

MINIMALISTIC APPROACH FOR TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI): OPEN VASCULAR VS. FULLY PERCUTANEOUS APPROACH

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ABSTRACT

Background: Aortic stenosis (AS) is the most common valvular heart disease in elderly people. Transcatheter aortic valve implantation (TAVI) has emerged as a revolutionary treatment for elderly patients with symptomatic severe aortic stenosis. The authors present the first experiences with transcatheter aortic valve implantation treatment in Macedonia and compare their findings in regard to differences between open vascular vs. minimalistic transfemoral TAVI approach.

Methods: The procedure was performed in 54 patients with severe and symptomatic AS in the period from December 2014 until February 2018. All patients were deemed having high surgical risk or were denied surgery. Pre-procedural screening included detailed clinical and echocardiographic evaluation, coronary, peripheral and carotid angiography and computed tomography scan of the aortic root. A self-expandable aortic valve (Core Valve/Evolut R, Medtronic, USA) was implanted in all patients.

Results: Mean patient age was 75 ± 7.2 years, 28 (52%) were female, 26 patients (48%) male. All interventions were successfully performed through right transfemoral approach with 100% implantation success. Ancillary right radial and ulnar approach was used for correct valve positioning and control. 22(40%) cases were performed under general anesthesia and open vascular access to the femoral artery. All other 32(60%) cases were performed with minimalistic approach (local anaesthesia and analgesedation of the patients, access site was closed with closure devices). Patients in the minimalistic approach group were older, with more chronic conditions as anaemia, chronic kidney disease, poor mobility and peripheral vascular disease ($p < 0.0001$). Also 4(12.5%) patients in the minimalistic group had bicuspid valve TAVI implantation ($p < 0.0001$). Procedural time and contrast amount spent were shorter in this group with 97 ± 38 vs. 121 ± 38.3 ($p < 0.0001$) and 287 ± 122 vs. 330 ± 115 ml, while fluoroscopy time was similar in both groups. Immediate hemodynamic improvement was obtained in all patients. Echocardiographic peak gradient decreased from 85 ± 25 to 17 ± 8 mmHg ($p < 0.001$) and mean pressure gradient from 49 ± 26 to 8.3 ± 4.2 mmHg, ($p < 0.001$). Effective valve orifice area was 1.8 ± 0.4 cm² after intervention. None of the patients had significant aortic regurgitation after implantation. After intervention 7(12%) patients developed a permanent heart block and required implantation of a permanent pacemaker. There was a larger Hgb drop after intervention with open vs. minimalistic approach 1.9 ± 0.9 vs. 0.7 ± 0.2 g/dL ($p < 0.0001$). 3 (13% vs. 0%) patients from the open vascular access group had a major bleeding complication with 2 requiring transfusion after intervention ($p < 0.0001$). Mortality was 5.5%, 2 with open-vascular and 1 with minimalistic approach. MACCE rate that included MI, Stroke, Major bleeding and Death rate, was recorded in 5(18%) patients with open vascular approach vs. 1(3.1%) in minimalistic approach ($p < 0.0001$). Hospital discharge was 8.7 ± 3.1 vs. 4 ± 3.1 days respectively ($p < 0.0001$). All TAVI patients with minimalistic approach were discharged the following day after intervention. All discharged patients had a good neurological condition,

which was assessed based on the CPC-1 (Cerebra Performance Categories Scale). After median follow up of 26 months, the survival rate was 95% with clinical improvement in all patients.

Conclusion: Percutaneous aortic valve implantation can be successfully conducted with high success rate and low rate of complications in patients with severe aortic stenosis. Using a less invasive approach with local anaesthesia and analgosedation is associated with shorter length of stay and a decrease in post-procedural complication rates and MACCE.

Keywords: Aortic stenosis, Transcatheter aortic valve implantation (TAVI)

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become a dominant topic of conversation and published studies in the field of cardiology over the last couple of years. TAVI has enabled treatment of severe aortic stenosis in a group of patients that previously had been denied surgery, because of high operative risk [1, 2]. Current treatment of choice according to guidelines is still valve replacement surgery, due to long experience and clinical results [3, 4, 5]. Despite this, there are still a large number of patients (up to 30%) that are not referred to surgery and are qualified as high risk patients. This was one of the most important reasons for the evolution of the TAVI procedure in the world.

This new approach has led to important developments and collaboration between cardiologists, surgeons and anaesthesiologists and formation of so-called Heart Teams, new research in the field of valvular diseases and transcatheter procedures and development of minimalistic techniques in treatment of these patients, whose number is increasing day by day.

Currently, published studies are heading in the direction of expanding TAVI procedures in intermediate risk, even low risk patients and implementing their positive results into the next guidelines for treatment [6-10]. The latest 2017 ESC guidelines for structural heart disease (5) have expanded the indication for TAVI in intermediate risk patients for surgery according to the decision of the Heart team and the Food and drug administration (FDA) has approved the use of the Core Valve in intermediate risk patients for surgery in the USA.

The current article represents a national single centre experience with TAVI and a development of a TAVI program in our country, as a new life-changing method for many patients stricken with this disease.

METHODS

Heart team and Patient selection for TAVI

Our team consists of 2 interventional cardiologists, 1 or 2 cardiac surgeons, 2 anaesthesiologists and an echocardiographer. The Heart Team before selection for the procedure screens patients. Pre-procedure screening includes detailed clinical and echocardiographic evaluation, coronary, peripheral and carotid angiography and computed tomography scan of the aortic root. After assessment, all cases are discussed and approved by the Team. All members of the Team are present during all implants. First cases were done by proctorship of experienced TAVI operators with over 100 TAVI cases per year.

Patients had to have a clear indication for aortic valve replacement (symptomatic severe aortic stenosis with a valve area of less than 0.8 cm² and a mean gradient of greater than 40 mmHg), but deemed too high risk for operative aortic valve replacement (Euro SCORE > 10, or STS score > 10), or have a condition deemed as a contra-indication for open valve replacement (e.g., previous radiation treatment, chronic kidney disease with high serum creatinine, severe chronic obstructive pulmonary disease, previous valve surgery, cirrhosis of the liver, immunosuppressive therapy and NYHA class > 3). All patients provided written informed consent. Contra-indications to TAVI include: unsuitable aortic annulus size, significant peripheral vascular disease and unprotected left coronary obstruction. Patients underwent transthoracic echocardiography (TTE) to assess the severity of the disease as well as annulus size measurement and suitability of the landing zone of the prosthesis. The iliac and-femoral arteries were assessed by conventional angiography and computer tomography (CT) angio. CT scan of the aortic root was performed to assess the annulus size. The final decision on the valve size was made with an annulus measurement using CT scan.

Technique

All procedures were performed in the cardiac catheterization laboratory, with equipment for cardiopulmonary bypass and sternotomy/thoracotomy on standby. Patients were preloaded with aspirin (300 mg) and after arterial access was obtained, loaded with at least 5 000 IU of heparin. Aspirin (75-100 mg) and Clopidogrel (75 mg) was continued at least for 3 months. Medtronic CoreValve™ systems were utilized per the manufacturer instructions for use (Medtronic, Inc., Minneapolis, Mn) for transfemoral procedures.

Venous access

Central venous access through the left femoral vein or left cubital vein was obtained, and a 5 French balloon-tip pacing wire was positioned within the right ventricle under fluoroscopy. The pacing system was tested and pacing rate was set at 60 beats per minute.

Arterial access

Arterial access was obtained via the right radial or ulnar artery for insertion of a pigtail catheter into the ascending aorta for angiography and hemodynamic assessment. Femoral arterial access for the 18 F/22F sheath was obtained using surgical arterial cut down of the right femoral artery in the first 22 cases with the help of vascular surgeons. The last 32 cases were performed using a minimalistic approach with percutaneous arterial transfemoral (TFA) access (14F sheath) under angiographic (fluoro) guidance.

Crossing the valve

A 5F pigtail catheter was advanced to the ascending aorta from the right radial or ulnar ancillary approach and the distal tip of the catheter was positioned in the non-coronary cusp of the aortic valve.

Then the optimal annular viewing plane was then identified to allow visualization of all 3 coronary sinuses in the same plane, preferably in the left anterior oblique projection, using contrast injections under fluoroscopy.

The aortic valve was crossed using a straight hydrophilic 0.035" wire (Terumo, Japan) delivered through an AL2 diagnostic catheter and exchanged for a pigtail catheter once at the left ventricle. An Amplatz extra-stiff guide wire or dedicated TAVI wire (Safari, Boston Scientific, USA) was exchanged and positioned in the left ventricular apex. In only 4 cases, a 20 mm balloon was used to pre-dilate the aortic valve under rapid ventricular pacing. The valve was then positioned fluoroscopically and deployed under

rapid ventricular pacing when needed. Immediate success was assessed with supra aortic contrast injection from the pigtail catheters as well as with TEE. Post-dilatation was needed in 4 patients due to suboptimal valve expansion and moderate paravalvular leak. The arteriotomy site in the groin was closed surgically in the open vascular access cases or with percutaneous closure by using Abbott Vascular two Perclose ProGlide devices in the cases with minimalistic approach. The radial or ulnar arteriotomy site was closed using mechanical compression with a TR Band (Terumo). The right ventricular pacing electrode was removed (except in 12 cases) and femoral venous haemostasis was obtained by manual compression.

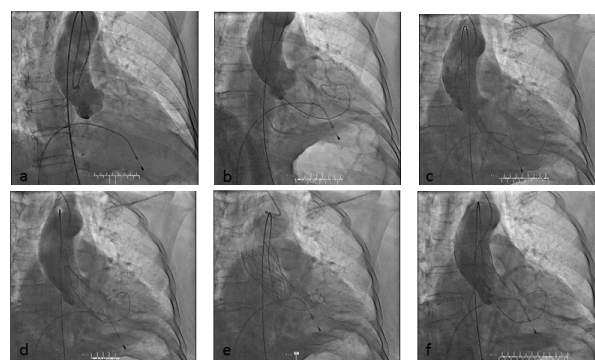


Fig 1. TAVI step by step:
a. Preprocedural aortography
b. Crossing of the aortic valve (AL2 catheter, straight hydrophilic wire, extra supportive stiff wire)
c. Positioning of the self expandable aortic valve (Evolut R 29mm)
d. Partial deployment of the aortic valve
e. Full deployment of the aortic valve
f. Final aortography without aortic regurgitation

Fig. 1. TAVI step by step

Data collection

Data were collected prospectively and entered into a dedicated database. Categorical variables were expressed as proportions and continuous variables as mean $\pm$ standard deviations throughout the manuscript. Statistical analysis was performed with JMP 11.0 for Windows (SAS Inc.).

Study end-points

We assessed each patient for any complications, including stroke, major vascular complications requiring acute intervention or blood transfusion, conduction abnormalities requiring permanent pacing, acute kidney injury, renal failure requiring dialysis, procedural success rate and mortality. Patients were assessed at 30-days, 6 month, 1 and 2 years and up to 4 years of follow up after TAVI. New York Heart Association functional status was assessed after the procedure.

RESULTS

Mean patient age was 75 ± 7.2 years, 28 (52 %) were female, 26 patients (48%) male. All interventions were successfully performed through right transfemoral approach with 100% implantation success. Ancillary right radial and ulnar approach was used for correct valve positioning and control. 22 (40 %) cases were performed under general anaesthesia and open vascular access to the femoral artery. All other 32 (60 %) cases were performed with minimalistic approach (local anaesthesia and analgesation of the patients, access site was closed with closure devices). Patients in the minimalistic approach group were older, with more chronic conditions as anaemia, chronic kidney disease, poor mobility and peripheral vascular disease ($p < 0.0001$).

Immediate hemodynamic improvement was obtained in all patients. Echocardiographic peak gradient decreased from 89 ± 25 to 18 ± 8 mmHg, $p < 0.001$ and mean pressure gradient from 49 ± 32 to 8.8 ± 4.2 mmHg, $p < 0.001$). Effective valve orifice area was 1.7 ± 0.4 cm² after intervention.

TAVI was performed in 4 (12.5%) patients with bicuspid aortic valve using minimalistic approach. Only one patient had a valve in valve implantation, 16 years after original surgical biological valve implantation.

Procedural time and contrast amount spent were shorter in the minimalistic approach group with 97 ± 38 vs. 121 ± 38.3 ($p < 0.0001$) and 287 ± 122 vs. 330 ± 115 ml, while fluoroscopy time was similar in both groups.

Table 1. Patient characteristics

n (%) or mean $\pm$ SD	All TAVI N=54	Open Vascular N=22	Minimalistic N=32	p
Age, years	75 ± 7.2	73.6 ± 6.8	76 ± 6.9	0.0308
Female	28 (52%)	13 (59%)	15 (46%)	0.3764
BMI	26.5 ± 4.0	27.6 ± 4.2	28 ± 3.9	0.5866
LVEF	64 ± 9.3	65 ± 9	65 ± 8.7	0.2225
STS Score, %	10.4 ± 4.4	11.6 ± 0.9	10 ± 1	0.5252
AdditiveEuroSCORE, %	10.3 ± 5.6 9.6 ± 3	10.4 ± 3.1	10.5 ± 3.7	0.5846
Diabetes mellitus	15 (28%)	6 (27%)	9 (28%)	0.9452
Hypertension	51 (94%)	21 (95%)	30 (93%)	0.7859
Serum creatinine CKD STAGE>2	17 (31%)	5 (22%)	12 (37%)	0.2451
Prior stroke	3 (5.5%)	1 (4.5%)	2 (6.2%)	0.7859
Prior TIA	3 (5.5%)	2 (9%)	1 (3.1%)	0.4301
Peripheral vascular disease	5 (9.2%)	0	5 (15%)	0.0182
Prior CABG	3 (5.5%)	1 (4.5%)	2 (6.2%)	0.7859
Prior PCI	8 (14.8%)	3 (13%)	5 (15%)	0.8392
Prior MI	8 (14.8%)	2 (9%)	6 (19%)	0.3136
Permanent AF	10 (18.5%)	3 (13%)	7 (21%)	0.4371
NYHA Class III/IV	34 (62%)	12 (54%)	22 (68%)	0.5230
COPD	9 (16%)	2 (9%)	7 (22%)	0.2009
Anaemia	11 (20%)	0	11 (34%)	p<0.0001
Poor mobility	29 (54%)	10 (45%)	19 (59%)	0.5082
Chirrosis of liver	1 (1.8%)	0	1 (3.1%)	0.3033
Imunosuppressive therapy	1 (1.8%)	0	1 (3.1%)	0.3033
Previous Cancer	4 (7.4%)	2 (9%)	2 (6.2%)	0.7859

LVEF=Left ventricular ejection fraction, CKD= chronic kidney disease, TIA=transitory ischemic attack, CABG=coronary artery bypass grafting, PCI=percutaneous coronary intervention, MI=myocardial infarction, AF=atrial fibrillation, COPD=chronic obstructive pulmonary disease.

Table 2. *Implantation data*

	All TAVI N=54	Open vascular N=22	Minimalistic N=32	P value
Bicuspid valve	4 (7.4%)	0	4 (12.5%)	0.0358
Valve in valve	1 (1.8%)	1 (4.5%)	0	0.1769
2 valves	1 (1.8%)	1(4.5%)	0	0.1769
Procedure time, min	107±28	121± 38.3	97± 38	0.0579
X ray time, min	16±6	13.8± 3.8	18± 3.8	0.3450
Contrast application, ml	304±113	330± 115	287± 122	0.0745
PreopVmax m/s	4.6± 0.6	4.7± 0.7	4.4± 0.7	
Preop max aortic gradient, mmHg	85± 25	90± 29.8	82±39	
Preop mean aortic gradient, mmHg	49± 26	51±3.6	48±17	
Preop aortic valve orifice area, cm2	0.6± 0.2	0.6±0.15	0.6±0.16	
Conversion to sternotomy and AVR, n (%)	0	0	0	/
Valve implantation				
23 mm, n	1(1,8%)	1 (4,5%)	0	
26 mm, n	18(48%)	9 (40%)	9 (28%)	
29 mm, n	34(63%)	12 (54%)	22 (68%)	
34 mm, n	1 (1,8%)	0 (0%)	1 (3.1%)	
Pre-dilatation during index procedure	4 (7.4%)	2(9%)	2 (6.2%)	0.6728
Post-dilatation during index procedure	4 (7,4%)	3 (13%)	1 (3.1%)	0.1033
Hospital stay, days	6± 5	8.7± 3.1	4± 3.1	P<0.0001
AVR=aortic valve replacement surgery				

Procedural outcomes

Procedural success was achieved in all patients (100%). After the intervention 7 (12%) patients developed a permanent heart block and required implantation of a permanent pacemaker, without difference between two groups.

Mortality was 5.5%, 2 with open-vascular and 1 with minimalistic approach. In the open-vascular group 1(1,8%) patient had major stroke 7 days after intervention, developed acute kidney injury and died 2 weeks after hospitalization and 1(1,8%) patient died 1 week after procedure due to long recovery and immobilization after ventricular wire perforation and open surgical correction. In the second group 1(1,8%) patient died several hours after valve implantation. (9% vs. 3.1%)

There was a larger Hgb drop after intervention with open vs. minimalistic approach 1,9±0.9 vs. 0.7±0,2 g/dL (p<0.0001). 3 (13% vs.0%) patients from the open vascular access group had major vascular bleeding complication with 2 requiring transfusion after intervention (p<0.0001 both). During hospitalization MACCE (MI, Stroke, Major bleeding and Death rate) was recorded in 5 (18%) patients with open vascular approach vs. 1 (3.1%) in minimalistic approach (p<0.0001). No other complications were recorded during hospitalization. None of the patients had significant aortic regurgitation after implantation.

Table 3. Echocardiographic results over time

	Discharge	6 months	1 year
Vmax (m/s)	1.9± 0.6	2.1± 0.37	1.8± 0.4
Pmax (mm Hg)	17± 8	17± 5.9	17.2± 8
Pmean (mm Hg)	8.3± 4.2	9.7± 3.8	9.3± 6.9
Valve area cm ²	1.8± 0.4	1.8± 0.2	2.0± 0.05
AI moderate	2 (3.7%)	1(1.8%)	2(3.7%)
AI=aortic insufficiency			

Table 4. In hospital complications

Characteristic, mean ± SD	TAVI (n=54)	Open vascular N=22	Minimalistic N=32	p
All-cause mortality	3(5.5%)	2 (9%)	1 (3.1%)	0.3514
Disabling stroke	1(1.8%)	1(4.55%)	0	0.7877
All stroke	1(1.8%)	1(4.55%)	0	0.7877
Overt life-threatening or major bleeding	2(3.7%)	2 (9%)	0	0.0810
Hgb drop after implantation g/L	1.1±1	1.9±0.9	0.7±0.2	P<0.0001
Transfusion of PRBCs* - n (%)	2 (3.7%)	2 (9%)	0	0.1569
Acute kidney injury, stage 2-3	3 (5.5%)	2 (9%)	1 (3.1%)	0.3514
Major vascular bleeding complication	3 (5.5%)	3 (13%)	0	0.0175
Cardiac perforation	2 (3.7%)	2 (9%)	0	0.0543
Cardiogenic shock	1 (1.8%)	1(4.55%)	0	0.1769
Permanent pacemaker implant	7 (12%)	3 (13%)	4 (12.5%)	0.9030
Atrial fibrillation	1 (1.8%)	0	1	0.3033
Myocardial Infarction	0	0	0	0
Aortic valve reintervention	0	0	0	0
Temp pacemaker	12 (22%)	4 (18%)	8 (25%)	0.5504
MACCE (MI,Stroke,Major bleeding and Death)	5 (9.2%)	4 (18%)	1 (3.1%)	0.1481
Hgb=hemoglobin, MACCE=major adverse cardiovascular and cerebrovascular events, MI=Myocardial Infarction.				

Hospital discharge was 8.7±3.1 vs. 4±3.1 days respectively. All TAVI patients with minimalistic approach were discharged the following day after intervention. All discharged patients had a good neurological condition, which was assessed based on the CPC-1 (Cerebra Performance Categories Scale).

Minor vascular access related complications were frequent (occurred in 14% of cases), but uneventful.

Early postoperative prosthetic valve performance was good with maximal and mean gradients of 18 ± 8 and 8.8 ± 4.2 mmHg, respectively. Effective valve orifice area was 1.8±0.4 cm²

at discharge. None or trivial aortic insufficiency (AI) was present in 68% of patients, mild AI in 30% and moderate AI in 1.8%.

30-day mortality was 5% the same as at discharge. 1 (3.1%) patient with open-vascular approach had and MI 7 days after the initial TAVI Intervention, but the event was not connected with valve occlusion of coronary arteries. Patient was successfully treated with primary PCI and stenting of the LAD artery with 5F guiding catheter through the Corevalve. There was no single case of MACCE registered in the minimalistic approach group during follow up. No other complications were recorded during follow up.

After median follow up of 26 months (1-4 years), overall survival rate was 95% with clinical improvement in all patients.

DISCUSSION

Transcatheter aortic valve implantation has grown rapidly since the first implants and first Partner trial more than a decade ago [1, 2]. TAVI has become the treatment of choice according to guidelines for high risk patients and patients denied surgery for severe aortic stenosis [3, 4, 5]. Randomized trials as Partner II, SURTAVI and NOTION [6, 7, 8] state that there are no major differences between TAVI and SAVR (surgical aortic valve replacement) in intermediate risk patients, with better results when TAVI is performed by TFA. These randomized trials are leading to a change in the guidelines and expansion of using TAVI in intermediate risk patients. Small studies that have been published recently explore the usage of minimalistic TFA approach with TAVI (without general anaesthesia) and have better results in terms of speedy recovery and mobilization of the patients [9, 10]. More randomized studies with larger number of patients are necessary to explore this new development in TAVI treatment. Results from our small study also prove rapid mobilization and early discharge in TAVI patients with minimalistic approach and lower procedural and post-procedural complications (MACCE $n=1$ (3.1%) vs. 5 (18%) $p<0.0001$), but we need a greater number of patients to prove our results.

Still patient selection remains a problem and developed risk scores for patient assessment tend to over or underestimate patients risk. Current risk scores used in randomized clinical trials for patient selection are the Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM) and the EURO score, but they lack in selection for different groups of patients. TAVI specific risk score is needed for correct selection of patients. That is why currently individual patient selection by the Heart team remains the most correct way to access the patient suitability for TAVI procedure. Also further studies are on the way to access the durability of current bio-prosthetic valves with follow up of TAVI patients [11].

Our implantation rate was successful with 100% success in valve implantation. Survival rate at hospitalization and 26 month median follow up was 95%.

30 day mortality was low at 5%, which compares well with published data of other groups [12, 6, 7, 9].

One year follow up was available for all cases and up to 3 year follow up for the first 15 cases.

Major vascular complications were present in 5.5% of cases, and 2 patient had a reduction in blood count that required blood transfusion. All patients were from open vascular access group. Also since we started using the minimalistic approach we only registered 4 cases with minimal access site hematoma without further consequences or major vascular complications, also Hgb drop after intervention was significantly smaller ($p<0.0001$).

The procedure's learning curve is also very important in the development of the TAVI program. We started under proctorship of experienced TAVI operators and our study's numbers show that procedure-related parameters improved with experience.

There is still need for significant progress in this field by exploring influence of imaging modalities in aortic root anatomy and patient selection and managing current complications from the TAVI procedure as paravalvular leaks and reason for total AV block and permanent pacemaker implantation.

Dedicated cardiologists in this field and increasing number of randomized studies with better selection of patients will lead to future total dominance of the TAVI procedure over SAVR with TAVI procedures numbers expanding in all corners of the world.

CONCLUSION

Percutaneous aortic valve implantation programme can be successfully started with high success rate and low rate of complications in patients with severe aortic stenosis. The minimalistic approach for TAVI is probably the new future in these interventions, but more randomized studies are needed to compare different groups of patients.

REFERENCES

1. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363: 1597–607.
2. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364: 2187–98.
3. Nishimura RA, Otto CM, Bonow RO et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2017 Jul 11; 70(2): 252–289
4. Vahanian A, Alfieri O, Andreotti F et al. The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2012; 33 (19): 2451-2496. doi: 10.1093/eurheartj/ehs109
5. Baumgartner H, Falk V, Bax J et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease, *European Heart Journal*, Volume 38, Issue 36, 21 September 2017, Pages 2739–2791, <https://doi.org/10.1093/eurheartj/ehx391>
6. Reardon MJ, Van Mieghem NM, Popma JJ et al. SURTAVI Investigators. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med*. 2017 Apr 6; 376(14): 1321–1331. doi: 10.1056/NEJMoa1700456. Epub 2017 Mar 17.
7. Leon MB, Smith CR, Mack MJ, et al. PARTNER 2 Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med* 2016; 374:1609-1620.DOI: 10.1056/NEJMoa1514616
8. Thyregod HG, Steinbruchel DA, Ihlemann N et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial. *J Am Coll Cardiol*. 2015; 65: 2184–2194
9. Condado J. F., Haider M. N., Lerakis, S., et al. Does minimalist transfemoral transcatheter aortic valve replacement produce better survival in patients with severe chronic obstructive pulmonary disease? *Cathet. Cardiovasc. Intervent*. 2017 Mar 1; 89(4): 775–780. doi:10.1002/ccd.26683
10. Holzhey DM, Caixeta A., Lemos, P. A. Transcatheter aortic valve replacement by a minimalist approach: A breath of fresh air for patients with chronic obstructive pulmonary disease. *Cathet. Cardiovasc. Intervent.*, 89: 781–782. doi:10.1002/ccd.27015
11. Foroutan F, Guyatt GH, Otto CM, et al. Structural valve deterioration after transcatheter aortic valve implantation. *Heart*. 2017 Dec; 103(23): 1899–1905. doi: 10.1136/heartjnl-2017-311329
12. Hänsig M, Walther T, Seeburger J, et al. Transapical aortic valve implantation - The Leipzig experience. *Ann Cardiothorac Surg*. 2012 Jul;1(2): 129–37. doi: 10.3978/j.issn.2225-319X.2012.06.09.

Резиме

МИНИМАЛИСТИЧКИ ПРИСТАП ПРИ ТРАНСКАТЕТЕРСКА ИМПЛАНТАЦИЈА НА АОРТАЛНА ВАЛВУЛА (TAVI) – ОТВОРЕН ВАСКУЛАРЕН НАСПРОТИ ЦЕЛОСНО ПЕРКУТАН ПРИСТАП

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Историја: Аортната стеноза е најчестата валвуларна болест на срцето кај постарите лица. Транскаатетерната имплантација на аортната валвула (ТАВИ) се проби како револуционерен третман на лица со симптоматска тешка аортна стеноза. Авторите во овој труд ги презентираат првите искуства со транскаатетерна имплантација на аортна валвула во Македонија и ги споредуваат своите резултати меѓу два пристапи за ТАВИ: отворен васкуларен наспроти минимално инвазивен трансфеморален ТАВИ-пристап.

Методи: Ова беше проспективна, опсервациона студија, која ги вклучи сите 54 пациенти кај кои беше изведена процедурата ТАВИ во периодот од декември 2014 г. до февруари 2018 г. на Универзитетската клиника за кардиологија во Скопје, Република Македонија. Сите пациенти беа со тешка аортна стеноза и висок хируршки ризик за операција или одбиени за операција на аортна валвула. Претпроцедуралниот скрининг вклучуваше детална клиничка и ехокардиографска процена, коронарна, периферна и каротидна ангиографија и КТ-ангиографија на аортниот корен. Само експандирачка аортна валвула (Core Valve/Evolut R, Medtronic, USA) беше имплантирана кај сите пациенти.

Резултати: Средната возраст на пациентите беше $75 \pm 7,2$ години, 28 (52 %) жени и 26 (48 %) мажи. Сите интервенции беа успешно изведени преку десен трансфеморален пристап со 100 % успех при имплантацијата. Помошен десен радијален и улнарен пристап беа користени за точно позиционирање на валвурата и контрола. 22 (40 %) случаи беа изведени со општа анестезија и отворен васкуларен пристап преку феморалната артерија. Сите други 32 случаи (60 %) беа изведени со минимално инвазивен пристап (локална анестезија и аналгоседација на пациентите). Пациентите во оваа група беа постари, со повеќе хронични заболувања, како анемија, хронична бубрежна болест, слаба подвижност и периферна васкуларна болест ($p < 0,0001$). Исто така, кај 4 (12,5 %) пациенти со минимално инвазивен пристап, беше изведена ТАВИ имплантација кај бикуспидна аортна валвула ($p < 0,0001$). Процедуралното време и потрошен контраст беа помали во оваа група со 97 ± 38 наспроти $121 \pm 38,3$ ($p < 0,0001$) и 287 ± 122 наспроти 330 ± 115 ml, додека времето на зрачење беше еднакво. Веднаш беше забележано хемодинамско подобрување кај сите пациенти. Ехокардиографскиот врвен притисочен градиент се намали од 85 ± 25 на 17 ± 8 mmHg ($p < 0,001$) и средниот притисочен градиент од 49 ± 26 на $8,3 \pm 4,2$ mmHg, ($p < 0,001$). Ефективната ареа на валвурата беше $1,8 \pm 0,4$ cm² по интервенција. Ниеден пациент немаше значајна аортна регургитација по интервенција. По интервенцијата 7 пациенти (12 %) развија траен АВ блок и имаа потреба од имплантација на траен пејсмејкер. Поголем пад во вредноста на хемоглобинот по интервенција беше забележан кај отворениот васкуларен наспроти минимално инвазивниот пристап $1,9 \pm 0,9$ vs. $0,7 \pm 0,2$ g/dL ($p < 0,0001$). 3 (13 % vs. 0 %) пациенти со отворен пристап имаа мајорно крварење, од кои две со потреба од трансфузија по интервенција ($p < 0,0001$). Морталитетот беше 5,5 %, 2 со отворен и еден со минимално инвазивен пристап. МАССЕ-стапката, која вклучува миокарден инфаркт, цереброваскуларен инсулт, мајорно крварење и смрт, беше забележана кај 5 пациенти (18 %) со отворен васкуларен пристап наспроти 1 (3,1 %) со минимално инвазивен пристап ($p < 0,0001$). Пуштањето од болница беше $8,7 \pm 3,1$ наспроти $4 \pm 3,1$ дена ($p < 0,0001$). Сите ТАВИ-пациенти со минимално инвазивен пристап беа пуштени од болница следниот ден по интервенцијата. Сите пациенти беа испишани во добра невролошка состојба, проценета според CPC-1 (Cerebra Performance Categories Scale). По средно следење од 26 месеци (1–4 години), стапката на преживување е 95 %, со клиничко подобрување кај сите пациенти.

Заклучок: Перкутаната имплантација на аортна валвула може да се изведува со висока стапка на успех и ретки компликации кај пациентите со тешка аортна стеноза. Користењето помалку инвазивен пристап со локална анестезија и аналгоседација е поврзан со пократка хоспитализација и намалување на постпроцедуралните компликации и мајорни кардиоваскуларни и цереброваскуларни збиднувања.

Клучни зборови: аортна стеноза, транскатетерска имплантација на аортална валвула (TAVI)