Long-term outcomes in patients after left atrial appendage occlusion: The results from the LAAO SILESIA registry

Krzysztof Myrda[1], Witold Streb[2], Wojciech Wojakowski[3], Jacek Piegza[1], Katarzyna Mitręga[2], Grzegorz Smolka[3], Jolanta Nowak[1,4], Tomasz Podolecki[2], Ewa Gasiewska-Żurek[3], Alicja Nowowiejska-Wiewióra[1], Malwina Smolarek-Nicpoń[3], Michał Skrzypek[5], Mariusz Gąsior[1, 4], Zbigniew Kalarus[2]

[1]3rd Department of Cardiology, Silesian Center for Heart Diseases, Zabrze, Poland
[2]Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Division of Medical Sciences in Zabrze, Medical University of Silesia, Zabrze, Poland
[3]Department of Cardiology and Structural Heart Diseases, 3rd Division of Cardiology, Medical University of Silesia, Katowice, Poland
[4]3rd Department of Cardiology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland
[5]Department of Biostatistics, School of Health Sciences in Bytom, Medical University of Silesia, Katowice, Poland

Correspondence to:
Krzysztof Myrda, MD, PhD,
3rd Department of Cardiology,
Silesian Center for Heart Diseases,
M Skłodowskiej-Curie 9,
41–800 Zabrze, Poland,
phone: +48 506 603 277,
e-mail: k_myrda@interia.pl

DOI: 10.33963/KP.a2022.0047

Received:
September 24, 2021

Accepted:
February 12, 2022

Early publication date:
February 15, 2022

ABSTRACT

Background: The benefits of oral anticoagulation (OAC) therapy are undeniable. However, such treatment is contraindicated in 2%–10% of patients. According to the latest guidelines, percutaneous left atrial appendage occlusion (LAAO) may be considered in stroke prevention.

Aims: We analyzed the data of patients from the Polish population, who had undergone LAAO procedures in the Silesian Province based on limited reports.

Methods: The data from the SILCARD database of all patients who underwent LAAO between 2006 and 2019, and the data from the databases of the centers performing the procedures in the Silesian Province were included in the LAAO SILESIA registry. We analyzed the efficacy and safety of the procedure and its relationship with the occurrence of stroke and bleeding in the post-hospital follow-up.

Results: We analyzed 649 patients with the mean values of CHA2DS2-VASc and HAS-BLED scores of 4.1 and 3.2, respectively. The predominant indication for LAAO was a history of bleeding during OAC. The most frequent in-hospital major adverse cardiac events were anemia, which required blood transfusion (5.5%), and pericardial effusion, which was treated either conservatively (0.9%) or interventionally (1.2%). During hospitalization, stroke was detected in 4 patients and three patients died of any cause. LAAO reduced the annual risk of stroke by 84% and the annual risk of bleeding by 27%.

Conclusions: Based on a "real-life" cohort of patients from the Silesian Province, we concluded that LAAO is related to low in-hospital major cardiovascular adverse events. In the long-term follow-up, LAAO reduced the rates of stroke and bleeding.

Key words: atrial fibrillation, left atrial appendage occlusion, stroke

INTRODUCTION

Atrial fibrillation (AF) is the predominant cardiac arrhythmia whose prevalence increases with age. In addition to clinical symptoms, a diagnosis of AF is associated with a higher risk of stroke and a poorer prognosis [1, 2]. Many papers and study results demonstrate that anticoagulant therapy is effective in reducing the risk of ischemic stroke and overall mortality in patients with AF [3, 4]. Although the benefits of oral anticoagulation (OAC) therapy are undeniable, such treatment is contraindicated in 2%–10% of patients [5, 6]. In the light of the above, according to the latest guidelines of the European Society of Cardiology (ESC) and the 2016 and 2020 guidelines of the Polish Cardiac Society, percutaneous left

WHAT'S NEW?

The benefits of oral anticoagulation (OAC) therapy are undeniable. However, such treatment is contraindicated in some patients. According to the latest guidelines, percutaneous left atrial appendage occlusion (LAAO) may be considered in stroke prevention. Evidence for the benefits of this form of therapy is provided by subsequent studies. Among these studies, the analyses based on patient data from the Polish population are limited. Therefore, we analyzed details of patients undergoing LAAO with the unique methodology of SILCARD registry with data from the centers in which such procedures were performed. We found LAAO to be associated with low in-hospital major cardiovascular events, and reduce rates of stroke and bleeding in the long-term follow-up

atrial appendage occlusion (LAAO) may be considered in stroke prevention [3, 4].

Since the introduction of the first LAAO procedures in the early 2000s, clinical experience and knowledge in this field have increased [7–9]. Various studies have shown that LAAO is associated with good short- and mid-term results regardless of the type of device used [8, 10–17].

Among these studies, the analyses based on patient data from the Polish population are limited. This prompted us to analyze patients undergoing LAAO in the Silesian Province using the unique methodology of the SILCARD registry completed with data from centers performing such procedures. The specific aim of our study was to analyze the efficacy and safety of the procedure and its relationship with the occurrence of stroke and bleeding in the post-hospital follow-up in a "real-life" cohort of patients.

METHODS

Data source

The data utilized in our registry were collected as part of the Silesian Cardiovascular Database (SILCARD) (ClinicalTrials.gov identifier, NCT02 743 533; https://clinicaltrials.gov/ct2/show/NCT02743533). General information on SILCARD was previously reported [18]. Briefly, the database contains records from all hospitals (n = 310) in the Silesian Province, which is a large administrative region in southern Poland with a population of 4.57 million people (approximately 12% of the total population of Poland), including 3.80 million adults. The Silesian Province provides a well-developed hospital network with two tertiary cardiology hospitals, three cardiac surgery departments, and 20 catheterization laboratories. The National Health Fund (NHF), which is the only public health care provider in Poland, has supplied all data to the database since 2006. The inclusion criteria were as follows: each hospitalization in the departments of cardiology, cardiac surgery, diabetology, or vascular surgery and hospitalization with a cardiovascular diagnosis in the department of internal medicine or intensive care. The exclusion criteria were hospitalizations of patients living outside of the Silesian Province and patients younger than 18 years on admission. The collected data included information on initial hospitalization with a diagnosis of cardiovascular disease (CVD) with a potential transfer to another department or hospital, other hospitalizations, and data from outpatient visits. If the patient was rehospitalized for CVD within 24 hours, both hospitalizations were considered one admission. According to the applicable rules, hospitals are obliged to report to the NHF on the principal diagnosis with up to two comorbidities defined by the International Classification of Disease, 10th Revision (ICD-10), and on medical procedures defined by the ICD-9 classification. CVD was defined as R52, J96, or any "I" code based on the ICD-10. The hospital registry number and the national identification number (PESEL) were used to match the information on each patient. All data were anonymized. The SILCARD registry was approved by the local Bioethics Committee.

The selected parameters of baseline characteristics and in-hospital course were completed from the databases of the centers performing the procedures (Silesian Center for Heart Diseases in Zabrze; Upper-Silesian Medical Center in Katowice; American Heart of Poland — Medical Center in Bielsko-Biała).

Study population

The analysis included all patients from the SILCARD database from January 1, 2006 to December 31, 2019 with atrial flutter or atrial fibrillation coded according to the ICD-10 as I48 who underwent percutaneous LAAO with the principal procedure coded according to the ICD-9 (international classification system for surgical, diagnostic, and therapeutic procedures, 9th Revision) as 37.4901. The exclusion criteria included residency outside of the Silesian Province and age under 18 years at the time of LAAO. As a result, the patient registry became known as the LAAO SILESIA.

Study data

Data available from the NHF included the total number of patients who had undergone percutaneous LAAO, their sex, age, comorbidities, hospitalization, and mortality. Screening for comorbidities was performed in hospital settings. Data were reported to the NHF using the ICD-10 and ICD-9 codes as primary or coexisting diagnoses. For the study, variables were defined as indicated in Table 1. Based on these baseline characteristics, stroke risk was calculated using the CHA2DS2-VASc clinical risk scale.

Table 1. Analyzed variables according to the ICD-9 and ICD-10 diagnostic codes

Analyzed parameters	Adopted ICD-10 codes
Arterial hypertension	I10–I13, I15
Bleeding, including bleeding from the gastrointestinal tract, genital tract, urinary tract, and respiratory tract	K62.5, K92.0, K92.1, K92.2, N02, R31, N93, R04.2, R04.8, R04.9
Chronic coronary syndrome	I25, I20.1, I20.8, I20.9
Chronic kidney disease	N17–N19
Death	I46.1, R96.0, I46.9, R96.1, R99
Diabetes mellitus	E10–E14
Hematopoietic system disease	D60, D61, D63, D64, D68, D69
Heart failure	I50, I42
Hemorrhagic shock or hemorrhage	R57.1, R58
Intraocular bleeding	H35.6, H43.1, H44.8, H45.0
Myocardial infarction	I21–I22
Pericardial effusion treated conservatively	I31.3, I31.2
Peripheral artery disease	I65–I67, I70.0, I70.1, I70.2, I70.8, I70.9, I77–I79
Ischemic, hemorrhagic, and undetermined stroke	I60–I64
Systemic arterial embolism	I74.0, I74.1, I74.2, I74.3, I74.4, I74.5, I74.8, I74.9
Transient ischemic attack	G45
Unstable angina	I20.0, I24.0, I24.8, I24.9
Analyzed procedures	**Adopted ICD-9 codes**
Blood transfusion requirement	99.04
CRT device implantation	00.50, 00.51, 00.52, 00.53, 0054, 37.792, 37.997
Coronary artery bypass grafting	36.11, 36.12, 36.13, 36.14, 36.15, 36.16, 36.17, 36.19
ICD implantation	37.941-944, 37.961, 37.962, 37.97, 37.991, 37.996
Percutaneous coronary intervention	00.45, 00.46, 00.47, 00.48, 00.661, 00.662, 36.06, 36.07, 36.09, 36.10
Pericardial effusion treated interventionally or surgically	37.0, 37.123
Pacemaker implantation	37.8

Abbreviations: CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator

From the databases of the centers performing the procedures, the additional detailed in-hospital data were included (1) the major bleeding risk score according to the HASBLED score; (2) a history of bleeding during oral anticoagulation therapy without a reversible cause; (3) periprocedural successful implant deployment; and (4) the anti-platelet/anti-thrombotic drugs at the discharge.

The following follow-up data were collected: (1) bleeding, including the need for blood transfusion; (2) transient ischemic attack (TIA), stroke, including fatal and non-fatal stroke; (3) systemic embolism; and (4) all-cause mortality.

Statistical analysis

Continuous variables were summarized using the arithmetic mean with standard deviation (SD) for normal distribution or the median with interquartile range (IQR) for non-normal distribution. Normality of distribution was verified using the Shapiro-Wilk test. Categorical variables were summarized using frequency tables.

The event-free survival probability (stroke and bleeding) after discharge was presented using the Kaplan-Meier method. The time to occurrence of the event (i.e. stroke and bleeding) was calculated after the discharge. If the events did not occur until February 1, 2020, this date was considered the end of the follow-up for all patients.

The patient annual risk of stroke was recorded based on the subject's CHA2DS2-VASc score, and then the average risk score for the study population was calculated. The annual risk of stroke and bleeding was then extrapolated from the published literature [19] and related to risk score estimation to determine the influence of LAAO on risk reduction in the analyzed group.

The calculations were performed using STATISTICA PL version 10 (StatSoft, Inc., Tulsa, OK, US).

RESULTS

The group we analyzed, included 649 patients. The number of procedures per year reached 25 in 2011, 6 in 2012, 8 in 2013, 62 in 2014, 71 in 2015, 92 in 2016, 116 in 2017, 124 in 2018, and 145 in 2019. The following number of LAAO procedures was performed per center in the analyzed period: (1) Silesian Center for Heart Diseases in Zabrze — 325; (2) Upper-Silesian Medical Center in Katowice — 208; (3) American Heart of Poland — Medical Center in Bielsko-Biała — 116.

Baseline characteristics

The mean (SD) age of patients eligible for LAAO was 73 (8) years. The mean (SD) values of CHA2DS2-VASc and HAS-BLED scores were 4.1 (1.9) and 3.2 (1.0), respectively. A history of bleeding on OAC without a reversible cause was the main indication for the LAAO procedure (81% of patients). In 17% of patients, a contraindication to OAC therapy was listed as an indication for LAAO. However, it was not specified. In addition, the ineffectiveness of long-term optimal anticoagulation in 9 patients and hematological disorders in 3 patients were reported. In most patients, chronic coronary syndrome, chronic heart failure, and hypertension were diagnosed. Baseline characteristics are listed in Table 2.

In-hospital course

The deployment of the occluder was successfully performed in 99.1% of patients. Postprocedural dual anti-platelet therapy with aspirin and clopidogrel was the primary treatment. Table 3 shows other important in-hospital course data, including the in-hospital need for blood transfusion in 36 patients (5.5%). In 8 patients, interventional or surgical treatment was necessary due to pericardial effusion, and stroke was reported in 4 patients. Two adverse events were reported in 3 patients, whereas 3 adverse events were observed in one patient during an in-hospital stay. In a 71-year-old female, pericardiocentesis followed by surgical treatment was necessary due to periprocedural tamponade. During hospitalization, 3 patients died of any

Table 2. Baseline characteristics

Characteristics	
Age, years, mean (SD)	73 (8)
Sex, male, n (%)	378 (58.2)
Atrial fibrillation, n (%)	649 (100)
CHA2DS2-Vasc score, mean (SD)	4.1 (1.9)
HASBLED score, mean (SD)	3.2 (1.0)[a]
Hypertension, n (%)	443 (68.3)
Heart failure, n (%)	274 (42.2)
Coronary artery disease, n (%)	361 (55.6)
Peripheral artery disease, n (%)	147 (22.7)
Diabetes mellitus, n (%)	154 (23.7)
Chronic kidney disease, n (%)	54 (8.3)
Previous MI, n (%)	110 (16.9)
Previous UA, n (%)	137 (21.1)
ACS until 12 months before LAAO, n (%)	76 (11.7)
Previous PCI, n (%)	192 (29.6)
Previous CABG, n (%)	37 (5.7)
Previous TIA, n (%)	40 (6.2)
Previous stroke, n (%)	145 (22.3)
Previous ischemic stroke, n (%)	109 (16.8)
Previous hemorrhagic stroke, n (%)	45 (6.9)
Previous bleeding, total, n (%)	431 (80.9)*
Previous systemic embolism, n (%)	8 (1.2)
Hematopoietic system disease, n (%)	75 (11.6)
Implanted PM/CRT-P, n (%)	116 (17.9)
Implanted CRT-D/ICD, n (%)	64 (9.9)

[a]Data available for 533 patients

Abbreviations: ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; LAAO, left atrial appendage occlusion; MI, myocardial infarction; PCI, percutaneous coronary intervention; PM, pacemaker; SD, standard deviation; TIA, transient ischemic attack; UA, unstable angina

Table 3. In-hospital course data

Characteristics	
Successful implant deployment, n (%)	528 (99.1)[a]
Drugs at discharge	
Aspirin, n (%)	530 (99.4)[a]
Clopidogrel, n (%)	529 (99.2)[a]
In-hospital adverse events	
Pericardial effusion, conservative treatment, n (%)	6 (0.9)
Need for blood transfusion, n (%)	36 (5.5)
Pericardial effusion, interventional/surgical treatment, n (%)	8 (1.2)
TIA, n (%)	3 (0.5)
Stroke, total, n (%)	4 (0.6)
Non-fatal stroke, n (%)	3 (0.5)
Fatal stroke, n (%)	1 (0.2)
In-hospital death, n (%)	3 (0.5)

[a]Data available for 533 patients

Abbreviation: TIA, transient ischemic attack

cause. Pericardial effusion and multiorgan failure leading to death were observed in a 74-year-old male on day 29 after LAAO. On the first day after the procedure, a 77-year-old female died due to a stroke. After successful surgical removal of the occluder directly after LAAO in a 51-year-old female, multiorgan failure developed, which resulted in the patient's death on the same day.

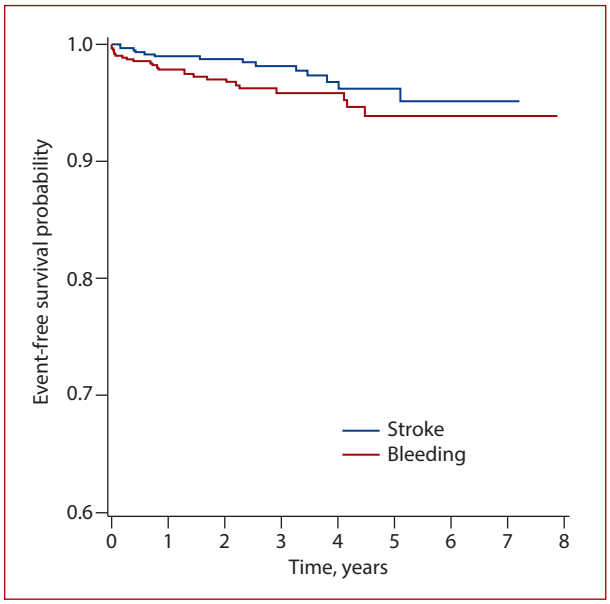

Figure 1. Freedom from stroke (the blue curve) and bleeding (the red curve) after discharge presented by the Kaplan-Meier curve

Follow-up data

In a long-term follow-up with a median (interquartile range, [IQR]) of 777 (339–1324) days, TIA was diagnosed in 9 (1.4%) patients and stroke in 14 (2.2%) patients, including one subject who died due to a stroke. Among patients with stroke, 13 subjects were diagnosed with ischemic stroke and 1 with hemorrhagic stroke. Bleeding was reported in 25 patients (3.9%), including 9 patients (1.4%) who required blood transfusion. Systemic embolism was observed in 4 patients.

In a 12-month follow-up, ischemic stroke was reported in 5 patients (0.8%), whereas bleeding in 14 patients (2.2%). Considering the above and based on CHA2DS2-Vasc and HASBLED scores, LAAO reduced the annual risk of stroke by 84% and the annual risk of bleeding by 27% (Figure 2). Among the group of patients discharged from the hospital, 132 (20.4%) subjects died of any cause in the long-term follow-up (Table 4).

DISCUSSION

The presented data of patients who underwent percutaneous LAAO were obtained from a large regional registry. We analyzed baseline characteristics, selected in-hospital and long-term follow-up parameters, and information related to adverse events and death of any cause. Based on the results, we can presume that LAAO is safe and is associated with promising long-term efficacy to prevent stroke in AF patients with poor compliance to OAC.

LAAO was performed mainly in elderly patients (mean age, 73 years) with a high risk of stroke estimated by the CHA2DS2-Vasc scale — 4.1 (1.9). Both outcomes were similar to most results obtained from available registries [12, 16, 20, 21]. In a few registries, such as in the multicenter Amplatzer Cardiac Plug (ACP) registry [11], the mean age of patients who underwent the procedure was even higher, and the

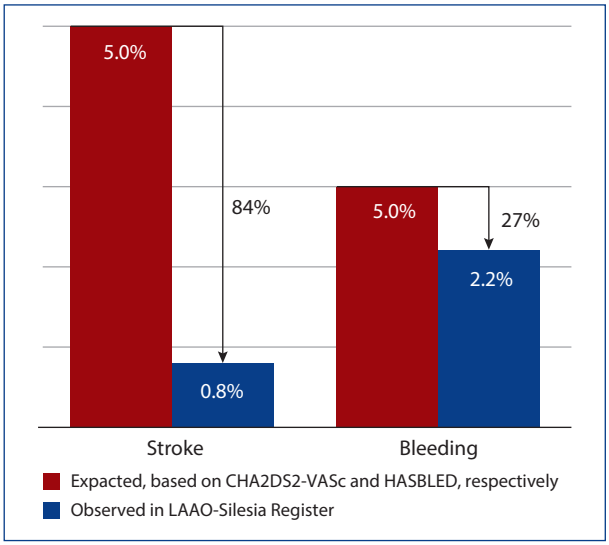

Figure 2. Effectiveness of LAAO in a 12-month reduction in ischemic stroke and bleeding after discharge

Abbreviations: see Table 2

Table 4. Analyzed follow-up data

Characteristics	N (%)	Median time to event in days (IQR)
Follow-up duration, days	646 (99.5)	777 (339–1324)
TIA	9 (1.4)	253 (106–802)
Stroke, total	14 (2.2)	493 (218–1177)
Ischemic stroke	13 (2.0)	547 (250–1187)
Non-fatal stroke	11 (2.0)	714 (155–1272)
Fatal stroke	3 (0.5)	1348 (184–1525)
Bleeding, total	25 (3.9)	302 (74–809)
Bleeding requiring blood transfusion	9 (1.4)	83 (25–246)
Systemic embolism	4 (0.6)	1115 (341–1989)
Death, any cause	132 (20.4)	579 (213–1071)

Abbreviations: see Table 3

percentage of patients >75 years of age constituted 55% of the group. In addition, patients were usually affected by multiple diseases, including chronic coronary syndrome, chronic heart failure, and hypertension. Compared to the above registries, a significant difference in the collected data was related to a high percentage of heart failure (42.2%) and a proportionally low percentage of patients with chronic kidney disease (8.3%). It can be related to an increasing number of patients with heart failure in the Polish population [22] or the exclusion of this group of patients from the previous analyses [8, 10, 23, 24]. The obtained results may also be affected by the registry restriction, arising from a limited number of diagnoses reported to the NHF.

Notably, the predominant indication for LAAO in the Silesian population was bleeding related to OAC, which was reported in 80.9% of cases (including the incidence rates of hemorrhage or hemorrhagic shock, hemorrhagic stroke, or ocular hemorrhage). These indications are consistent with the consensus document prepared by the Association of Cardiovascular Interventions and the Heart Rhythm Section of the Polish Cardiac Society [25]. It is a rather high percentage compared to other European registries, where bleeding was the indication for LAAO in 42%–80% of patients [11, 16, 17, 20, 21]. These discrepancies are even greater when compared with the results of the analyses based on German registries. In the prospective LAARGE [17] registry, the frequency of major bleeding was low and occurred in 28.9% (bleeding was defined as severe in the case of transfusions, surgical treatment, intracranial hemorrhage, and/or hemodynamically unstable patients requiring urgent medical support) and was even lower (18%) in a study based on a single-center registry published by Kleinecke et al. [26]. Therefore, it may suggest that more different indications for LAAO are considered in the above-mentioned countries.

Interestingly, the percentage of successful implant deployment during LAAO was high and reached 99.1% in our population. The high percentage of successful implantations was previously reported [7, 10], and it increased with the experience of operators. Their expertise has an impact on the reduction of adverse events [8], particularly pericardial effusion and the need for blood transfusion. These data were confirmed by the Italian registry [27]. In our observation, the in-hospital prevalence of pericardial effusion depending on the treatment strategy (conservative or interventional) affected 6 (0.9%) and 8 (1.2%) patients, respectively. This percentage of pericardial effusion is comparable to the previous data from the ACP registry [11] where tamponade was diagnosed in 1.24% of patients or in the LAARGE registry [17] where pericardial effusion requiring intervention was reported in 2.3% of cases.

Interpretation of the comparative analysis of bleeding is difficult due to the dissimilarity of selected definitions of major bleeding for each study. In our analysis, the major bleeding was defined as the in-hospital need for blood transfusion and affected 36 patients (5.5%). The LAARGE prospective registry [17] reported the incidence of major in-hospital bleeding at 1.1% (seven patients). On the other hand, in the EWOLUTION registry [12], major bleeding occurred in 11% of patients within 30 days of the procedure.

Unfortunately, 3 patients (0.5%) died in the in-hospital period in the analyzed group. Two patients developed multiorgan failure after interventional treatment of pericardial effusion, and another patient died of a stroke. The risk of in-hospital death related to LAAO was low in the available registry data and ranged between 0.2% and 0.7% [12, 17, 20, 21]. In the ACP registry [11], three periprocedural deaths were reported. They were due to intracranial bleeding, cardiac tamponade, and embolization with a device, respectively. Other deaths occurred postoperatively due to arrhythmia, cardiac tamponade leading to multiorgan failure, an acute ST-elevation myocardial infarction (STEMI), device embolization on day 6 after the procedure, and pneumonia. In turn, Betts et al. [16] reported one death related to pericardial tamponade after transseptal puncture and advancement of the delivery sheath into the LAA. In the EWOLUTION registry [12] and long-term patient outcomes, including bleeding and

incidence of stroke/transient ischemic attack (TIA) three deaths were reported, none of which was directly related to the procedure (right ventricular failure on the day of the procedure, respiratory insufficiency on day 4, and cardiac death on day 6 postoperatively).

The possibility for cessation of OAC without increasing thromboembolic complications is the essence of the LAAO procedure. In our database, in a long-term follow-up of 777 days, TIA and stroke occurred in 9 (1.4%) and 14 patients (2.2%), respectively. Bleeding was reported in 25 patients (3.9%), 9 (1.4%) of whom required blood transfusion (Figure 1). Based on the above findings, an 84% reduction in the incidence of ischemic stroke and a 27% reduction in the incidence of bleeding were observed compared to the estimated value [19] (Figure 2). As we mentioned above, a detailed comparison of the prevalence of TIA, stroke, and bleeding episodes is problematic due to differences in reporting methods [11, 14, 17, 20, 21, 28]. However, the confirmed reduction of the occurrence of these adverse events should be indicated. The above registries report the annual risk of stroke after LAAO at 1.2%–2.2% [17, 20, 21, 28] ranging from 0.9% (ACP registry) [11] during a 13-month follow-up to 4.2% (Korean study) [14] during a 21.9-month follow-up. In large registries, the annual risk of major bleeding was estimated at 0.4-2.0% [17, 21, 28]. In turn, in the analysis of Kleinecke et al. [26], bleeding with varying degrees of severity occurred in 8 patients, which constituted 16% of the observed group.

In our cohort of patients, after a median follow-up of 777 days, more than 20% of patients died of any cause. This percentage seems to be high. As we mentioned above, patients undergoing LAAO represented the elderly Silesian population, often with many comorbidities that increase the risk of death. Compared to the international registries, the percentage of deaths increased with a higher mean age of patients and ranged from 5.2% during a 21.9-month follow-up to 11.5% during a one-year follow-up of the prospective registry [14, 17, 29]. Notably, the risk of death was independent of the type of occluder used for LAAO [21].

Limitations of the study

The above analysis was retrospective, with the typical limitations of this method. The LAAO-SILESIA registry based on the electronic database of a single healthcare provider is limited to core variables, coded according to ICD-9 and ICD-10, such as demographic data, comorbidities, in-hospital events (need for blood transfusion, TIA/stroke, in-hospital death, pericardial effusion depends on the method of treatment) and major cardiac events in a follow-up (death, bleeding, TIA/stroke). It does not cover data on laboratory results, echocardiographic parameters, fluoroscopy data, or the cause of death during the follow-up, which represents a major limitation of the study. The quality of data may be challenged by differences in the quality of data reported by different centers. The study does not account for patients who moved to another Province.

CONCLUSIONS

Based on a "real-life" cohort of patients from the Silesian Province, we conclude as follows:

The LAAO procedure is related to low in-hospital major adverse cardiac events.

LAAO reduced the rates of stroke and bleeding in a long-term follow-up.

Article information

Conflict of interest: None declared.

REFERENCES

1. Tu HTH, Campbell BCV, Christensen S, et al. Pathophysiological determinants of worse stroke outcome in atrial fibrillation. Cerebrovasc Dis. 2010; 30(4): 389–395, doi: 10.1159/000316886, indexed in Pubmed: 20693794.
2. Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. Circulation. 2014; 129(8): 837–847, doi: 10.1161/CIRCULATIONAHA.113.005119, indexed in Pubmed: 24345399.
3. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J. 2016; 37(38): 2893–2962, doi: 10.1093/eurheartj/ehw210, indexed in Pubmed: 27567408.
4. Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2020; 42(5): 373–498, doi: 10.1093/eurheartj/ehaa612, indexed in Pubmed: 32860505.
5. O'Brien EC, Holmes DN, Ansell JE, et al. Physician practices regarding contraindications to oral anticoagulation in atrial fibrillation: findings from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) registry. Am Heart J. 2014; 167(4): 601–609.e1, doi: 10.1016/j.ahj.2013.12.014, indexed in Pubmed: 24655711.
6. Steinberg BA, Greiner MA, Hammill BG, et al. Contraindications to anticoagulation therapy and eligibility for novel anticoagulants in older patients with atrial fibrillation. Cardiovasc Ther. 2015; 33(4): 177–183, doi: 10.1111/1755-5922.12129, indexed in Pubmed: 25930214.
7. Sievert H, Lesh MD, Trepels T, et al. Percutaneous left atrial appendage transcatheter occlusion to prevent stroke in high-risk patients with atrial fibrillation: early clinical experience. Circulation. 2002; 105(16): 1887–1889, doi: 10.1161/01.cir.0000015698.54752.6d, indexed in Pubmed: 11997272.
8. Holmes DR, Kar S, Price MJ, 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, doi: 10.1016/j.jacc.2014.04.029, indexed in Pubmed: 24998121.
9. Hirnle G, Lewkowicz J, Suwalski P, et al. Effectiveness of surgical closure of left atrial appendage during minimally invasive mitral valve surgery. Kardiol Pol. 2020; 78(11): 1137–1141, doi: 10.33963/KP.15539, indexed in Pubmed: 32735408.
10. Reddy VY, Doshi SK, Sievert H, et al. PROTECT AF Investigators. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial. Circulation. 2013; 127(6): 720–729, doi: 10.1161/CIRCULATIONAHA.112.114389, indexed in Pubmed: 23325525.
11. Tzikas A, Shakir S, Gafoor S, et al. Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plug. EuroIntervention. 2016; 11(10): 1170–1179, doi: 10.4244/EIJY15M01_06, indexed in Pubmed: 25604089.

12. Boersma LVA, Schmidt B, Betts TR, et al. EWOLUTION investigators. Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. Eur Heart J. 2016; 37(31): 2465–2474, doi: 10.1093/eurheartj/ehv730, indexed in Pubmed: 26822918.
13. Reddy VY, Doshi SK, Kar S, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. J Am Coll Cardiol. 2017; 70(24): 2964–2975, doi: 10.1016/j.jacc.2017.10.021, indexed in Pubmed: 29103847.
14. Kim JS, Lee H, Suh Y, et al. Left atrial appendage occlusion in non-valvular atrial fibrillation in a Korean multi-center registry. Circ J. 2016; 80(5): 1123–1130, doi: 10.1253/circj.CJ-15-1134, indexed in Pubmed: 26984716.
15. Tzikas A, Holmes DR, Gafoor S, et al. Percutaneous left atrial appendage occlusion: the Munich consensus document on definitions, endpoints and data collection requirements for clinical studies. EuroIntervention. 2016; 12(1): 103–111, doi: 10.4244/EIJV12I1A18, indexed in Pubmed: 27173870.
16. Betts TR, Leo M, Panikker S, et al. Percutaneous left atrial appendage occlusion using different technologies in the United Kingdom: A multicenter registry. Catheter Cardiovasc Interv. 2017; 89(3): 484–492, doi: 10.1002/ccd.26782, indexed in Pubmed: 27651124.
17. Brachmann J, Lewalter T, Akin I, et al. Interventional occlusion of left atrial appendage in patients with atrial fibrillation. Acute and long-term outcome of occluder implantation in the LAARGE Registry. J Interv Card Electrophysiol. 2020; 58(3): 273–280, doi: 10.1007/s10840-019-00635-7, indexed in Pubmed: 31707534.
18. Roleder T, Hawranek M, Gąsior T, et al. Trends in aortic stenosis diagnosis and treatment in the years 2006–2016 according to the SILesian CARDiovascular (SILCARD) database. Pol Arch Intern Med. 2018; 128(12): 739–745, doi: 10.20452/pamw.4352, indexed in Pubmed: 30335053.
19. Friberg L, Rosenqvist M, Lip GYH. Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182 678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study. Eur Heart J. 2012; 33(12): 1500–1510, doi: 10.1093/eurheartj/ehr488, indexed in Pubmed: 22246443.
20. Berti S, Santoro G, Brscic E, et al. Left atrial appendage closure using AMPLATZER™ devices: A large, multicenter, Italian registry. Int J Cardiol. 2017; 248: 103–107, doi: 10.1016/j.ijcard.2017.07.052, indexed in Pubmed: 28797952.
21. Kefer J, Aminian A, Vermeersch P, et al. Transcatheter left atrial appendage occlusion for stroke prevention in patients with atrial fibrillation: results from the Belgian registry. EuroIntervention. 2018; 13(13): 1603–1611, doi: 10.4244/EIJ-D-17-00076, indexed in Pubmed: 28966159.
22. Niedziela JT, Parma Z, Pawlowski T, et al. Secular trends in first-time hospitalization for heart failure with following one-year readmission and mortality rates in the 3.8 million adult population of Silesia, Poland between 2010 and 2016. The SILCARD database. Int J Cardiol. 2018; 271: 146–151, doi: 10.1016/j.ijcard.2018.05.015, indexed in Pubmed: 30223348.
23. Holmes DR, Reddy VY, Turi ZG, et al. PROTECT AF Investigators. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. Lancet. 2009; 374(9689): 534–542, doi: 10.1016/S0140-6736(09)61343-X, indexed in Pubmed: 19683639.
24. Reddy VY, Möbius-Winkler S, Miller MA, et al. Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology). J Am Coll Cardiol. 2013; 61(25): 2551–2556, doi: 10.1016/j.jacc.2013.03.035, indexed in Pubmed: 23583249.
25. Grygier M, Wojakowski W, Smolka G, et al. [Left atrial appendage occlusion: consensus document of Association of Cardiovascular Interventions and Heart Rhythm Section of Polish Cardiac Society]. Kardiol Pol. 2018; 76(3): 677–697, doi: 10.5603/KP.a2018.0057, indexed in Pubmed: 29441512.
26. Kleinecke C, Park JW, Gödde M, et al. Twelve-month follow-up of left atrial appendage occlusion with Amplatzer Amulet. Cardiol J. 2017; 24(2): 131–138, doi: 10.5603/CJ.a2017.0017, indexed in Pubmed: 28198520.
27. Berti S, Pastormerlo LE, Santoro G, et al. Intracardiac Versus Transesophageal Echocardiographic Guidance for Left Atrial Appendage Occlusion: The LAAO Italian Multicenter Registry. JACC Cardiovasc Interv. 2018; 11(11): 1086–1092, doi: 10.1016/j.jcin.2018.05.008, indexed in Pubmed: 29880104.
28. Mazzone P, Angelo G, Regazzoli D, et al. 16-27: Percutaneous Left Atrial Appendage Closure with WATCHMAN device: results from the TRAPS Registry. EP Europace. 2016; 18(suppl_1): i7–i7, doi: 10.1093/europace/18.suppl_1.i7b.
29. Burysz M, Litwinowicz R, Burysz A, et al. Causes of death and morbidity in patients with atrial fibrillation after left atrial appendage occlusion. Kardiol Pol. 2019; 77(11): 1047–1054, doi: 10.33963/KP.14966, indexed in Pubmed: 31495824.