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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Left atrial appendage occlusion devices – a contemporary approach to stroke prevention with a presentation of results in Serbia from 2014 to 2025

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SUMMARY
Introduction/Objective Atrial fibrillation is the most common sustained cardiac arrhythmia and one of the most significant independent risk factors for ischemic stroke and systemic thromboembolism. In patients with non-valvular atrial fibrillation, the left atrial appendage (LAA) is the predominant site of intracardiac thrombus formation. This has led to the development of mechanical elimination of the thrombogenic substrate, i.e., percutaneous LAA occlusion (LAAO), as an alternative to long-term oral anticoagulant therapy in patients with contraindications to anticoagulation.
Methods The first LAAO device in Serbia was implanted on April 24, 2014, at BASICS+8, University Clinical Center of Serbia, by Prof. Dr. Milan A. Nedeljković and Prof. Dr. Branko Beleslin. LAAO device implantation is currently performed at four centers: University Clinical Center of Serbia, Dedinje Institute for Cardiovascular Diseases, Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica, and Bežanijska kosa University Clinical Center. Before LAAO implantation, either transesophageal echocardiography (TEE) or computed tomography is performed to determine the morphology of the LAA and confirm the absence of thrombus, which represents a contraindication to the procedure. The intervention is performed via femoral venous access under short-term analgosedation or general anesthesia, depending on the practice of the center, with fluoroscopic guidance and TEE monitoring. The key step is transseptal puncture to gain access to the left atrium. TEE guidance is used to ensure precise puncture of the inferoposterior portion of the interatrial septum and facilitate positioning of the delivery system at the LAA ostium.
Results Between 2014 and 2025, a total of 30 LAAO devices were implanted at four centers in Serbia. With support from the Republic Health Insurance Fund, two devices were implanted at University Clinical Center of Serbia in 2014, followed by one additional device in 2015. No data on the use of this method in angiography suites in Serbia were available for the period from 2016 to 2022. In 2023, a total of six devices were implanted (four at Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica and two at Dedinje Institute for Cardiovascular Diseases). In 2024, a total of 10 devices were implanted (six at Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica, one at Dedinje Institute for Cardiovascular Diseases, and three at Bežanijska kosa University Clinical Center). In 2025, a total of 11 devices were implanted (five at Dedinje Institute for Cardiovascular Diseases and six at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica).
Conclusion The use of percutaneous LAAO in Serbia demonstrates gradual development, from the initial sporadic application of the method at a single center to its expansion to multiple tertiary cardiology centers. Further development of LAAO in Serbia should be accompanied by the establishment of a national registry and standardized data collection.
Keywords: atrial fibrillation; left atrial appendage; percutaneous left atrial appendage occlusion; oral anticoagulant therapy; direct oral anticoagulant therapy; stroke

INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and one of the most significant independent risk factors for ischemic stroke and systemic thromboembolism. Thromboembolic complications of AF are associated with substantial morbidity, mortality, and long-term disability, making stroke prevention one of the primary goals of treatment in patients with AF. In patients with non-valvular AF, the left atrial appendage (LAA) is the predominant site of intracardiac thrombus formation. This recognition has led to the development of the concept of mechanical elimination of the thrombogenic substrate, namely percutaneous LAA occlusion (LAAO), as an alternative to long-term oral anticoagulant therapy (OAC). Oral anticoagulation, initially with vitamin K antagonists and subsequently with direct oral anticoagulants (DOACs), represents the cornerstone of thromboembolic event prevention in patients with AF. Although effective, long-term anticoagulation carries a risk of bleeding, may be challenging in patients with previous hemorrhagic events or other contraindications, and represents a significant treatment burden for some patients. These limitations have prompted the development of interventional approaches aimed at providing adequate thromboembolic protection while reducing the long-term risk of bleeding. The development of LAAO devices began with the demonstration of the feasibility and efficacy of this strategy compared with warfarin. Early randomized trials, particularly PROTECT AF [1, 2] and PREVAIL

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Table 1. Left atrial appendage occluders in Serbia, 2014–2025, according to available data from the Working Group for Interventional Cardiology of the Cardiology Society of Serbia, BASICS+ (Belgrade Summit of Interventional Cardiology, Cardiovascular Therapy and Imaging)

Year	Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica	University Clinical Centre of Serbia	Dedinje Institute for Cardiovascular Diseases	Bežanijska kosa University Clinical Center	Total
2014	N/A	2*	N/A	N/A	2
2015	N/A	1*	N/A	N/A	1
2016	N/A	N/A	N/A	N/A	0
2017	N/A	N/A	N/A	N/A	0
2018	N/A	N/A	N/A	N/A	0
2019	N/A	N/A	N/A	N/A	0
2020	N/A	N/A	N/A	N/A	0
2021	N/A	N/A	N/A	N/A	0
2022	N/A	N/A	N/A	N/A	0
2023	4**	N/A	2**	N/A	6
2024	6**	N/A	1**	3**	10
2025	6**	N/A	5**	N/A	11
Total	16	3	8	3	30

*Procedure funded by the Republic Health Insurance Fund;
**Procedures performed using occluders procured through hospital tenders

[3], provided the basis for the acceptance of LAAO as a potential alternative to oral anticoagulation. At the same time, experience from the initial studies highlighted the importance of procedural risk and led to the development of new generations of devices, with the aim of achieving better adaptation to the diverse anatomical characteristics of the LAA, more complete sealing, and a reduction in complications. With the advent of direct oral anticoagulants (DOACs), the context in which the role of LAAO is evaluated has also changed. PRAGUE-17 [4] represented an important milestone, as LAAO was directly compared with DOAC therapy in patients at high thromboembolic and bleeding risk. Furthermore, studies such as Amulet IDE [5] and PINNACLE FLX [6] enabled comparisons between different devices and assessment of the safety and efficacy of contemporary generations of occluders. The latest data from large randomized trials, including OPTION [7] and CHAMPION-AF [8], have further expanded the potential indications for LAAO, while the results of the CLOSURE-AF study [9] simultaneously indicate that this strategy cannot be considered a universal replacement for contemporary medical therapy. While international landmark trials continuously expand the clinical landscape and indications for LAAO, evaluating how these guidelines translate into real-world practice within smaller, resource-constrained healthcare systems remains essential.

Thus, the development of LAAO represents an example of the continuous evolution of interventional therapy – from the initial proof of concept and comparison with warfarin, through improvements in procedural safety and the development of new devices, to direct comparisons with contemporary anticoagulant therapy. Understanding the results of key randomized trials is essential for appropriately defining the role of LAAO in contemporary stroke prevention in patients with AF. The aim of this paper is to present, through a review and critical analysis of the most important randomized clinical trials, the evolution of evidence regarding the efficacy and safety of LAAO, the development of the devices themselves, their comparison with OAC, and the current role of LAAO in the strategy for preventing thromboembolic complications in patients with non-valvular AF, as well as the results of LAAO implantation in catheterization laboratories in Serbia from 2014 to 2025.

METHODS

In Serbia, the first LAAO device was implanted on April 24, 2014, using the BASICS+8 device at University Clinical Center of Serbia by Prof. Dr. Milan A. Nedeljković and Prof. Dr. Branko Beleslin (Table 1) [10]. LAAO device implantation is currently performed at four centers: the University Clinical Center of Serbia, Dedinje Institute for Cardiovascular Diseases, Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica and Bežanijska kosa University Clinical Center. Prior to the decision to implant an LAAO device, either transesophageal echocardiography (TEE) or computed tomography (CT) is performed to determine the morphology of the LAA (chicken wing, broccoli, windsock, or cactus morphology) and to confirm the absence of thrombus within the appendage, as the presence of thrombus represents a contraindication to the procedure. The size of the occluder is determined based on the measurements obtained, primarily the depth of the appendage and the diameter of the appendage ostium, which are assessed by TEE in multiple views (0°, 45°, 90°, and 135°), as well as by CT image reconstruction.

The procedure is performed via femoral venous access under short-term conscious sedation or general anesthesia, depending on the center's practice, with fluoroscopic guidance and TEE monitoring. The key step is transseptal puncture to gain access to the LAA. This is performed under TEE guidance to ensure precise puncture of the inferoposterior portion of the interatrial septum and facilitate advancement of the delivery system toward the appendage ostium. After reconfirming the dimensions of the appendage by TEE, an appropriately sized occluder is selected and positioned within the LAA. Following occluder

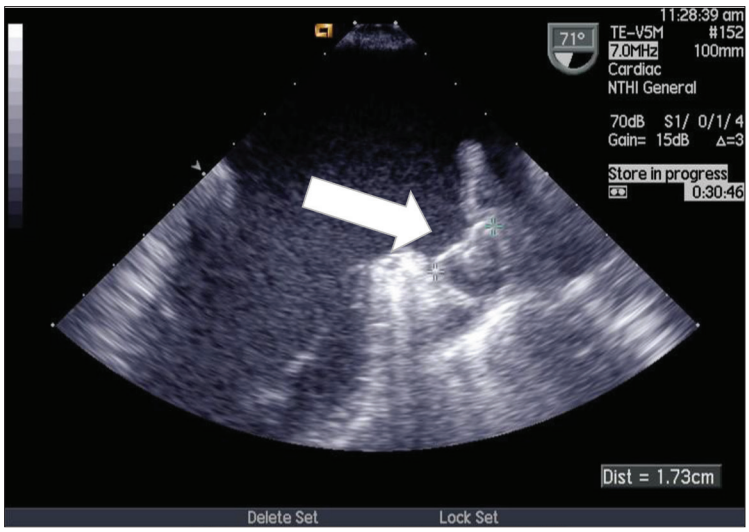


Figure 1. The first Watchman™ occluder (Watchman, Boston, MA, USA) implanted in a catheterization laboratory in Serbia on April 24, 2014

implantation and before its definitive release, several key parameters are assessed, including appropriate device position and size, as determined by the degree of compression, device stability, and the absence of peri-device leak.

Potential periprocedural complications include pericardial effusion, occluder embolization, and procedure-related stroke [11, 12].

In catheterization laboratories in Serbia, the Watchman™ (Figure 1) and Watchman FLX™ occluders (Watchman, Boston, MA, USA) and the Amplatzer™ AMULET™ occluder (Abbott Laboratories, Abbott Park, IL, USA) have been used.

Ethics: This study was conducted in accordance with the ethical standards of the institutional ethics committee.

RESULTS

Between 2014 and 2025, a total of 30 LAA occluders were implanted at four centers in Serbia. In 2014, with the support of the Republic Health Insurance Fund, two occluders were implanted at University Clinical Center of Serbia. The Republic Health Insurance Fund covered one additional procedure in 2015, which was also performed at University Clinical Center of Serbia.

Between 2016 and 2022, no data on the use of this method in catheterization laboratories in Serbia are available according to the data published by the Working Group for Interventional Cardiology of the Cardiology Society of Serbia in the Belgrade Summit of Interventional Cardiology, Cardiovascular Therapy and Imaging (BASICS+) program.

In 2023, a total of six procedures were performed (four at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica and two at Dedinje Institute for Cardiovascular Diseases) according to the available data from the Working Group for Interventional Cardiology of the Cardiology Society of Serbia.

In 2024, a total of 10 occluders were implanted (six at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica, one at Dedinje Institute for Cardiovascular Diseases, and three at Bežanijska kosa University Clinical Center).

In 2025, a total of 11 occluders were implanted (five at Dedinje Institute for Cardiovascular Diseases and six at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica).

DISCUSSION

The results of this analysis indicate a gradual development of the percutaneous LAAO program in Serbia, with a particularly pronounced increase in the number of procedures during the last three years of the study period. According to the available data, a total of 30 LAA occluders were implanted at four centers in Serbia between 2014 and 2025. Following the initial procedures performed in 2014 and 2015 [10], the number of interventions increased substantially from 2023 onward, with six procedures recorded that year, while the highest number, a total of 11 was recorded in 2025. This trend indicates the gradual expansion of the use of this method in Serbia [13, 14].

The first procedures were recorded in 2014, when two occluders were implanted at the University Clinical Center of Serbia with financial support from the Republic Health Insurance Fund, followed by one additional procedure in 2015. This period marked the beginning of LAAO implementation in Serbia, at a time when the method was already the subject of intensive clinical investigation and development. LAAO was developed with the aim of reducing the risk of thromboembolic events in selected patients with AF, particularly when long-term OAC is unsuitable or associated with an unacceptable risk. Current European guidelines recognize LAAO as part of stroke prevention strategies in carefully selected patients, with an individualized assessment of its potential benefits and risks [15, 16].

In the study by Pison et al. [17], published in 2015, LAAO was still described as a relatively new and insufficiently widespread procedure. Most European centers performing the procedure had carried out ≤ 30 interventions throughout 2014, with the most common indication being a high thromboembolic risk in the presence of a contraindication to OAC.

The distribution of procedures across centers indicates that the use of LAAO in Serbia is concentrated in several tertiary cardiology institutions. In 2023, four procedures were performed at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica and two at Dedinje Institute for Cardiovascular Diseases. In 2024, six procedures were performed at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica, one at Dedinje Institute for Cardiovascular Diseases, and three

at Bežanijska kosa University Clinical Center. In 2025, five procedures were performed at Dedinje Institute for Cardiovascular Diseases and six procedures were performed at the Institute for Cardiovascular Diseases of Vojvodina – Sremska Kamenica. Such concentration may be expected during the early development of a new interventional technique, as it facilitates the accumulation of experience, establishment of multidisciplinary teams, and concentration of technical and diagnostic resources. European data also indicate substantial variation in procedural volume between centers, with some centers performing very few interventions annually.

In an international consensus practical guide, Potpara et al. [18] emphasized that the contemporary development of LAAO has been associated with improvements in procedural safety and its increasingly frequent use in patients with AF for whom long-term anticoagulation is not an appropriate option.

The stark contrast between the expanding indications for LAAO in international guidelines and the modest real-world volume of 30 cases over more than a decade in Serbia highlights significant structural hurdles. The complete absence of recorded procedures between 2016 and 2022 reflects a temporary nationwide standstill of the program, primarily driven by strict economic constraints, inconsistent reimbursement pathways by the National Health Insurance Fund, and logistical issues with hospital tenders, rather than a lack of operator expertise.

This long-term stagnation emphasizes that transitioning from a sporadic, center-specific approach to a structured national registry is a mandatory next step. Establishing such a framework will be vital to provide the standardized clinical data necessary to justify broader and more consistent financial coverage for this stroke-prevention strategy in the future.

CONCLUSION

The use of percutaneous LAAO in Serbia has demonstrated gradual development, from the initial sporadic application of the technique at a single center to its expansion to several tertiary cardiology centers. The first procedures, described in the study by Nedeljković and colleagues, marked the beginning of the implementation of this method in Serbia, while available data from the period 2023–2025 indicate an increase in the number of procedures and expansion of the LAAO program to multiple centers. This trend is consistent with the development of LAAO in Europe and its increasingly important role in the prevention of thromboembolic events in carefully selected patients with AF for whom long-term OAC is not an appropriate option.

Further development of LAAO in Serbia should be accompanied by the establishment of a national registry and standardized data collection, enabling assessment of procedural availability and quality, comparison of outcomes between centers, and appropriate positioning of LAAO within contemporary treatment strategies for patients with AF.

Conflict of interest: None declared.

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Оклудери аурикуле леве преткоморе – савремени приступ у превенцији можданог удара са приказом резултата у Србији 2014–2025

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САЖЕТАК

Увод/Циљ Атријална фибрилација представља најчешћу трајну срчану аритмију и један од најзначајнијих независних фактора ризика за настанак исхемијског можданог удара и системске тромбоемболије. Код болесника са невалвуларном атријалном фибрилацијом, аурикула леве преткоморе (*LAA*) представља доминантно место настанка интракардијалног тромба. Ово је довело до развоја механичке елиминације тромбогеног супстрата, односно перкутане оклузије *LAA* (*LAAO*) као алтернативе дуготрајној оралној антикоагулантној терапији код болесника код којих постоји контраиндикација за њену примену.

Методе У Србији је први уређај за *LAAO* уграђен 24. априла 2014. године на *BASICS*+8 у Универзитетском клиничком центру Србије, а процедуру су извели проф. др Милан А. Недељковић и проф. др Бранко Белеслин. Имплантација оклудера обавља се у четири центра: Универзитетском клиничком центру Србије, Институту за кардиоваскуларне болести „Дедиње", Институту за кардиоваскуларне болести Војводине – Сремска Каменица и Универзитетском клиничком центру „Бежанијска коса". Пре доношења одлуке о извођењу *LAAO* раде се трансезофагеална ехокардиографија (TEE) или компјутеризована томографија како би се утврдио облик леве аурикуле и потврдило одсуство тромба у аурикули, с обзиром на то да присуство тромба представља контраиндикацију за извођење саме процедуре. Интервенција се изводи приступом преко феморалне вене, у краткотрајној аналгоседацији или општој анестезији, у зависности од праксе центра, уз флуороскопију и под контролом TEE. Основни корак представља транссептална пункција, којом се приступа левој аурикули. Она се изводи под контролом TEE како би се омогућила прецизна пункција инферопостериорног септума и олакшало усмеравање система за испоручивање ка улазу у аурикулу.

Резултати Између 2014. и 2025. године укупно је имплантирано 30 оклудера за *LAA* у четири центра у Србији. Захваљујући Републичком фонду за здравствено осигурање, 2014. године су у Универзитетском клиничком центру Србије уграђена два оклудера, а 2015. године још један. Између 2016. и 2022. године нема доступних података о примени ове методе у ангиографским салама у Србији. Године 2023. изведено је укупно шест имплантација (четири у Институту за кардиоваскуларне болести Војводине – Сремска Каменица и две у Институту за кардиоваскуларне болести „Дедиње"). Године 2024. уграђено је укупно 10 оклудера (шест у Институту за кардиоваскуларне болести Војводине – Сремска Каменица, један у Институту за кардиоваскуларне болести „Дедиње" и три у Универзитетском клиничком центру „Бежанијска коса"). Године 2025. уграђено је укупно 11 оклудера (пет у Институту за кардиоваскуларне болести „Дедиње" и шест у Институту за кардиоваскуларне болести Војводине – Сремска Каменица).

Закључак Примена перкутане *LAAO* у Србији показује постепен развој од иницијалне, спорадичне примене методе у једном центру до њеног ширења на више терцијарних кардиолошких центара. Даљи развој *LAAO* у Србији требало би да буде праћен формирањем националног регистра и стандардизованим прикупљањем података.

Кључне речи: атријална фибрилација; аурикула леве преткоморе; перкутана оклузија аурикуле леве преткоморе; орална антикоагулантна терапија; директна орална антикоагулантна терапија; мождани удар