

Transcatheter aortic valve implantation: our experience and perspective

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Abstract

Purpose: Trans-catheter aortic valve implantation is today an alternative therapy for symptomatic severe aortic valve stenosis in high-risk patients with co-morbidity. **Material and methods:** From March 2011 to Februar 2015, 24 patients with symptomatic severe aortic valve stenosis reach criteria and underwent trans-catheter aortic valve implantation's procedures in Clinical center of Montenegro. All patients received percutaneous aortic valve prosthesis (CoreValve – Medtronic, Minneapolis USA). In thirteen patients femoral approach were performed and one case we used subclavian approach.

Results: Patients mean age was 72.7 ± 2.72 years (seven males and seven females) mean left ventricular ejection fraction was 51.25 ± 6.34 mean peak gradient across aortic valve 94.7 ± 26.61 mmHg) and aortic valve area 0.66 ± 0.19 . Society of Thoracic Surgeons score was 9.4 ± 3.18 . The follow-up examinations were performed six months after valve implantation.

At the control examinations there were no deaths. Three serious complications has been recorded. One patient received stroke with left side hemiparesis, Two patients had AV block, which was solved by installing pace maker. At control examination mean left ventricular ejection fraction was 54.44 ± 6.8 (NS) mean peak gradient across aortic valve was 20.28 ± 13.13 mmHg. ($p > 0.01$)

Conclusions: Surgical aortic valve replacement remains the standard treatment of patients with aortic stenosis. Trans-catheter aortic valve implantation should be reserved for patients who have unacceptable surgical risks, and who have decreased life expectancy. Main procedure limitations today is stiff and wide delivery equipment and imperfections of attendant imaging software.

Keywords: aortic valve disease; aortic stenosis; valve prosthesis; Heart Valve Annuloplasty; Valvuloplasty

Introduction

Nowadays aortic stenosis become age related disease. In near past congenital etiology of aortic stenosis was predominant. Today most frequent etiology is degenerative changes of aortic leaflets and annulus of aortic valve in elderly patients. It is one of the most common valvular disorders in older adults, with incidence of 8% at age 85 (1). Rapid progression after the appearance of symptoms (2), resulting in a high rate of death (approximately 50% in the first years after symptoms appear (3),(4) among untreated patients. As the incidence of aortic stenosis multiplies with age, and as the life span of our population increases, a larger number of elderly patients have severe degenerative aortic stenosis. Aortic-valve replacement is the most effective treatment to eliminate progression of symptoms and improve survival in patients with critical aortic stenosis. More than before elderly patients will require aortic valve replacement. However, a substantial number of these patients should have coexisting conditions, and illness that increase surgical risk. Since outcomes with medical management are uniformly poor, a less invasive and safer alternative to surgical aortic valve replacement is needed for this expanding group of patients (5). Trans-catheter aortic valve implantation (TAVI) is a new procedure, in which a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve. Since 2002, when the procedure was

introduced in clinical practice by Cribier (6), there has been rapid growth in its use throughout the world for the treatment of severe aortic stenosis in patients who have high surgical risk.

Trans-catheter aortic-valve implantation (TAVI) has emerged as an alternative treatment for aortic stenosis in patients who are considered to have a high or prohibitive surgical risk. Number of patients with clinical significant aortic stenosis, in late live years, with high surgical risk for aortic valve replacement, will rise in future years. Same kind of interventional procedure will be ideal for treatment of those patients.

TAVI can be performed either by a retrograde approach, in which a catheter is inserted through the common femoral artery, or by an antegrade, transapical approach, in which a catheter is inserted through the apex of the left ventricle with the use of anterolateral thoracotomy. Recently safe and precise approach through mini lateral tracheotomy and direct aortic puncture has been described. (7)

Materials and methods

Cardiovascular interventional team from Clinical Center Montenegro since March 2011 have treated 24 patients with severe aortic stenosis by transcatheter aortic valve replacement. We decided to use Core Valve (Medtronic, Minneapolis USA) equipment.

Patients selection for TAVI.

Patients who have been considered by a multidisciplinary team consisted of cardiac surgeons interventional cardiologists, anesthesiologists, and radiologists.

The leading point in decision making have been:

1. Presence of aortic stenosis, with area < 1 mm² and flow velocity > 4 m/s.
2. "High risk" patient for surgical valve replacement (STS score of >8.)

Intervention team has been trained for the safe performance of procedures. The manufacture instructions for insertions and deploying of valve have been followed. In three teen patients trans femoral approach was performed and in one because of acute aortic arch configuration we did subclavian approach.

Statistical analyzes were performed using the „T" test for parametric and Fishers test for nonparametric data.

Results

Preprocedural and clinical results

Between March 2011 to February 2015 24 symptomatic patients (10 men and 14 women) with a mean age of 72.71±2.72 years (67-82), were included in the study.

All were done with the 18-F device, by surgical preparation of femoral artery.

All patients had severe symptomatic aortic stenosis. Trans-valvular peak gradient of 94.07±26.61 mmHg. The pre procedural calculated aortic valve area was 0.66 ± 0.19 cm² (range 0.4 to 1.1 cm²) and the systolic left ventricular ejection fraction 51.35 ± 6.34 (range 33 to 60%).

In 19 patients, a mild-to-moderate aortic regurgitation was present (6 patients with grade "1+", 7 patients with grade "2+", and 6 patients with grade 3+).

Twelve patients had mitral regurgitation before the procedure (5 with MR "1+", 6 with MR "2+" and 1 patient with MR "3+")

All patients had calcified aortic valve, and one patient was identified as bicuspid aortic valve.

Associate disease had 12 patients. Diabetes type II, were noted in six patients. In this series there were two patients with peripheral vascular disease, three with previous myocardial infarction, one with cerebrovascular disease and no patients with previous myocardial revascularisation. One patient had a previously implanted artificial aortic valve

The mean calculated logistic EuroSCORE II of the study population was 8,56 ± 6,27 and 12 of patients were New York Heart Association functional class III or IV.

Peri-procedural and clinical results

In all 24 patients the procedure was assessed as successful. During the hospitalization in two patient complete AV block was found. There were no deaths or other MACE complications,

Follow-up clinical results

Overall mortality at six months was 0%. Combined rate of death, stroke and myocardial infarction is 4,1%. Complications were defined as MACE registered as a stroke with left-sided hemiparesis in one patient and AV block in two patient. Aortic regurgitation was found in ten patients, Peak gradient at the controls was 20.28 ±13.13 mmHg Remarkable relief of symptoms was observed from a mean New York Heart Association functional class of 2.5 ± 0.70 before to 1.14 ± 0.37 after valve implantation (p < 0.001).

Discussion

Although a TAVI procedure was introduced in clinical practice one decade ago there are still some open questions which remain to be answered.

Who is making decision for TAVI procedures? Who is candidate for TAVI? Is TAVI safe procedure in the longer follow up?

Interventional cardiologist play main role in this decision-making and performing TAVI procedures. But they must involve surgeons. Patients advanced age cannot be used as an exclusion criterion for surgery. Aortic-valve replacement is currently being performed in octogenarians with excellent results. Anesthesiologists and radiologists should be involved in deciding about TAVI procedure because their role is not formal in the team. Before procedures, it is important for operators to be introduced in anatomic measurements of the aortic annulus, aortic root, aortic valve, coronary ostia, arteries, and vascular access site. The role and relative importance of different imaging modalities is evolving. Multidetector computed tomography (CT) has assumed an increasingly important. Complementary role before and after TAVI, and provides detailed anatomic assessment of the aortic root structures and ilio-femoral access, adding to the information obtained with echocardiography and angiography. Therefore, routine screening with multidetector computed tomography (MDCT) is used by several leading groups (8).

Candidate for TAVI procedure are patients with indication for aortic valve replacement with associate disease and increased surgical risk. The team who decided about implantation's should consists of intrventional cardiologists, cardio surgeons, radiologists and anastheziologist.

Outcome	PARTNER (one year) 348 patients	Our patients (one year) 24 patients	P Value
Death	84 (24.2 %)	0	NS
Stroke	17 (5.1 %)	1 (4.1%)	NS
Myocardial infarction	1 (0.4 %)	0	NS
New pacemaker	19 (5.7 %)	2 (8.2%)	NS
New-onset atrial fibrillation	42 (12.1 %)	0	NS
Vascular complications	39 (11.3 %)	0	NS

Patients follow up clinical data. Correlation between PARTNER study and our data

One interventional procedure can be recognized as alternative to official treatment only if it has compatible results to known methods. The aim of this study was to make a contribution in this regard.

The main drawbacks still limiting the general applicability of the TAVI: Imaging limitations, "heavy" loading devices, and the high price of TAVI device (9).

Today's imaging equipment requires a lot of experience in positioning the valve in place safe for implantation. The most challenging part of procedure is position and deployment of valve. It is necessary to develop new imaging capabilities that will be useful for that purpose. There are encouraging reports. Develop new imaging systems (ZIGO Siemens, Erlangen) in special software will be able to give fully support to TAVI procedure in terms of effective imaging (10).

This procedure carries the high incidence of para-valvular leak and regurgitation. Delivery system for trans-catheter aortic valve implantation is stiff and huge (18 F). Passing catheter through vessels, aorta and aortic valve is not easy and safe. Vessels related complications were noted in literature. It is likely to develop the proper technology and more flexible, and smaller diameter equipment.

Equipment, prize is now higher than surgical valve replacement in the most countries. Prize of intervention probably will fall down with increasing number of procedures.

The most famous trial comparing the results of surgical aortic valve replacement and TAVI is PARTNER study (11). PARTNER trial, is a prospective, randomized, multi center trial to determine the optimal method of treating patients with critical aortic stenosis who were considered not to be suitable candidates for surgery.

Comparison of results of patients who had TAVI procedures in the PARTNER trial of our patients who underwent TAVI procedure we obtained the following results.

The clinical data was statistically significant difference in age of treated patients. In Montenegro, the clinical manifestations of atherosclerosis and, therefore, degenerative changes in the aortic valve, manifest earlier in life than in developed countries. That is why our patients were almost ten years younger on average than in the PARTNER trial. This confirms the fact that difference in STS score is statistically non significant. That shows we didn't treat patients who had less severe aortic stenosis than in the PARTNER trial.

Other clinical criteria to compare death, myocardial infarction, arrhythmias needs for a pace maker stroke, atrial fibrillation, vascular complications are not statistically significant differences between our series and PARTNER trial

Increased frequency of permanent pacemaker implantation was described in literature in patients who underwent procedures TAVI (12) In our series of patients we've noted that complication in two patients (14,25%). Stroke as periprocedural and late complications is also possible in TAVI procedures (13). We noted it in one patient (7,14%)

Conclusion

Despite the promising results of the PARTNER trial, surgical aortic-valve replacement remains the standard for the treatment patients with severe aortic stenosis. TAVI should be reserved for patients at inordinately high risk who are not suitable candidates for surgery and who have decreased life expectancy.

Our initial results, even though in a small series are encouraging. We believe procedure TAVI is as the most complicated and most demanding procedure in interventional cardiology. It brings addition to direct benefits for patients and also is excellent training for the expected minimally invasive and hybrid operation in future of interventional cardiology.

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