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+381 11 4092 776, Fax: +381 11 3348 653

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Milan A. Nedeljković*

Transcatheter aortic valve implantation (TAVI) in the treatment of aortic stenosis – from high-risk to low-risk patients with a presentation of results in Serbia from 2014 to 2025

Транскатетерска имплантација аортне валвуле (TAVI) у лечењу аортне стенозе – од високоризичних до нискоризичних болесника са приказом резултата у Србији од 2014. до 2025. године

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***Correspondence to:**

Milan A. NEDELJKOVIĆ

Serbian Medical Society, Džordža Vašingtona 19, 11000 Belgrade, Serbia

milanned@hotmail.com

Transcatheter aortic valve implantation (TAVI) in the treatment of aortic stenosis – from high-risk to low-risk patients with a presentation of results in Serbia from 2014 to 2025

Транскатетерска имплантација аортне валвуле (TAVI) у лечењу аортне стенозе – од високоризичних до нискоризичних болесника са приказом резултата у Србији од 2014. до 2025. године

SUMMARY

Introduction/Aim Transcatheter aortic valve implantation (TAVI) is a treatment modality intended for patients with aortic stenosis older than 70 years who also have comorbidities that would make open-heart surgery high risk. The first TAVI procedure was performed on April 16, 2002, in Rouen, France, by Alain Cribier. Since 2008, randomized controlled trials (PARTNER 1B) have been conducted in extremely high-risk patients with a Society of Thoracic Surgeons (STS) score > 15, demonstrating the noninferiority of this method compared with surgical bioprosthetic valve replacement. Subsequent studies (PARTNER 1B and CoreValve HR) in high-risk patients with an STS score > 8 also demonstrated the noninferiority of this method compared with surgical bioprosthetic valve replacement. In intermediate-risk patients with an STS score of 4–8 (PARTNER 2 and SURTAVI), the studies likewise demonstrated the efficacy of this method compared with surgical bioprosthetic valve replacement. The TAVI procedure was also applied in low-risk patients with an STS score < 4 (PARTNER 3, Evolut Low Risk), where the results again confirmed that the TAVI valve was not inferior to surgical bioprosthetic valve replacement. In our country, the first TAVI intervention was performed at the University Clinical Centre of Serbia on April 22, 2014 (Prof. Dr. Milan A. Nedeljković, Prof. Dr. Branko Beleslin).

Methods In our three centers, self-expanding and balloon-expandable TAVI valves were used and implanted via the transfemoral approach (through the femoral artery). Before the TAVI procedure, we performed a comprehensive assessment of the severity of aortic stenosis, left ventricular function, and the size and type of valve to be implanted. The non-invasive diagnostic evaluation included:

1. Transthoracic echocardiography (TTE);
2. Transesophageal echocardiography (TEE) (when indicated);
3. Computed tomography of the heart and aorta is one of the most important examinations performed before the TAVI procedure. It is used to assess and measure the aortic valve and annulus, as well as the aorta and the blood vessels through which the catheter will be advanced (most commonly the femoral arteries). This examination is essential for selecting the appropriate prosthetic valve and determining the optimal vascular access route;

4. Coronary angiography;
5. Electrocardiogram (ECG);
6. Laboratory tests;
7. Chest X-ray;
8. Assessment of the patient's overall clinical condition.

All of these data were required by the Heart Team to assess the procedural risk for each patient.

Results From 2014 to 2021, a total of 73 TAVI valves were implanted in three centers in Serbia. In 2022, annual procurement of valves by the Health Insurance Fund of Serbia began, and 221 TAVI valves were implanted that year. In 2023, 318 TAVI valves were implanted, and in 2024, 231 TAVI valves. In 2025, 562 TAVI valves were implanted. In Serbia, a total of 1405 TAVI valves were implanted from 2014 up to and including 2025. These results demonstrate the continuous development of the TAVI program, particularly following the introduction of systematic funding. However, they also indicate that there is still room to improve access to the procedure and to further expand the network of TAVI centers in Serbia.

Conclusion This method has been widely accepted worldwide, and in certain countries it is used to treat more than 50% of patients with aortic stenosis.

Keywords: TAVI; aortic stenosis; STS score

САЖЕТАК

Увод / Циљ Транскатетерска имплантација аортне валвуле (TAVI) метода је лечења предвиђена за болеснике са аортном стенозом који су старији од 70 година и који имају и друга обољења, тако да би сама хирургија на отвореном срцу за њих била високоризична. Прва TAVI метода изведена је 16. априла 2002. године у Руану (Француска), а извршио ју је Алан Крибије (Alain Cribier).

Од 2008. године почеле су да се раде рандомизоване контролисане студије (PARTNER 1B) код екстремно ризичних болесника чији је скор Друштва торакалних хирурга (STS) > 15, које су показале неинфериорност ове методе у односу на хируршку замену биолошком валвулом. Касније спроведене студије (PARTNER 1B и CoreValve HR) код високоризичних болесника чији је STS скор > 8 такође су показале неинфериорност ове методе у односу на хируршку замену биолошком валвулом. Код средње ризичних болесника чији је STS скор 4–8 (PARTNER 2 и SURTAVI) студије су такође показале ефикасност ове методе у односу на хируршку замену биолошком валвулом. TAVI метода је примењена и код нискоризичних болесника са STS скором < 4 (PARTNER 3, Evolut Low Risk), где су резултати поново потврдили да TAVI валвула није инфериорна у односу на хируршку замену биолошком валвулом. У нашој земљи прва TAVI интервенција урађена је 22. априла 2014. године у Универзитетском клиничком центру Србије (проф. др Милан А. Недељковић, проф. др Бранко Белеслин).

Метода У наша три центра употребљаване су самоширеће и балонширеће TAVI валвуле које су пласиране трансфеморалним путем (преко артерије феморалис). Пре TAVI процедуре радили смо детаљну процену тежине аортне стенозе, функције леве срчане коморе и величине и типа записка који ћемо употребити. Независне дијагностичке методе укључивале су:

1. трансторакалну ехокардиографију (TTE);
2. трансофагеалну ехокардиографију (TEE) (по потреби);
3. Компјутеризована томографија срца и аорте један од најважнијих прегледа пре TAVI процедуре, којим се процењују и мере аортни зализак и прстен, као и аорта и крвни судови кроз које ће се увести катетер (најчешће феморалне артерије). Ово је неопходно за адекватни одабир вештачке валвуле, као и одабир адекватног васкуларног приступа;
4. коронарну ангиографију;
5. електрокардиограм (ЕКГ);
6. лабораторијске анализе;
7. рендген грудног коша;
8. процену општег здравственог стања.

Сви ови подаци били су потребни срчаном тиму (Heart Team) ради процене ризика саме процедуре код болесника.

Резултати Од 2014. до 2021. године укупно у три центра у Србији урађене су 73 TAVI валвуле. Од 2022. године почиње годишња набавка валвула од стране Фонда здравственог осигурања Србије, тако да је те године урађено 221 TAVI валвула. Године 2023. урађено је 318 TAVI валвула, а 2024. године 231 TAVI валвула. Године 2025. урађено је 562 TAVI валвула. Укупно је у периоду од 2014. до 2025. године имплантирана 1405 TAVI валвула. Ови резултати показују континуиран развој TAVI програма, посебно након увођења системског финансирања, али и даље указују на простор за повећање доступности процедуре и даљи развој TAVI центара у Србији.

Закључак Ова метода је широко прихваћена у свету и у одређеним земљама се њоме лечи више од 50% болесника са аортном стенозом.

Кључне речи: TAVI; аортна стеноза; STS скор

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a treatment modality intended for patients with aortic stenosis who are over 70 years old and have significant comorbidities, making conventional open-heart surgery a high-risk procedure. The first TAVI procedure was performed on April 16, 2002, in Rouen, France, by Alain Cribier.

Randomized controlled trials evaluating TAVI began in 2008. The first, PARTNER 1B [1], published in 2010, enrolled patients at extreme surgical risk with a Society of Thoracic Surgeons (STS) Risk Score >15. The study demonstrated the superiority of TAVI over medical therapy and its non-inferiority compared with surgical aortic valve replacement (SAVR) in the treatment of aortic stenosis.

The PARTNER 1A trial [2], published in 2011, included high-risk patients with an STS score of 8–15 and demonstrated that TAVI was non-inferior to SAVR. Both the PARTNER 1B and PARTNER 1A trials used balloon-expandable intra-annular valves.

In 2014, the US CoreValve High Risk trial [3] was published, enrolling high-risk patients with an STS score of 8–15. In this study, TAVI was shown to be non-inferior – and even superior – to SAVR. A self-expanding supra-annular aortic valve prosthesis was used.

The PARTNER 2A trial [4], published in 2016, enrolled patients at intermediate surgical risk (STS score 4–8). The study demonstrated that TAVI was non-inferior to SAVR. A balloon-expandable intra-annular aortic valve prosthesis was used.

One year later, in 2017, the SURTAVI trial [5] was published, also including intermediate-risk surgical patients with an STS score of 4–8. The study demonstrated that TAVI was non-inferior to SAVR with respect to the composite endpoint of all-cause mortality or disabling stroke. A self-expanding supra-annular aortic valve prosthesis was used.

In 2019, two landmark trials were published: PARTNER 3 [6] and Evolut Low Risk [7], both enrolling low-risk surgical patients with an STS score < 4.

In the PARTNER 3 trial, TAVI proved superior to SAVR with respect to early clinical outcomes, whereas in the Evolut Low Risk trial, TAVI was shown to be non-inferior to SAVR in low-risk patients.

The PARTNER 3 trial used a balloon-expandable intra-annular aortic valve prosthesis, while the Evolut Low Risk trial used a self-expanding supra-annular valve prosthesis.

In 2024, the NOTION 10-year study [8], involving low-risk patients (STS score < 4), was published. Its long-term results demonstrated sustained efficacy and durability of TAVI prostheses. A self-expanding supra-annular prosthesis was used.

In Serbia, the first TAVI procedure was performed on April 22, 2014, at the University Clinical Centre of Serbia by Prof. Milan A. Nedeljković and Prof. Branko Beleslin [9–14] (Figure 1).

METHODS

At the four participating centers – the University Clinical Centre of Serbia, “Dedinje” Institute for Cardiovascular Diseases, and the Institute for Cardiovascular Diseases Sremska Kamenica, the Military Medical Academy (starting with August 18, 2025) – both self-expanding and balloon-expandable TAVI prostheses were used. The valves were implanted predominantly via the transfemoral approach (through the femoral artery).

In addition to the primary vascular access used for valve implantation, a secondary access site (radial or femoral artery) is required for the introduction of a pigtail catheter into the non-coronary cusp to facilitate fluoroscopic guidance and accurate assessment of implantation

depth. One of the steps preceding valve implantation is pre-dilation of the aortic valve with a balloon, which is performed with electrical stimulation with a pacemaker (so-called “Rapid pacing”), most often via a wire placed in the left ventricle or, less often, via a temporary pacemaker placed in the right ventricle.

Before the TAVI procedure, a comprehensive assessment of the severity of aortic stenosis, left ventricular function, and the size and type of prosthetic valve to be implanted was performed.

The pre-procedural non-invasive diagnostic evaluation included:

1. Transthoracic echocardiography (TTE) to confirm the severity of aortic valve stenosis, assess left ventricular function, and evaluate the condition of the remaining heart valves;
2. Transesophageal echocardiography (TEE), when indicated, to provide detailed visualization of the cardiac valves and intracardiac structures;
3. Computed tomography of the heart and aorta, one of the most important investigations before TAVI, used to assess and measure the aortic valve, annulus, aorta, and access vessels (most commonly the femoral arteries) through which the delivery catheter will be advanced. This examination is essential for selecting the appropriate prosthetic valve size and determining the optimal vascular access route. Although the transfemoral approach is preferred, alternative access routes include the axillary, subclavian, carotid, transcaval, and transapical approaches;
4. Coronary angiography;
5. Electrocardiography (ECG);
6. Laboratory investigations;

7. Chest radiography;
8. Assessment of the patient's overall clinical condition.

All of these data were reviewed by the multidisciplinary Heart Team, which assessed the procedural risk and determined the most appropriate treatment strategy for each patient [15].

Ethics: This retrospective investigations were carried on in accordance with ethical standards of the Serbian Archives of Medicine and the Declaration of Helsinki.

RESULTS

Between 2014 and 2021, a total of 73 TAVI valves were implanted across the three TAVI centers in Serbia. In 2022, the National Health Insurance Fund of Serbia initiated annual procurement of TAVI valves, resulting in 221 TAVI procedures performed that year. In 2023, 318 TAVI valves were implanted, followed by 231 procedures in 2024. In 2025, the annual number increased to 562 TAVI procedures. Overall, from 2014 through the end of 2025, a total of 1405 TAVI valves were implanted in Serbia (Table 1).

DISCUSSION

First, it is evident that between 2014 and 2021 the number of TAVI procedures performed in Serbia was very low, with only 73 valves implanted across three centers. This limited procedural volume can be attributed to the early stage of the national TAVI program, restricted availability of prosthetic valves, and the fact that the procedure was not yet systematically funded by the National Health Insurance Fund of Serbia during that period [16].

A major turning point occurred in 2022, when the National Health Insurance Fund of Serbia initiated regular procurement of TAVI valves. As a result of this healthcare policy, the number of procedures increased dramatically – from a total of 73 procedures performed during the preceding eight-year period to 221 procedures in 2022 alone. This trend indicates that systematic reimbursement was a key prerequisite for the broader implementation of TAVI and improved access to treatment for patients with severe aortic stenosis.

The upward trend continued in 2023, with 318 procedures performed, reflecting increasing operator experience, further development of the national TAVI program, and expansion of indications in accordance with contemporary European and international guidelines. The lower number of procedures in 2024 (231) most likely reflects organizational factors, the dynamics of valve procurement, or the allocation of healthcare resources rather than a reduced clinical need for this treatment modality. Therefore, this finding should be interpreted with caution in the absence of additional data.

The highest annual procedural volume was recorded in 2025, with 562 TAVI procedures, representing more than a twofold increase compared with the previous year. This substantial growth suggests that TAVI in Serbia has progressed from an initial developmental phase to routine clinical practice, accompanied by a marked expansion of healthcare system capacity and increasing experience of multidisciplinary Heart Teams.

Overall, between 2014 and 2025, a total of 1405 TAVI valves were implanted in Serbia. These findings demonstrate the continuous development of the national TAVI program, which accelerated considerably following the introduction of systematic reimbursement. Although the number of procedures has increased substantially, it remains lower than that reported in most developed countries, indicating that there is still considerable potential for further

expansion of the program, improved patient access, and the establishment of additional TAVI centers throughout the country [17, 18, 19].

CONCLUSION

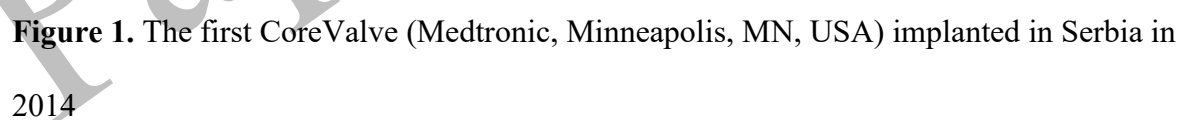
TAVI represents an effective and safe therapeutic option for the treatment of patients with severe symptomatic aortic stenosis. Advances in technology, improvements in implantation systems, and increasing operator experience have led to a significant reduction in periprocedural complications and improved both short- and long-term outcomes. Results from numerous clinical trials confirm that TAVI provides a high procedural success rate, improvement in functional status and quality of life, with long-term durability of bioprosthetic valves. Individual patient selection, based on the assessment of a multidisciplinary Heart Team, remains crucial for achieving optimal outcomes. Further technological advancements and the availability of long-term outcome data are expected to expand the indications for TAVI in patients with different levels of surgical risk.

This method has been widely adopted worldwide, and in some countries, it is used to treat more than 50% of patients with aortic stenosis.

Conflict of interest: None declared.

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TAVI in Serbia 2014–2025

• 2014 TAVI= 5 (Clinical Center of Serbia) • 2015 TAVI = 6 (Clinical Center of Serbia – 2, Institute for CVD Dedinje – 2, Institute for CVD Sremska Kamenica – 2) • 2016 TAVI = 1 (Clinical Center of Serbia) • 2017 TAVI = 2 (Military Medical Academy) • 2018 TAVI = 2 (Military Medical Academy) • 2019 TAVI = 1 (Military Medical Academy) • 2019 TAVI = 24 (Institute for CVD Dedinje) • 2020 TAVI = 9 (Institute for CVD Dedinje) • 2021 TAVI = 23 (Institute for CVD Dedinje) TOTAL (2014–2021) = 73	• 2022 TAVI* = 166 (Institute for CVD Dedinje) = 24 25 (Institute for CVD Sremska Kamenica) = 30 (University Clinical Center of Serbia) = TOTAL 221 • 2023 TAVI = 167 (Institute for CVD Dedinje) = 80 (Institute for CVD Sremska Kamenica) = 71 (University Clinical Center of Serbia) = TOTAL 318 • 2024 TAVI = 97 (Institute for CVD Dedinje) = 75 (Institute for CVD Sremska Kamenica) = 53 (University Clinical Centre of Serbia) = 6 (Military Medical Academy) = TOTAL 231 • 2025 TAVI = 294 (Institute for CVD Dedinje) = 133 (Institute for CVD Sremska Kamenica) = 127 (University Clinical Center of Serbia) = 8 (the Military Medical Academy)** TOTAL (2022–2025) = 562 TAVI in Serbia 2014–2025 = TOTAL 1405
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Table 1. TAVI procedures in Serbia, 2014–2025;

*In 2022 annual procurement of valves by the Health Insurance Fund of Serbia began;

**The National Health Insurance Fund of Serbia included the Military Medical Academy starting with August 2025