Slovenian Medical Journal

Results of transcatheter aortic valve implantation (TAVI) in the international centre for cardiovascular diseases MC Medicor

Rezultati katetrskega vstavljanja aortne zaklopke (TAVI) v mednarodnem kardiovaskularnem centru MC Medicor

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Key words:
aortic stenosis; transcatheter aortic valve implantation; results

Ključne besede:
aortna stenoza; katetrska vstavitev aortne zaklopke; rezultati

Received: 20. 8. 2020
Accepted: 13. 11. 2020

Abstract

Background: Transcatheter aortic valve implantation (TAVI) has become a standard of care for the treatment of symptomatic aortic stenosis in the elderly. The aim of the present study is to describe initial results in the international cardiovascular centre MC Medicor and compare them with the results of the recently published pivotal international trials.

Methods: A retrospective analysis of consecutive patients undergoing TAVI was performed. The data were obtained from a prospective Medicor registry of percutaneous cardiovascular interventions.

Results: Between 12 December 2016 and 6 June 2020, a total of 109 TAVI were performed. The patients were on average 81 years old and had EuroScore II of 3.95. Mean aortic valve gradient by echocardiography was 46 mmHg and aortic valve area 0.8 cm^2. Percutaneous femoral approach was used in all but one patient. Balloon predilatation was performed in 36.7%. TAVI valve was successfully implanted in 98.2% and balloon postdilatation was performed in 15.6%. Mean post TAVI gradient was 9 mmHg. Moderate aortic regurgitation was recorded in 3.7% and severe in none of the patients. New permanent pacemaker was required in 22.9% (95% confidence interval (CI) 15.4% - 32.0%). One patient had a transient ischemic attack. Emergency pericardiocentesis was performed in 2.7% (95%, CI 0.6% - 7.8%), open-heart surgery in 1.8% (95%, CI 0.2% - 6.5%), vascular surgery in 0.9% (95%, CI 0.0% - 5.0%) and additional haemostasis of the ileofemoral artery with covered stents in 1.8% (95%, CI 0.2% - 6.5%) In-hospital and 30-day mortality rates were 1.8% (95%, CI 0.2% -6.6%), 1-year mortality 3.1% (95%, CI 0.0% - 6.5%), 2-year mortality 5.6% (95%, CI 0.0% - 11.4%) and 3-year mortality 14.2% (95%, CI 0.0% - 29.6%).

Conclusion: Initial TAVI results in MC Medicor are good and comparable with the results of recently published international pivotal trials.

Izvleček

Izhodišče: Katetrska vstavitev aortne zaklopke (TAVI) je v zadnjih letih postala prevladujoča metoda za zdravljenje degenerativne aortne stenoze pri starejših bolnikih. Prispevek prikazuje prve rezultate zdravljenja s TAVI v mednarodnem kardiovaskularnem centru MC Medicor in jih primerja z najpomembnejšimi mednarodnimi raziskavami zadnjih let.

Metode: V retrospektivno raziskavo smo vključili zaporedno serijo bolnikov, pri katerih smo opravili TAVI. Podatke smo pridobili iz lastnega registra perkutanih kardioloških posegov.

Rezulati: Med 12. decembrom 2016 in 6. junijem 2020 smo TAVI opravili pri 109 bolnikih s povprečno starostjo 81 let in EuroScore II 3,95. Srednji ultrazvočni gradient na aortni zaklopki je znašal 46 mm Hg, izračunana površina ustja pa 0,8 cm^2. Pri vseh bolnikih, razen pri enem, smo uporabili perkutani pristop preko femoralne arterije. Balonsko predilatacijo smo izvedli v 36,7 %, novo zaklopko vsadili v 98,2 % in jo balonsko postdilatirali v 15,6 %. Srednji ultrazvočni gradient po TAVI je znašal 9 mm Hg. Zmerna aortna regurgitacija je bila prisotna v 3,7 % (95 % IZ 1,0–9,1 %), huda pa pri nobenem od bolnikov. Nov srčni spodbujevalec je potrebovalo 22,9 % bolnikov (95 % IZ 15,4–32,0 %). En bolnik je imel tranzitorno ishemično kap. Urgentno perikardiocentezo smo opravili v 2,7 % (95 % IZ 0,6–7,8 %), srčno operacijo v 1,8 % (95 % IZ 0,2–6,5 %), žilno operacijo v 0,9 % (95 % IZ 0,0–5,0 %) in hemostazo s prekritimi žilnimi opornicami v 1,8 % (95 % IZ 0,2–6,5 %). Bolnišnična in 30-dnevna umrljivost sta bili 1,8 % (95 % IZ 0,2–6,5 %), enoletna 3,1 % (95 % IZ 0,0–6,5 %), dvoletna 5,6 % (95 % IZ 0,0–11,4 %) in triletna 14,2 % (95 % IZ 0,0–29,6 %).

Zaključek: Začetni rezultati TAVI v Medicorju so ugodni in primerljivi z najpomembnejšimi mednarodnimimi raziskavami zadnjih let.

Cite as/Citirajte kot: Pleskovič A, Rojko M, Černič Šuligoj N, Cvetičanin B, Špan M, Noč M, et al. Results of transcatheter aortic valve implantation (TAVI) in the international centre for cardiovascular diseases MC Medicor. Zdrav Vestn. 2021;90(3–4):139–49.

DOI: https://doi.org/10.6016/ZdravVestn.3150

1 Introduction

Transcatheter aortic valve implantation (TAVI) has in recent years become the method of choice for the treatment of degenerative aortic stenosis in the elderly, regardless of the risk of open heart surgery (1-3). Treatment with TAVI, which is less invasive and enables rapid rehabilitation for patients, is at least as effective or even more effective than standard aortic valve replacement surgery. With technological advancements in valve manufacturing, with ever smaller diameters of catheter introducers and with greater provider experience, complications become less frequent and the medium and long-term valve function is the same or even better than with surgically inserted biological valves. The goal of our study was to present the first results of TAVI in the international cardiovascular centre MC Medicor and compare them to recently published pivotal international studies.

2 Patients and methods

We performed a retrospective descriptive study, which included consecutive patients in whom we performed TAVI in Medicor. We obtained the data from our own register of percutaneous cardiac procedures, which was approved by the National Medical Ethics Committee on December 7, 2012. The register provides the patient with anonymity, and the obtained data are used for real-time analysis of results, improvement of the quality of work and as a source for our own research, which is published in both domestic (4-7)

and international literature (8-9). All patients received a comprehensive explanation, after which they signed a consent form for their data to be entered into the register.

We performed a clinical exam, transthoracic cardiac ultrasound, coronarography and a CT angiography using a TAVI protocol (CTA-TAVI) in all TAVI candidates in the planning phase; the latter was additionally analyzed by a specialist of each type of valve's manufacturer. All patient's reports were then presented to a TAVI medical council, consisting of the patient's cardiologist, an echocardiography specialist, a radiologist, specializing in CTA-TAVI, a cardiovascular surgeon and an interventional cardiologist. We then informed the patient of the council's opinion and obtained written consent if they agreed with the procedure. Whenever there was a concurrent indication for percutaneous coronary intervention (PCI), we had it performed 1-2 weeks before TAVI. Our strategy for PCI, which is based on revascularization of angiographically significant stenosis (>70% of the diameter) in initial and middle parts of main coronary arteries, was summarized after the experience of leading international experts, as there is a lack of relevant randomized studies in this field. An anaesthesiologist saw the patient immediately prior to the procedure and led the patient through the procedure itself.

The procedure was performed under general anaesthesia in the initial period, and later conscious sedation and local anaesthesia for arterial puncture were used. Using the recommended procedure, we inserted the valve through the right or left femoral artery, and we did not use alternative approaches. We used either a self-expanding valve (Evolut R/Pro, Medtronic, Minneapolis, MN, USA) or a balloon-expandable valve (SAPIEN 3, Edwards Lifescience, Irvine, CA, USA). We based the decision on the type and size of the valve on CTA-TAVI, by which we also assessed whether there was a significant likelihood of coronary artery occlusion. In such cases we inserted a catheter introducer, coronary guide wire and stent though the radial artery into the left descending coronary artery prior to valve insertion (10). If partial or complete occlusion of a coronary artery occurred or was probable during valve insertion, we moved the stent to the ostium of the coronary artery and set it there. For valve placement we initially used the recommended coplanar projection of three cusps, and from 11 December 2019, in most patients with a self-expanding valve, the projection with cusp-overlap (overlapping of the right and left coronary cusps (Figure 1). An echocardiographer was present during the procedure and, if necessary, performed transthoracic echocardiography during the procedure, and always after the procedure, with the help of which we assessed the pericardium, left ventricular function and the artificial valve. During TAVI a cardiovascular team and an operating theatre were on standby, which enabled immediate surgery in case of complications. After the procedure we woke the patient in the catheter laboratory itself and then admitted them to a non-intensive ward, where we monitored the electrocardiogram, arterial pressure and oxygen saturation of arterial hemoglobin with pulse oximetry for the next 48 hours. In case of delayed recovery from anaesthesia or hemodynamic/respiratory instability following TAVI we admitted the patient into a post-operative intensive care unit. Temporary pacemakers were usually removed after 48 hours, except in patients who already had a permanent pacemaker. In case of significant bradycardia we inserted a permanent pacemaker. All patients were completely mobilized

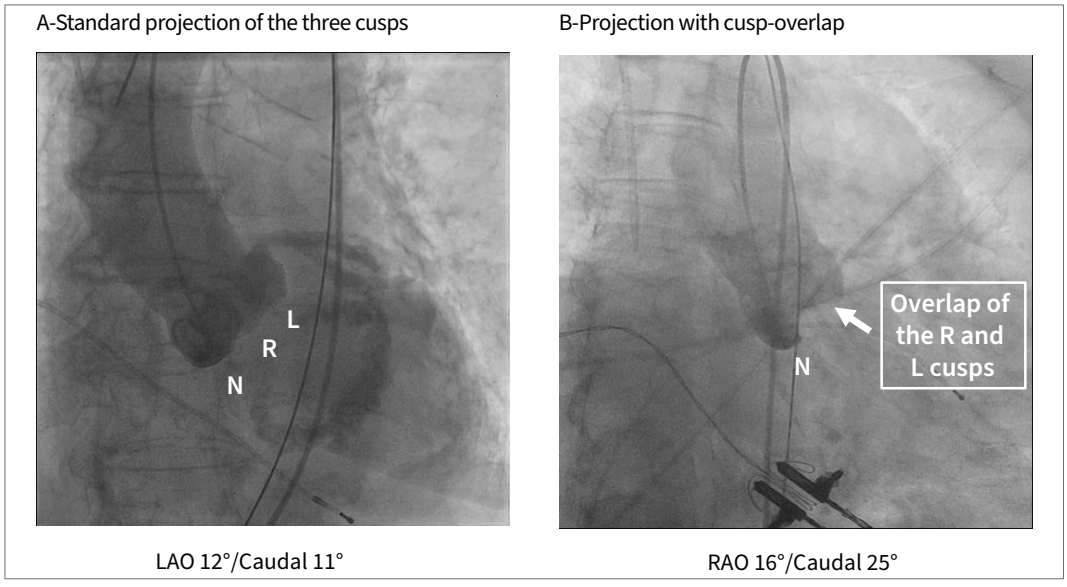

Figure 1: Standard coplanar projection of the three cusps (A) and the projection with cusp-overlap (overlapping of the left and right coronary cusps) (B).
Legend: N = non-coronary cusp; R = right cusp; L = left cusp.

prior to discharge and had a transthoracic cardiac ultrasound performed, with which we once again confirmed proper aortic valve function, absence of significant regurgitation and measured pressure gradients. After the procedure, patients usually received acetylsalicylic acid 100 mg daily for life and clopidogrel 75 mg daily for 3 months. In patients with prior anticoagulation therapy we continued with it without adding acetylsalicylic acid and/or clopidogrel, unless they needed dual antiplatelet therapy for a prior PCI.

All patients are regularly followed in the cardiology clinic at MC Medicor, where they have cardiac ultrasounds performed, usually 3-6 months and 12 months after the procedure. In case of clinical worsening or elevation of the mean pressure gradient above 20 mmHg, we perform a CTA-TAVI due to suspicion of cusp thrombosis to confirm or refute the existence of a phenomenon known as HALT/RELM (hipoattenuated leaflet thickening/reduced leaflet movements), which requires treatment with anticoagulants for several months (11). During the Covid-19 epidemic we additionally contacted all patients by telephone and instructed them to stay in their home environment and avoid contact with people from another environment. Numerical data were presented as mean values with 95% confidence interval (95% CI) or as medians with 1st and 3rd quartiles. Variability was additionally demonstrated by standard deviation. Categorical data were expressed as absolute values, percentages and 95% CI. Data on the exact date of death of deceased patients were obtained via the information system "BIRPIS" with the help of the health insurance card. Long-term survival was shown with the Kaplan-Meier curve. To compare the frequency of insertion of a new permanent pacemaker according to the insertion technique and the type of valve we used the chi-squared test. P-values of less than 0.05 were considered statistically significant.

Table 1: General characteristics of patients who had TAVI performed in Medicor.

General patient characteristics	n = 109
Age (years), mean value + SD	81 ± 6
Men	56 (51.4%)
EuroScore ll	
• Mean value + SD	3.95 ± 3.56
• Median (1.-3. quartiles)	2.85 (1.75–4.67)
Logistic EuroScore	
• Mean value + SD	18.46 ± 14.65 (1.66–80.44)
• Median (1.-3. quartiles)	13.48 (8.97–22.39)
STS for mortality	
• Mean value + SD	3.07 ± 2.03 (0.43–12.07)
• Median (1.-3. quartiles)	2.58 (1.73–3.75)
Concomitant obstructive coronary disease	44 (40.4%)
Prior PCI/CABG	41 (37.6%)
Left ventricle ejection fraction (%)	57 ± 12
Significant electrocardiographic characteristics	
• Left bundle branch block	12 (11.0%)
• Right bundle branch block	8 (7.3%)
• Bifascicular block	2 (1.8%)
• Trifascicular block	3 (2.8%)
• First-degree AV block	14 (12.8%)
• Atrial fibrillation with bradycardia	2 (1.8%)
• Permanent cardiac pacemaker already present	6 (5.5%)
Ultrasound characteristics of the aortic stenosis	
Maximum gradient, mm Hg	
• Mean value +SD	74 ± 19
• Median (1.–3. quartiles)	74 (62–86)
Mean gradient, mm Hg	
• Mean value + SD	46 ± 13
• Median (1.-3. quartiles)	44 (38–55)
Aortic valve area, cm^2	
• Mean value + SD	0.8 ± 0.2
• Median (1.-3. quartiles)	0.8 (0.7–0.9)

3 Results

Between 12 December 2016 and 6 June 2020, we performed TAVI in 109 consecutive patients at our institution. Their average age was 81 years, and men predominated (51.4%) (Table 1). The mean and median values for EuroScore II were 3.95 and 2.85, respectively, and for the Society of Thoracic Surgeons score (STS) for hospital mortality 3.07 and 2.58, respectively. The ejection fraction of the left ventricle averaged 57%, and 40.4% of patients had concomitant obstructive coronary heart disease. Some patients already had electrocardiographic features, which predict a higher likelihood of the need for a permanent pacemaker, prior to the procedure. Thus, right bundle branch was found in 7.3%, bifascicular block in 1.8%, and trifascicular block in 2.8% of patients. The mean aortic valve gradient by echocardiography was 46 mm Hg and the calculated valve area was 0.8 cm^2. Two patients had bicuspid valves and one patient had a degenerated surgical biological valve. In 30% of patients, PCI was performed prior to TAVI as part of preparations for the procedure.

The procedure was performed under conscious sedation in majority of patients (Table 2). A percutaneous approach through the right or left femoral artery was performed in all patients, except one. Pre-implantation balloon aortic valvuloplasty of the native valve was performed in 36.7%, and a new valve was successfully inserted in 107 patients (98.2%). Balloon post-dilation of the new valve was performed in 15.6%. In two patients, delayed stent insertion into the left sinus of Valsalva had to be performed immediately following TAVI due to partial occlusion of the trunk of the left coronary artery. The mean aortic valve gradient by echocardiography following TAVI was 9 mm Hg,

General patient characteristics	n = 109
Gradient on the tricuspid valve, mm Hg (n=43)	
• Mean value + SD	35 ± 11
• Median (1.-3. quartiles)	33 (27–40)
Bicuspid valve	2 (1.8%)
Degenerated surgical valve	1 (0.9%)
Prior TAVI as part of TAVI preparations	33 (30%)

Legend: SD = standard deviation; STS = Society of Thoracic Surgeons score; PCRI = percutaneous coronary intervention; CABG = coronary artery bypass grafting.

Table 2: Description, results and complications of TAVI in Medicor.

Description, results and complications	
Conscious sedation	82 (75.2%)
Vascular approach for TAVI	
• Percutaneous	108 (99.1%)
• Surgical preparation	1 (0.9%)
Pre-implantation balloon aortic valvuloplasty	40 (36.7%)
Percutaneous valve successfully inserted	107 (98.2%)
• Self-expanding valve (Medtronic Evolut)	94 (87.9%)
• Balloon-expandable valve (Edwards SAPIEN 3)	13 (12.1%)
Balloon post-dilation of the TAVI valve	17 (15.6%)
PCI during TAVI	2 (1.8%)
TAVI results	
Mean aortic valve gradient by echocardiography, mm Hg	
• Mean value + SD	9 ± 3
• Median (1.-3. quartiles)	9 (7–11)
Moderate aortic insufficiency (% and 95% CI)	4 (3.7%; 1.0–9.1%)
Severe aortic insufficiency (% and 95% CI)	0 (0%; 0.0–3.3%)
Percutaneous occlusion of the femoral artery (% and 95% CI)	106/106 (100%; 96.6–100%)
New permanent cardiac pacemaker (% and 95% CI)	25 (22.9%; 15.4–32.0%)
Hospital complications of TAVI (% in 95% IZ)	
Emergency pericardiocentesis	3 (2.7%; 0.6–7.8%)
Emergency open-heart surgery – LV perforation	2 (1.8%; 0.2–6.5%)

moderate aortic regurgitation was present in 3.7%.

Emergency pericardiocentesis was performed in two patients with perforation of the left ventricle with a wire which was used for valve implantation. In one patient, during the catheter procedure, we continued with an unsuccessful attempt to surgically close a left ventricle perforation. The patient died during the procedure. Another patient was hemodynamically stabilized with pericardiocentesis and transferred to the operating theatre, where the surgical team closed the perforation and surgically replaced the aortic valve as the perforation occurred before TAVI. The post-operative course was normal and the patient survived. We performed additional pericardiocentesis and a 2-day catheter pericardium drainage in a patient with right heart perforation, which was probably caused by the wire of a temporary pacemaker. Surgery was not needed in this patient. In one patient, perforation of the common iliac artery, followed by hemorrhagic shock, occurred during insertion of the catheter introducer for TAVI before valve insertion. Despite successful hemostasis with the help of 3 covered vascular stents, additional vascular surgery with a femorofemoral bypass was required due to femoral artery occlusion and the need for additional hemostasis. This patient died on the 3rd post-operative day due to lower limb ischemia, refractory shock and organ failure. A covered vascular stent was also used in one patient for additional hemostasis of the puncture site, and a pseudoaneurysm of the femoral artery at the secondary vascular approach was resolved percutaneously with fibrin glue in 2 patients. One patient had a transient ischemic attack, which completely resolved in a few hours.

After discharge from hospital, one patient experienced sudden dyspnea on the

Description, results and complications	
Hemostasis with covered vascular stents	2 (1.8%; 0.2–6.5%)
Urgent vascular repair of the iliac artery	1 (0.9%; 0.0–5.0%)
Pseudoaneurysm of the femoral artery/ percutaneous occlusion	2 (1.8%; 0.2–6.5%)
Transient ischemic attack (TIA)	1 (0.9%; 0.0–5.0%)
Cerebrovascular insult (CVI)	0 (0%; 0.0–3.3%)
Length of hospitalization (days), mean value + SD	8 ± 4
In-hospital mortality (% and 95% CI)	2 (1.8%; 0.2–6.5%)
New severe aortic valve insufficiency and SAVR	1 (0.9%; 0.0–5.0%)
30-day mortality rate	2 (1.8%; 0.2–6.5%)

Legend: PCI = percutaneous coronary intervention; SD = standard deviation; CI = confidence interval; LV = left ventricle; SAVR = surgical aortic valve replacement.

14th day following a successful TAVI. With transesophageal ultrasound we found a new severe valvular and partially paravalvular aortic insufficiency, which, according to a repeat CTA-TAVI, was caused by an unexplained shift of the valve by an additional 5-6 mm into the left ventricle outflow tract. We surgically removed the TAVI valve and implanted a new valve. The surgery was without complications and the post-operative course was normal.

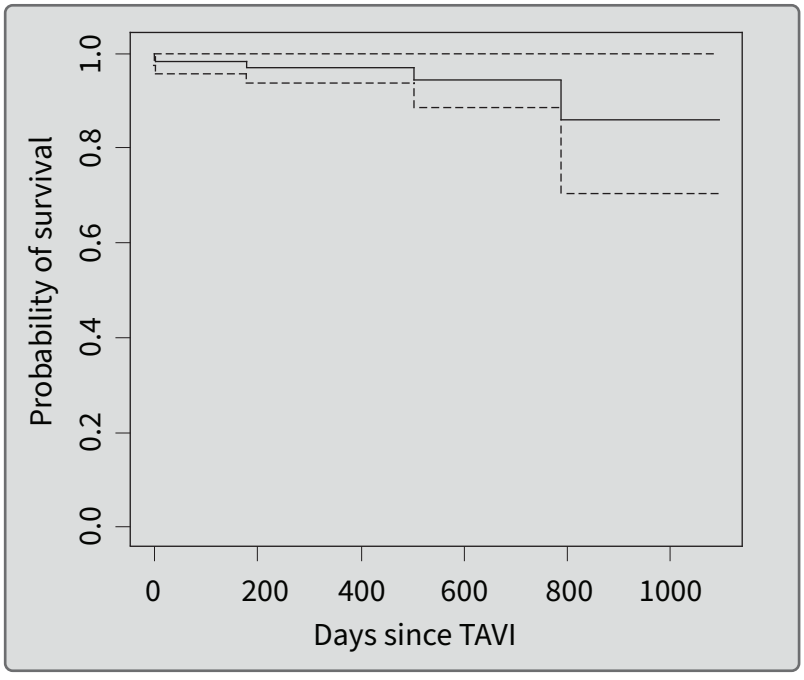

Figure 2: Kaplan-Meier curve showing patient survival following TAVI at MC Medicor. The dotted lines show the 95% confidence interval. The mean follow-up time, shown as a median and 1st and 3rd Quartiles, was 441 days (197 – 599 days).

The in-hospital and 30-day mortality were 1.8% (95% CI 0.2-6-5%). One-year mortality was 3.1% (95% CI 0.0-6-5%), two-year mortality 5.6% (0.0-11.4%), and three-year mortality 14.2% (0.0–29.6%) (Figure 2). The mean follow-up time, expressed as median and 1st and 3rd quartiles, was 441 days (197-599 days).

4 Discussion

Due to ever growing numbers of elderly patients with severe aortic stenosis and numerous comorbidities we started with TAVI at our institution in 2016. For this purpose, we established a TAVI medical council and team in accordance with international recommendations. By June 2020, we had performed 109 procedures.

We compared our results to the recently published randomised study SOLVE TAVI, which was done in top German centres with large numbers of yearly procedures and using the same valves as at our institution. We must keep in mind that comparison can only be approximate due to methodological differences between the two studies. Our study is much smaller in terms of the number of procedures performed and consists of consecutive patients in one centre, while SOLVE TAVI was a large multicenter randomized study in which patients were selected and included by researchers on the basis of previously established inclusion criteria. We used the Evolut R/Pro valve in more than 80% of cases, while in SOLVE TAVI, the proportions of the Evolut R/Pro and SAPIEN 3 valves were the same. We would especially like to emphasize that the values of individual parameters

from SOLVE TAVI, which were used for comparison, were calculated as the average of both groups with different types of valves. Taking into account all the described limitations, our patients were of comparable age (81 years versus 82 years), and the medians and 1st and 3rd quartiles in the pre-surgery risk assessment also overlapped. In our patients the Euroscore II was 2.9 (1.8-4.7); in SOLVE TAVI, it was 4.1 (2.5-7.5). STS in our study was 2.6 (1.8-3.8), while in SOLVE TAVI, it was 4.9 /2.9-9.9). The medians of the aortic valve areas (0.8 vs 0.7 cm^2) and mean aortic valve gradients by echocardiography (44 mm Hg vs 39 mmHg) were comparable. We used conscious sedation and local anaesthesia more often at our centre (75% vs 50%) and we were as successful at percutaneous closing the puncture of the femoral artery (100% vs 94%). If we add up all our severe (0.9%) and less severe (3.6%) vascular complications, we get a frequency of 4.5%, which is also comparable to 5.7% in SOLVE TAVI. As SOLVE TAVI did not report on the need for emergency open heart surgery and pericardiocentesis, we cannot compare it to our study in this particular segment. Our 30-day mortality of 1.8% (95% CI 0.2-6.5%) was comparable to SOLVE TAVI (2.7%). Taking into account the 95% confidence intervals, as shown in Table 2, this can also be said for the incidence of stroke (0% vs. 2.6%), the proportion of moderate/severe aortic insufficiency (4.6% vs. 2.4%) and the need for a permanent cardiac pacemaker (22.9% vs. 21.0%) (12).

As the SOLVE TAVI study currently reports only on the 30-day mortality, we compared our long-term survival to survival in other high-profile international randomized trials in moderate-risk patients, including SURTAVI (3) and PARTNER 2 (1). Researchers in these studies, unlike those in SOLVE TAVI, include mean instead of median values. Our patients were of comparable ages, while STS for mortality was lower in our patients (3.1) than in the PARTNER 2 (5.8) and SURTAVI studies (4.4). Our one-year mortality, which was 3.1% (95% CI 0.0-0.6%) was at least comparable to the PARTNER 2 (12,3%) and SURTAVI studies (6,7%), which, unfortunately, do not include confidence intervals. The same is true for the two-year mortality, which was 5.6% in our study (95% CI 0.0-11%), in the PARTNER 2 study 16.7%, and 11.4% in the SURTAVI study. Our thesis, that the pre-procedure morbidity has a decisive influence on long-term survival in patients who had a successful TAVI without complications, was also confirmed by the PARTNER 3 study, performed in low-risk patients; such patients were also included in our study. In these patients, with a mean age of 73 years, mean Euroscore II 1.5 and STS 1.9, the one-year mortality was only 1% (2). Unfortunately, apart from survival rates, we currently do not have long-term echocardiographic data on valve pressure gradients, rate of aortic insufficiency, and possible improvement or worsening of left ventricular ejection fraction, which would further contribute to the portrayal of the patient's post-TAVI condition. Regardless of the fact that the proportion of our patients who needed a permanent pacemaker after TAVI, even in light of our 95% confidence interval, is comparable to the SOLVE TAVI study (12) for self-expanding (27% vs. 23%) and balloon-expandable valves (23% vs. 19%), it is still too high. Part of the reason may be that a significant proportion of our patients already had electrocardiographic features prior to TAVI (bifascicular/trifascicular block, bradycardia, right bundle branch block) which would probably have caused them to receive a permanent pacemaker earlier in Germany. Such cases

wouldn't, of course, count in the "new cardiac pacemaker after TAVI" category. This hypothesis is supported by the fact that 10.8% of patients in SOLVE TAVI had a permanent pacemaker before the procedure; this figure was only 5.5% in Slovenia. As, according to some studies, the need for a permanent pacemaker is linked to worse long-term left ventricular function, and definitely with additional costs, we used a new cusp-overlap technique with self-expanding valve insertion. Our preliminary results confirm the effectiveness of this technique, as the need for insertion of a permanent pacemaker dropped from 27.4% to 9.5% when using a self-expanding valve. We cannot exclude the possibility that the previously described drop could be a consequence of the provider's learning curve, who, with more experience, implanted the self-expanding valve higher.

The influence of the learning curve probably also applies to complications which we have described and that are otherwise comparable to other studies, and which we expect to be further reduced with growing numbers of interventions. Further advancements in TAVI technology will also probably contribute to this, as will better preparations for the procedure following detailed CTA TAVI analysis. Based on this, we expect that in a few years, the TAVI procedure will become the same as PCI in our region. Due to favorable results of randomized trials and the growing number of better informed patients who want less invasive procedures, the indications for TAVI are spreading rapidly. In the most developed centres in Western Europe and the United States of America the classic open heart surgery is reserved only for younger patients with bicuspid aortic valves and concomitant disease of the ascendent aorta. In recent years, there appears an additional important indication for TAVI in patients with degenerated biological valves, inserted either surgically or with TAVI. Such patients, in which TAVI represent a significant technical challenge for the provider, will only grow in number. An important challenge for the TAVI medical council are the decisions with patients with severe comorbidities, in which TAVI would not significantly contribute to improvement to quality of life and would only prolong it. To make the best possible decision, it is necessary to carefully consider the impact of comorbidities. Only if aortic stenosis is the main problem is TAVI the correct solution for the patient.

All our patients have the option to be followed by non-invasive cardiologists following TAVI in our clinic at MC Medicor. Most of them choose this option, but some return to their cardiologists, which of course isn't problematic if their cardiologists know how to follow patients after TAVI. TAVI providers and the Slovenian Society of Cardiology, led by appropriate working groups, thus have an important mission to provide non-invasive cardiologists with specific, in particular echocardiographic, knowledge to identify possible complications such as endocarditis, valve leaflet thrombosis (HALT/RELM) (11) and late TAVI valve degeneration. If such complication is suspected, it is best to refer the patient to their TAVI provider.

Finally, it should be emphasized that the current bottleneck for performing a large number of TAVIs at MC Medicor are undoubtedly the administrative and financial constraints of the Health Insurance Institute of Slovenia (ZZZS) and the Ministry of Health, not the lack of suitable patients or the inability of the TAVI team to carry out all necessary interventions. Given our good starting results, which we have shown to be comparable with the most important international studies of

recent years, it is our hope that the decision-makers of our health care system will recognize this and also enable our centre to shorten the waiting period with a larger number of interventions.

5 Conclusion

We have shown the first results of treatment of aortic stenosis with TAVI at MC Medicor, which are good and comparable with the most important international studies of recent years.

6 Ackwnoledgment

We would first like to thank Prof. Dr. Oscar Mendiz of the Fundación Favaloro, Buenos Aires (Argentina) and Prof. Dr. Flavio Ribichini of the University of Verona (Italy), who taught TAVI to us as proctors. We owe special thanks to our surgical instrumentalist nurse Ana Čerpnjak, radiology technician Tjaša Godeša and anaesthesiology nurse Mirko Jović. We would also like to thank the team of our outpatient clinic (Dr. Nataša Gorkič, Assistant Professor Dr. Vojka Gorjup, Prof. Dr. Aleš Žemva, Senior Physician Dr. Borut Kolšek) and departmental cardiologists of MC Medicor (Dr. Milan Ignjatovič, Dr. Zoran Konstantinovič, Dr. Mirjana Čenanovič, Dr. Dragan Zečevič) and nurses under the leadership of Ms. Jasmina Grahovac for their contributions. For administrative help, we would like to thank Ms. Marija Grahovac and Ms. Mojca Luznar. Last but not least, we sincerely thank Prof. Dr. Roberto Favaloro of the Fundación Favaloro, Buenos Aires (Argentina), without whom we would not be able to take the first steps into the field of TAVI.

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