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Initial Experience With Transcatheter Aortic Valve Implantation in Montenegro

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Background: Transcatheter aortic valve implantation (TAVI) has emerged as an alternative treatment to classic aortic valve replacement (cAVR) for selected, high risk patients with severe aortic stenosis.

Objectives: In our study, we compared preoperative parameters and postoperative outcomes in patients with TAVI and classic aortic valve replacement.

Patients and Methods: From March 2011 to December 2013, 18 patients received TAVI and 143 patients underwent cAVR. We compared preoperative Euro SCORE, 30 day mortality, complications after six month and echocardiography findings.

Results: Patients received TAVI were older than patients underwent cAVR (72.7 ± 2.7: 65.3 ± 2.9; P < 0.001). Euro SCORE was higher in TAVI group (8.0%: 5.6%; P = 0.43). There were no statistically significant differences in 30-day (0.0%: 2.8%; P = 0.932) and 6-month mortality (5.5%: 3.5%; P = 0.822) as well in stroke incidence (11.1%: 2.8%; P = 0.822). Pacemaker implantation is more frequent in TAVI than in cAVR group (22.0%: 2, 1%; P < 0.001).

Conclusions: High risk patients needing AVR are optimal candidates for transcatheter aortic valve implantation. TAVI is a valuable solution for high risk patients needing AVR. Obtained results are comparable to results in transthoracic AVR in standard candidates for aortic valve implantation.

*Keywords:*Aortic Valve Stenosis; Heart Valve Prosthesis Implantation; Mortality

1. Background

Aortic stenosis is a common valvular condition in the elderly population, affecting 1.3-1.4% patients aged 65-74 years and 2.8-4.6% of patients aged 75 years and older (1, 2). In condition of aortic stenosis, aortic valve becomes narrow, obstruct the outflow of blood from the heart and thereby require the heart to work harder to pump blood around the body. In general, patients with North American Society of Thoracic Surgeons (STS) score of > 10% or EuroSCORE of > 20% are considered to be high risk (3, 4). The average life expectancy of patients with severe, symptomatic aortic valve stenosis (AVS) is 2-3 years with a significant risk of sudden death (5, 6). According to 2008 American College of Cardiology (ACC)/American Heart Association (AHA) guideline (7), the indication for conventional AVR includes: 1) Symptomatic patients with severe AS, 2) Patients with severe AS undergoing other heart operations, and 3) Patients with severe AS and LV systolic dysfunction (EF < 0.50). The current consensus is that the TAVI should be reserved for patients who meet standard indications for surgical AVR but it is defined as high-risk for operative mortality and morbidity with conventional AVR.

Transcatheter aortic valve implantation was developed in the early 1990`s by Andersen et al. (8) and in 2007 Walther et al. (9) showed that transapical aortic valve implantation might reduce the risk of conventional surgical aortic valve replacement (AVR) in very-high-risk patients. During the last few years, the number of procedures, as well as performing centers has rapidly increased. Our center was opened in 2003 and started with TAVI procedures three years ago (in 2011). The TAVI procedure can be performed using one of two different approaches, allowing the surgeon to choose which one provides the best and safest way to access the valve: 1) Transfemoral implantation through the blood vessel (femoral artery) in a leg. 2) Transsubclavian implantation through the arteria subclavia, used for patients whose arteries are too small or too diseased for the transfemoral approach.

Transcatheter aortic valve implantation (TAVI) has emerged as an alternative treatment to aortic valve replacement (AVR) for selected, high risk patients with severe aortic stenosis (AS). This less-invasive approach is an attractive feature to both patients and physicians. Depending on the incremental cost-effectiveness ratio (ICER), the threshold is selected and TAVI is potentially justified on both medical and economic grounds compared with medical therapy for patients deemed to be

surgically inoperable. Thus, it may be considered as a primary choice or treatment for high risk patients who refuse transfusion of blood or blood products (10).

2. Objectives

In this study, we examine the preoperative parameters and the postoperative course of patients undergoing transcatheter aortic valve implantation and compare them with classic aortic valve replacement (cAVR).

3. Patients and Methods

From March 2011 till December 2013, 161 patients had AVR. Out of that, 18 patients (11%) received a transcatheter bioprosthesis (TAVI) and 143 classic AVR (cAVR). TAVI was performed with the Core Valve Revalving System (Medtronic, Minneapolis, and MNUSA). Both, transfemoral (17 patients) and transsubclavian (1 patient) procedures were performed. We followed a transfemoral first policy and as consequence, transsubclavian procedures were performed only if the transfemoral approach was not feasible due to narrow and/or calcified aorto-iliac-femoral vessels. Each case was discussed by the local TAVI team which included a cardiac surgeon, interventional radiologist and an anesthesiologist. The preoperative examinations included clinical and laboratory examinations, MSCT (Multislice Computed Tomography), coronarography, transthoracic echocardiography, transesophageal echo. During the procedure, we did transesophageal echo and temporary pacemaker. Postoperative examination included transthoracic echo.

We collected and analyzed the following data: Age, Euro Score, left ventricle ejection fraction (LVEF), peak transvalvular pressure gradient (PTPG), mean aortic valve area (AVA), New York heart association (NYHA), mortality and morbidity. Comparison of variables was performed by the Student's t-test, Mann-Whitney U test and chi-square test. A statistically significant difference between the groups was accepted in accordance with the significance level criteria, $p< 0.05$ and calculated using SPSS software (ver. 13).

4. Results

Out of 161 patients (41% males and 59% females) with AVR, only 11.2% (18 patients) received TAVI procedure. Patients with cAVR (143 pts) had mean age of 65.3 years, mean preoperative Euro SCORE of 5.6%, Society of Thoracic Surgeons mortality score (STS score) of 3.2% and mean aortic valve area (AVA) was 0.71 cm^2. Out of 18 patients in whom the TAVI procedure was performed, four patients had previous heart operation (valve surgery 1 pt and CAB 3 pts) and there were 7 females and 11 males. Patients with TAVI (18 pts) had the mean age of 72.2 years, the mean Euro SCORE 8.0% and the mean STS score was 4.61%. All patients had significant aortic valve stenosis, with mean aortic valve area (AVA) of 0.66 cm^2 for TAVI and 0.71 for cAVR group ($P = 0.338$). Patients received TAVI were older than patients underwent cAVR (72.7 ± 2.7 vs. 65.3 ± 2.9; $P < 0.001$) and with a significantly higher operative risk Euro SCORE (8.0% vs. 5.6%; $P = 0.043$). Patients received TAVI had greater mean LVEF than patients underwent cAVR (51.2 ± 6.34 vs. 40.2 ± 6.15; $P < 0.001$). There were no significant difference ($P = 0.838$) in mean peak transvalvular pressure gradient (PTPG) before the surgery (94.7 ± 26.6 mmHg vs. 96.0 ± 25.3 mmHg) (Table 1).

Table 1. Preoperative Parameters in Transcatheter Aortic Valve Implantation and Conventional Aortic Valve Replacement Groups [a, b]

Parameter	TAVI (n = 18)	cAVR (n = 143)	P Value
Age, y	72.7 ± 2.7	65.3 ± 2.91	< 0.001
EuroSCORE, %	8.0 ± 5.9	5.6 ± 4.5	0.043
LVEF, %	51.2 ± 6.34	40.2 ± 6.15	< 0.001
PTPG, mmHg	94.7 ± 26.6	96.0 ± 25.3	0.838
AVA, cm^2	0.66 ± 0.19	0.71 ± 0.21	0.338

[a] Data are presented as Mean ± SD.
[b] Abbreviations: AVA, aortic valve area; cAVR, conventional aortic valve replacement; LVEF, left ventricle ejection fraction; PTPG, peak transvalvular pressure gradient; TAVI, transcatheter aortic valve implantation.

Table 2. Postoperative Outcome in Transcatheter Aortic Valve Implantation and Conventional Aortic Valve Replacement Groups [a, b]

Postoperative Outcome	TAVI (n = 18)	cAVR (n = 143)	P Value
30 day mortality	0.0	2.8	0.932
6 month mortality	5.5	3.5	0.822
Stroke	11.1	2.8	0.274
Implanted pacemaker	22.0	2.1	< 0.001
Bleeding	0.0	3.5	0.932
LVEF	54.4 (6.8)	46.5 (6.9)	< 0.001
PTPG, mmHg	20.3 (13.1)	27.3 (15.1)	0.062
NYHA I/NYHA II	85/15	98.6/1.4	0.005

[a] Abbreviations: cAVR, conventional aortic valve replacement; LVEF, left ventricle ejection fraction; NYHA, New York heart assosiation; PTPG, peak transvalvular pressure gradient; TAVI, transcatheter aortic valve implantation.
[b] Data are presented as % or Mean (%).

Postoperative results were: 30 day mortality was 0.0% in patients with TAVI, and 2.7% with cAVR (P = 0.932) and after six month mortality in patients with TAVI it was 5.5% (non-cardiac death) and in patients with cAVR 3.5% (P = 0.822). In TAVI group complications were 11.1% stroke (2 patients) and 22.2% implanted pacemaker (4 patients). In cAVR group, stroke was 2.8% (4 patients), pacemaker 2.09% (3 patients) and bleeding 3.49% (5 patients) (Table 2). Follow-up findings showed better (P < 0.001) LVEF in TAVI group than in cAVR (54.4 ± 6.8 vs. 46.5 ± 6.9). There were no significant differences (P = 0.062) in mean peak transvalvular pressure gradient (PTPG) (20.3 ± 13.1 vs. 27.3 ± 15.1). Patient in cAVR group had better (P = 0,005) NYHA condition (Table 2).

5. Discussion

TAVI is a minimally invasive technique for elderly patients with symptomatic AS and at high-risk for conventional surgery. Those with an extreme-risk profile are very fragile elderly patients with a very poor outcome in the absence of appropriate treatment. A European survey has demonstrated that nearly 30% of patients suffering from severe symptomatic aortic valve stenosis were not referred for surgery by their cardiologist or family physician due to advanced age or severe comorbidities or were considered inoperable by the cardiac surgeon and therefore not accepted for SAVR (11).

30-day mortality was lower in TAVI patients when compared to surgical AVR. 30-day complications rate was higher in TAVI group. Mortality after six months was higher in TAVI *vs.* surgical AVR. EuroSCORE and mean age were higher in TAVI group. In the case of postoperative atrioventricular (AV)-block degree III for more than three days, a cardiac pacemaker was implanted. In TAVI group, it was applied for 4 patients (22.2%) and in cAVR group for 3 patients (2.09%). Comparing our result with literature, we observe that Wilbring et al. (12) identified 561 patients (508 TAVI, and 53 AVR) with total EuroSCORE 28.4 ± 13.6% and the mean age of 77.8 ± 4.5 for all. They showed a hospital mortality of 9.4% in TAVI group and 5.7% in cAVR group, and 6-month mortality of 27% in TAVI group, 23.2% in cAVR group. They also showed that mean hospital stay did not differ significantly, and ICU stay is shorter in TAVI group. We also observed that D'Onofroio et al. (13) identified 1000 patients (605 TAVI, 395 cAVR). Patients undergoing TAVI were significantly older than cAVR patients (79.9 ± 7.1 vs. 75.5 ± 9.2 years). Furthermore, hospital mortality was similar (3.9% vs. 2.5%). It has been estimated that the prevalence of aortic valve stenosis is around 2% between 70 and 80 years of age and that it progressively increases after 80 years (2).

We must emphasize the importance of good selection of patients for TAVI procedure. TAVI has been introduced to reduce the surgical risk. High risk patients with previous surgery and needing AVR are optimal candidates for transcatheter valve implantation. TAVI is a valuable solution for high risk patients needing AVR. Obtained results are comparable to the results in transthoracic AVR in standard candidates for aortic valve implantation. Despite of the small number of patients, our initial experience with TAVI showed good results.

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