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Original Article

Transcatheter aortic valve implantation with Core Valve: First Indian experience of three high surgical risk patients with severe aortic stenosis

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ABSTRACT

The prevalence of aortic stenosis is increasing with aging population. However with multiple co-morbidities and prior procedures in this aging population, more and more patients are being declared unfit for the ‘Gold Standard’ treatment i.e. surgical aortic valve replacement (AVR). Among the patients who are unfit or high risk for aortic valve replacement (AVR) by open heart surgery, transcatheter aortic valve implantation (TAVI) has been proven to be a valuable alternative improving survival and quality of life. We report first Indian experience of Core Valve (Medtronic Inc.) implantation in three high surgical risk patients performed on 22nd and 23rd February 2012.

1. Introduction

Traditional aortic and mitral surgery have been the mainstay of treatment for valvular heart disease; prior to surgical techniques for valve replacement and repair, there were no effective therapies for patients with severe disease. In selected patients at experienced centers with expert surgeons, the results have generally been excellent with improved morbidity and mortality compared with medical therapy but at a cost of significant invasiveness and recovery time for the patient.¹ In clinical practice, at least 30% of patients with severe symptomatic aortic stenosis do not undergo surgery for replacement of the aortic valve, owing to advanced age, left ventricular dysfunction, or the presence of multiple coexisting conditions. For these patients, who are at high surgical risk, a less invasive treatment may be a worthwhile alternative. Transcatheter 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 first performed, there has been a rapid growth in its use throughout the world for the treatment of severe aortic stenosis in patients who are at high surgical risk.²

2. Case 1

Mrs. AD, 80 years old lady, who had undergone coronary bypass grafting twelve years ago for unstable angina with...
triple vessel disease presented to us with history of exertional chest pain, CCS class III. On evaluation, she was found to have severe calcific aortic stenosis – aortic valve area by continuity equation as 0.5 cm², mean pressure gradient across aortic valve of 62 mmHg and mild aortic regurgitation. The left ventricular ejection fraction was 55%. CT coronary angiography revealed patent grafts and a Porcelain Aorta. EuroScore risk for AVR was 32.7%. Surgical AVR was refused on account of high surgical and anesthesia risks.

The evaluation for TAVI using Core Valve (Medtronic Inc.) was done according to the set guidelines of clinical and imaging work up protocols. Imaging by Transthoracic echocardiography, Transesophageal echocardiography and CT scan were performed apart from the invasive coronary angiography. Key parameters of Imaging from TAVI work up perspective include aortic valve and Root analysis, coronary ostia length and peripheral vascular access vessel anatomy. The Core Valve size selection depends mainly on the aortic annulus perimeter and diameter detected on CT Aortography as well as Transesophageal echocardiography. Based on these measurements, 26 mm Core Valve was chosen for this patient.

2.1. The device

Core Valve consists of three porcine pericardial tissue leaflets mounted on a self expanding nitinol frame. It is available in three sizes viz 26 mm, 29 mm and 31 mm. When appropriate size is chosen, it provides good hemodynamic in most of the diseased aortic valves with complex anatomies.

2.2. Technique of implantation

The patient underwent TAVI through the transfemoral route. In this approach, the vascular access was taken via surgical cut down of the right common femoral artery and closure of the vascular access was also achieved surgically.

Two teams worked during the procedure simultaneously, one team prepared the Core Valve (crimping the valve under ice cold water and mounting it on the delivery catheter) to be ready for implantation while the operating team indulged in obtaining access, valvuloplasty and finally valve deployment. The procedure was carried out under general anesthesia. The deployment steps include the crossing of aortic valve, balloon aortic valvuloplasty to dilate the native valve and positioning the prosthesis at the level of the aortic valve. It is important to perform valvotomy only after confirmation from the team who is mounting the Core Valve that they are ready with the valve as sometimes during valvotomy, patient may develop acute severe aortic regurgitation with hemodynamic compromise necessitating urgent valve deployment. The
positioning of valve prosthesis (Figs. 6 and 7) is a very crucial step and done under fluoroscopy with the aid of calcification present on the valve serving as a guide in defining the level at which the deployment is done. Frequent Aortography injections by a pigtail catheter placed in aortic root are used to determine the position of the valve and the plane of alignment of the aortic cusps. Transesophageal echocardiography was also used as an additional confirmation modality of the valve position. Once correct position was confirmed, the prosthesis was released. Aortography and check coronary angiography shoots were performed after TAVI to confirm the position of the deployed prosthesis and the coronary artery patency. Transesophageal echocardiography confirmed the location of valve, aortic prosthesis regurgitation, and patency of coronary arteries. Hemopericardium and aortic dissection are other important complications to be ruled out.

2.3. Result

The hemodynamic performance of the prosthesis was assessed using pressure recordings and echocardiography. Patient had no significant transvalvular gradient and mild aortic regurgitation. After the procedure, the patient stayed in intensive care for 48 h and was closely monitored for vascular access, and rhythm disturbances, especially late atrioventricular block. She showed satisfactory recovery and was discharged on 29th February on dual antiplatelet treatment.

She is very active and asymptomatic on eight months follow up.
3. Case 2

Mr. PNM, 72 years gentleman with history of Coronary artery bypass surgery in the year 2000 was evaluated for recurrence of angina on exertion class III and dyspnea NYHA class III. Echocardiography showed critical aortic stenosis with valve area of 0.3 cm² and mean pressure gradient of 86 mmHg. A coronary angiography was done which revealed patent grafts. His EuroScore was 29.6%. A work up was done according to the set protocol of TAVI evaluation to determine anatomy of aortic valve, aorta and access route vessels. He underwent TAVI using 29 mm Core Valve (Medtronic Inc.) via retrograde femoral approach on 23.02.2012. The procedure was successfully done under angiography and Transesophageal echocardiographic guidance under general anesthesia. He was discharged in asymptomatic and stable condition on 29.02.2012.

He continued to remain asymptomatic from cardiac viewpoint on six-month follow up. Unfortunately, the patient died of acute bacterial meningitis a month after that.

4. Case 3

Mr. GPM, an octogenarian of 81 years age, who had a history of coronary artery bypass surgery done in the year 2000, presented to our hospital with symptoms of dyspnea NYHA class III. Evaluation at our institute revealed severe aortic valve stenosis as the underlying etiology. The coronary angiography done after admission revealed patent grafts. Transcatheter aortic valve implantation was chosen as the modality of treatment option in view of the increased risk of surgery at his age and frailty. The work up for TAVI was done by set protocol. Transcatheter aortic valve implantation with 29 mm Core Valve was done successfully. On second day after the procedure, patient developed asymptomatic complete heart block, which was picked up on telemetry. A dual chamber pacemaker implantation had to be done on 27.02.2012. The patient was discharged from the hospital on 02.03.2012 in good health and stable condition.

He is asymptomatic and active at six and nine month follow-up. His mean gradient across the aortic valve is 11 mmHg with mild aortic regurgitation.

4.1. Discussion

Patients with severe calcific aortic stenosis who carry very high anesthesia and surgical risk for open heart surgery can be helped by this interventional technique of valve implantation. The two main access routes of implantation constitute transfemoral and transapical routes. The valves implanted across the world in different major studies are the Core Valve from Medtronic and the Sapient valve from Edward Life Sciences. Second generation valves are also being studied. More than 50,000 TAVI procedures have been performed worldwide and now we have numerous single center reports and registries as sources of information.9–13 The patients treated were mostly over 80 years old, at high risk (e.g., Logistic EuroScore >20% in most cases), or with contraindications for surgery. Procedural success is over 90% in experienced centers and in the most recent registries. These valves perform well with a final valve area ranging from 1.5 to 1.8 cm² and mean gradients around of 10 mmHg, which is at least equivalent to that of a surgically implanted prosthesis. Interestingly, recent observations using Multi slice CT scan showed that in up to 20% of cases, the shape of the prosthesis may be elliptic after implantation, which may favor paravalvular aortic regurgitation. Mortality at 30 days ranges from 5–18% for the transfemoral approach, and 10–19% when using the transapical approach. Coronary obstruction is a rare (<1%) but dramatic complication. It may be due to external compression of the left main coronary artery by bulky valve calcification or obstructive low positioned coronary ostia. Acute myocardial infarction occurs in 2–5% of cases. Mild aortic regurgitation, mostly paravalvular, is observed in over 50% of the cases, and moderate regurgitation occurs in around 20% of the cases. The availability of larger prostheses and their more careful matching with the size of the aortic annulus, in order to slightly oversize the device, has led to a decrease in the incidence of severe aortic regurgitation to <10%. Prosthesis embolization is rare, around 1%. Stroke rate ranges from 2–9% with a trend towards a lower incidence of stroke when using the transapical approach. Vascular complications remain a significant cause of morbidity in the transfemoral approach, with an incidence ranging from 10–15% with the self expanding device, decreasing to 2–4% with decreasing profile of devices. Atioventricular block occurs in 4–8% of cases with the balloon expandable devices and up to 30% with self expandable devices, necessitating pacemaker implantation. The presence of previous right bundle branch block and the onset of left bundle branch block during the procedure are predictors of the need for pacemaker implantation after TAVI. Finally, the transapical approach, which requires a thoracotomy and ventriculotomy, may lead to specific postoperative complications as well as rare left ventricular apical aneurysms. Surgical conversion is rare but requires the immediate availability of cardiac support and surgical back up, at least in operable patients, in cases of life threatening complications such as coronary occlusion, massive aortic regurgitation or valve migration in the left ventricle. A learning curve effect is there on the success rate. Long-term results up to six years (though only one to a maximum of three years in most studies) show a survival rate of 70% at one year and 60% at two years, with a significant improvement in clinical condition and quality of life parameters in most cases, which is of utmost importance in this elderly population. Anecdotal cases of valve endocarditis or thromboembolism have been reported. The risk of bleeding could be a concern in elderly patients when receiving a combination of antiplatelet agents. The degree of aortic regurgitation remains stable over time and mild to moderate aortic regurgitation did not require re-intervention or cause severe hemolysis during limited follow-up. Serial echocardiographic studies have consistently shown good prosthetic valve function and no structural deterioration of valve tissue has been reported. Left ventricular ejection fraction improves after TAVI, while the degree of functional mitral regurgitation decreases. There are no studies comparing either one device against the other or one approach with the other. Valve in a valve implantation for
either acute failure of TAVI caused by intraprosthetic aortic regurgitation or for degenerated valve prostheses, either stented or stent-less is also feasible, however, it is too early to draw any definite conclusions on this attractive potential indication.

4.2. Conclusion

Transcatheter aortic valve implantation (TAVI) done successfully in these three patients in our institution is the first ever experience in India. It represents the first series of Core Valve implantation in our country and gives an impetus to the TAVI programme here. High surgical risk patients can now be safely treated with this new modality of percutaneous valve replacement therapy. It is a very exciting leap in the field of Interventional treatment with respect to structural heart disease therapies, going in parallel with world trends.

Conflicts of interest

All authors have none to declare.

References