common procedural complications have been shown to be pericardial effusion and device embolization[11]. In recent years, due to increase in operator

**Table 1. Baseline clinical and laboratory characteristics**

| Variables | Overall group (n= 29) |
|---|---|
| Age (years) | 78 (65-82) |
| Sex (male) | 17 (58.6) |
| Hypertension | 28 (96.6) |
| Diabetes mellitus | 17 (58.6) |
| Hyperlipidemia | 12 (41.4) |
| Smoke | 5 (17.2) |
| COPD | 4 (13.8) |
| Congestive heart failure | 12 (41.4) |
| Body mass index ($kg/m^2$) | 27 (22-29) |
| NYHA class | |
| 1 | 15 (51.7) |
| 2 | 10 (34.5) |
| 3-4 | 4 (13.8) |
| Coronary artery disease | 19 (65.5) |
| Prior PCI | 9 (31) |
| CABG | 7 (24.1) |
| Prior TIA | 2 (6.9) |
| Prior stroke | 6 (20.7) |
| GFR ($mL/min/1.73\ m^2$) | 59.3 (23.9-73.1) |
| Hemoglobin (g/dL) | 10.5 (9.8-12.1) |
| $CHA_2DS_2$VASc score | 4 (4-6) |
| HAS-BLED score | 3 (3-4) |
| Albumin (g/dL) | 3.5 (3-3.9) |
| Neutrophil ($\times10^3/\mu L$) | 4.6 (3.3-5.9) |
| Lymphocyte ($\times10^3/\mu L$) | 1.1 (0.9-1.7) |
| ALT (IU/L) | 14 (11-19) |
| AST (IU/L) | 17 (12-25) |
| Total cholesterol (mg/dL) | 163 (132-199) |

Categorical data are presented as numbers (percentages) and continuous data are presented as median (interquartile range).

ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, CABG: Coronary artery bypass grafting, $CHA_2DS_2$VASC: Congestive heart failure, hypertension, age, diabetes mellitus, stroke, vascular diseases, sex category, COPD: Chronic obstructive pulmonary disease, GFR: Glomerular filtration rate, HAS-BLED: Hypertension, abnormal renal/liver function, stroke, bleeding history, labile international normalized ratio or INR, elderly >65 years, drugs/alcohol, NYHA: New York Heart Association, PCI: Percutaneous coronary intervention, TIA: Transient ischaemic attack.

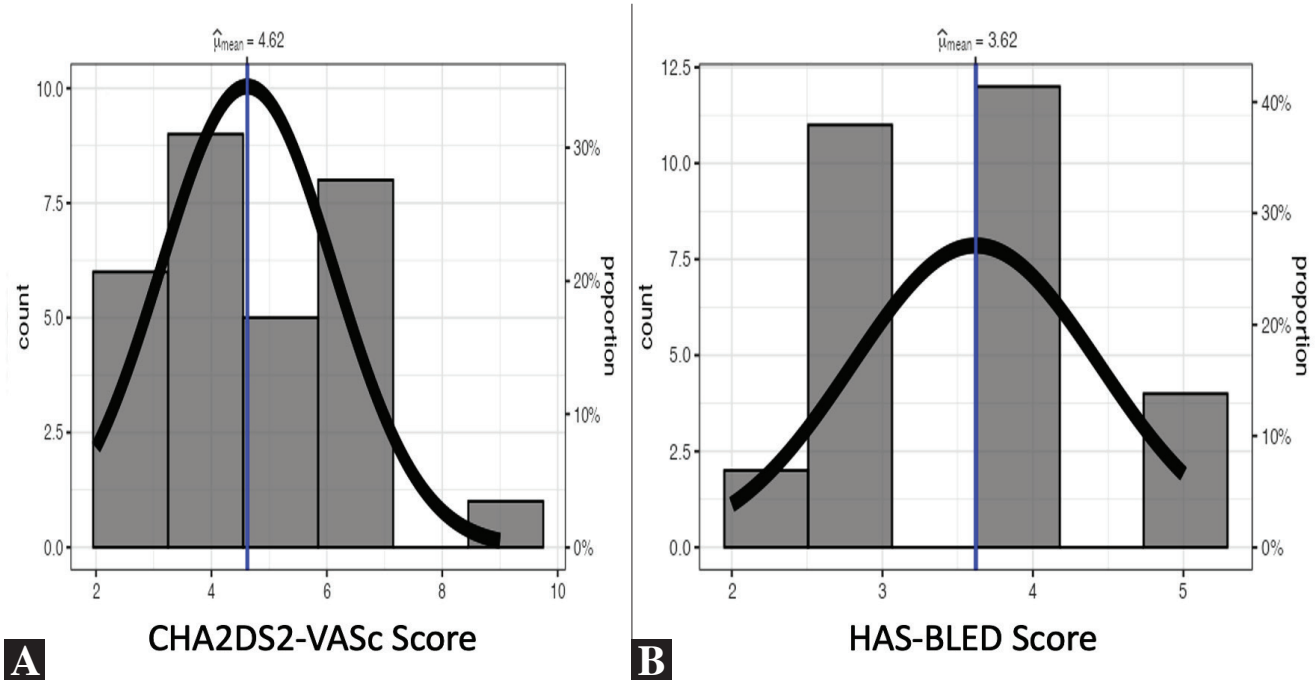


**Figure 1.** The histogram of HAS-BLED and CHA2DS2-VASc scores of all patients.

experience and the development of device features, the success rates of the procedure in LAAC have increased and the complication rates have been reduced. We had a high procedural success rate (93.1%) in our LAAC patients, in which we used the Amulet device. While device implantation success rate has been found as 90.9% in the PROTECT-AF study, the PREVAIL study has shown a 95.1% implantation success rate with new operators, similar to our study[8-10]. In the literature, it has been shown that pericardial effusions requiring surgical repair or pericardiocentesis decrease with increasing operator experience[8-11]. Pericardial effusion was seen in only one patient in our study, and device dislocation was also seen in one patient. A difference of our study to PROTECT-AF and PREVAIL studies is that the median CHA2DS2-VASc score was 4 compared to 2.2 in PROTECT-AF and to 2.6 in PREVAIL. However, CHA2DS2-VASc and HAS-BLED scores were similar to AMULET IDE (4.5 and 3.2, respectively)[8-11].

Since LAAC is a preventative treatment, it is extremely important to keep periprocedural complications low. Due to the heterogeneous anatomy of LAA, the procedure can be challenging. The success and complication of the procedure depend on several factors, such as patient characteristics and comorbidities, operator experience and device specifications. Good cardiac imaging is essential to evaluate LAA thrombus and its anatomical structure before the procedure and to ensure correct positioning of the device during the procedure. For this purpose, TEE, computed tomography (CT) is usually performed before the procedure, as well as TEE or intracardiac echocardiography during the procedure.

In nonvalvular AF, >90% of left atrial thrombi are found in LAA[7]. LAA is a tube-shaped blind sac with a volume of 5-15 mL extending from the main body of the atrium. It often has an oval-shaped mouth, and its inner surface is trabeculated by pectinate muscles. It can be a single-lobed and often more than one-lobed structure. Thrombus formation in this region is common during AF due to both atrial contractility, stasis and hypercoagulation, and the structure of LAA. In the literature, LAA has been classified into four main types according to its morphological structure[14]. These include chicken wing, windsock, cactus, and cauliflower, and the most common type is chicken wing. LAA morphology has been shown to affect the risk of thromboembolic events. Stroke or transient ischemic attack (TIA) is more common in the cauliflower type than in the chicken wing or windsock type. The morphological diversity of LAA also affects the success and complication rates of the interventional procedure. Chicken wing type LAA was observed in 51.7% of our patients.

**Study Limitations**

This study had several limitations. Although it was one of the centers where the most LAAC procedures were performed in the country during the study period, the number of patients in the study was small. Since the outcomes in our study were few, the results should be evaluated carefully. The retrospective design of the study was another important limitation.

**Table 2. Procedural and imaging characteristics**

| Variables | Overall group (n= 29) |
|---|---|
| LAA SEC | 8 (27.5) |
| NOAC use | 8 (27.6) |
| Warfarin use | 12 (41.4) |
| Antiplatelet use | 17 (58.6) |
| Reason of implantation | |
| GIS bleeding | 8 (27.6) |
| Intracranial bleeding | 3 (10.3) |
| High bleeding risk (no event) | 8 (27.6) |
| High bleeding risk (event) | 2 (6.9) |
| Recurrent bleeding | 6 (20.7) |
| Poor drug compliance | 1 (3.4) |
| Repeated CVA | 1 (3.4) |
| Complete closure (non/or <3 mm) | 27 (93.1) |
| Minor bleeding | 1 (3.4) |
| Immediate device dislocation | 1 (3.4) |
| Pericardial effusion | 1 (3.4) |
| LAA length (mm) | 22 (19-25) |
| LAA ostium (mm) | 19 (18-22.5) |
| Landing zone (mm) | 16 (14-17) |
| Device size (mm) | 25 (25-28) |
| LAA anatomy | |
| Chicken wing | 15 (51.7) |
| Windsock | 8 (27.6) |
| Cactus | 4 (13.8) |
| Cauliflower | 2 (6.9) |

Categorical data are presented as numbers (percentages) and continuous data are presented as median (interquartile range).

CVA: Cerebrovascular accident, GIS: Gastrointestinal system, LAA: Left atrial appendage, NOAC: Non-vitamin K antagonist, SEC: Spontaneous echo contrast.

## CONCLUSION

The success rate of the LAAC procedure is high in this single-center study conducted in our country with a relatively high number of patients. LAAC should be kept in mind as an alternative treatment in patients with nonvalvular atrial fibrillation (AF), who cannot receive long-term anticoagulant therapy, or who develop thromboembolism despite anticoagulant therapy.

**Ethics Committee Approval:** The study was approved by the ethics committee of Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee (Decision no: HNEAH-KAEK 2022/34, Date: 21.02.2022).

**Informed Consent:** This is retrospective study, we could not obtain written informed consent from the participants.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept/Design – GZ, CYK; Analysis/Interpretation – GZ, CYK; Data Collection - FC, ŞY; Writing – GZ, FC; Critical Revision – GZ, CYK, MAS; Final Approval - MAS; Statistical Analysis – CYK, MAS.

**Conflict of Interest:** The authors have no conflicts of interest to declare.

**Financial Disclosure:** The authors declare that this study has received no financial support.

## REFERENCES

1. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC Jr, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation 2014;130(23):199-267. [Crossref]
2. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, et al. 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 2016;37(38):2893-962. [Crossref]
3. Benjamin EJ, Muntner P, Alonso A, Bittencourt MS, Callaway CW, Carson AP, et al. Heart disease and stroke statistics-2019 update: A report from the American Heart Association. Circulation 2019;139(10): e56-528.
4. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland Jr JC, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons. Circulation 2019;140(2):125-51. [Crossref]
5. Hylek EM, D'Antonio J, Evans-Molina C, Shea C, Henault LE, Regan S. Translating the results of randomized trials into clinical practice: The challenge of warfarin candidacy among hospitalized elderly patients with atrial fibrillation. Stroke 2006;37(4):1075-80. [Crossref]
6. Kuno T, Takagi H, Ando T, Sugiyama T, Miyashita S, Valentin N, et al. Oral anticoagulation for patients with atrial fibrillation on long- term hemodialysis. J Am Coll Cardiol 2020;75(3):273-85. [Crossref]
7. Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: The Euro Heart Survey. Chest 2010;138(5):1093-100. [Crossref]
8. Reddy VY, Sievert H, Halperin J, Doshi SK, Buchbinder M, Neuzil P, et al. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: A randomized clinical trial. JAMA 2014;312(19):1988-98. [Crossref]
9. Holmes DR Jr, Kar S, Price MJ, Whisenant B, Sievert H, Doshi SK, et al. Prospective randomized evaluation of the Watchman left atrial appendage closure device in patients with atrial fibrillation versus long-term warfarin therapy: The PREVAIL trial. J Am Coll Cardiol 2014;64(1):1-12. [Crossref]
10. Reddy VY, Doshi SK, Kar S, Gibson DN, Price MJ, Huber K, et al.; PREVAIL and PROTECT AF Investigators. 5-year outcomes after left atrial appendage closure: From the PREVAIL and PROTECT AF trials. J Am Coll Cardiol 2017;70:2964-75. [Crossref]

11. Lakkireddy D, Thaler D, Ellis CR, Swarup V, Sondergaard L, Carroll J, et al. Amplatzer amulet left atrial appendage occluder versus watchman device for stroke prophylaxis (Amulet IDE): A randomized, controlled trial. Circulation 2021;144(19):1543-52. **[Crossref]**

12. Camm AJ, Kirchhof P, Lip GYH, Schotten U, Savelieva I, Ernst S, et al. Guidelines for the management of atrial fibrillation. Euro Heart J 2010;31:2369-429. **[Crossref]**

13. Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor based approach: The Euro Heart survey on atrial fibrillation. Chest 2010;137:263-72. **[Crossref]**

14. Di Biase L, Santangeli P, Anselmino M, Mohanty P, Salvetti I, Gili S, et al. Does the left atrial appendage morphology correlate with the risk of stroke in patients with atrial fibrillation? Results from a multicenter study. J Am Coll Cardiol 2012;60:531-8. **[Crossref]**