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Transcatheter Aortic Valve Implantation - Tavi

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Definition

The valves used for TAVI consists of biological heart valve mounted within a metal stent, this metal stent can be made from Ni–Ti super-elastic alloy, resulting in a self-expandable device, or from elasto-plastic metals (stainless steel). In both cases, the stent expansion pushes the native aortic valve leaflets against the aortic root. Degree and pattern of calcification of aortic valve may affect the expansion of the stent and patient's outcome. Stroke may potentially be associated to the breakdown of calcium deposits [1]. Edward-Sapien valves are made from bovine pericardium in a trileaflet configuration mounted on a stent 14 mm in length and 23 or 26 mm in diameter and is delivered via 24-26 F catheter (internal diameter) [2,3]. Edward-Sapien valve 23 mm has a height of 14 mm, height of skirt 10.1 and 7.74 mm and used for annulus 18-22mm. Edward-Sapien valve 26 mm has a height of 16 mm, height of skirt 11.4 and 8.67 mm and used for annulus 21-25mm.

The Sapien-X has cobalt-chromium alloy which needs a smaller delivery system. The Edward-Sapien XT has the sizes of 20,23,26 and 29 mm and is used for annulus (16-19), (18-22), (21-25) and (24-27) mm respectively. Cor-valve is made of porcine mono-layer pericardium in a trileaflet configuration mounted on a self-expandable nitinol frame with inflow 26-29 and 31 mm and can be used for annulus between 20-29 mm. It can be used with 18 F delivery system. CorValve 23 mm has a height of 53 mm, height of skirt 12 mm and is used for annulus 20-23mm. Sinus of valsalva should be equal or more than 27mm and sinotubular junction≤40 mm. Corvalve 26 mm has a height of 55 mm, height of skirt 12 mm and is used for annulus 23-27mm. Sinus of valsalva should be equal or more than 28mm and sinotubular junction≤43mm.

CorValve 31 mm is used for annulus 26-29mm. Sinus of valsalva should be equal or more than 28mm and sinotubular junction≤43 mm. Medtronic Valve are supra-valvular valves and ADVANCE trial showed survival rate 95.5% at 30 days and 87.2 % at 6 months, MACE about 8.3% in 30 days and stroke 2.9% and success implantation 97.8% [4].

Keywords: TAVI; Migration; Paravalvular Leakage; Surgery; Anatomy; Transcatheter Aortic-valve Replacement

History

Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. PATNER I trial showed that in 25 patients with severe AS and STS 8.9 and Euroscore 25%, TAVI was successfully performed for all 25 patinets, mortality was 0 at 30 days and mean age was 85 years and mean AVA achieved to 1.6±0.27 form 0.59 ±0.15 cm^2 [5]. In PARTNER II Trial, intermediate risk (STS=4) patients with symptomatic severe AS were entered in the study and were followed for 2 years, the endpoints were death or disabling stroke. The patients underwent TAVI or surgical AVR. The event rate was similar for TAVI and SAVR, at 2 years, endpoints was 19.3% for TAVI and 21.1% for SAVR, P=0.25. In the transfemoral-access cohort, TAVI resulted in a lower rate of death or disabling stroke than surgery (P=0.05), whereas in the transthoracic-access cohort, outcomes were similar in the two groups of TAVI and SAVR.

TAVI resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation. In PARTNER II trial, the balloon-expandable SAPIEN XT heart-valve system was used .The major differences of the SAPIEN XT system, as compared with the first-generation SAPIEN valve system, are a thinner strut cobalt–chromium frame, a partially closed resting geometry of the bovine pericardial leaflets, the addition of a valve size that is 29 mm in diameter, and a reduced-profile delivery catheter.

A total of 18 patients (0.9%; 10 patients in the TAVI group and 8 in the surgery group) died during the procedure or within 3 days. A second transcatheter valve was placed within the first valve in 22 additional patients (2.2%) because of moderate or severe aortic regurgitation. In the TAVI group at 30 days, mild paravalvular aortic regurgitation was observed

in 22.5% of patients, and moderate or severe paravalvular aortic regurgitation in 3.7%. Patients in the TAVI group who had moderate or severe paravalvular aortic regurgitation at 30 days had higher mortality during 2 years of follow-up than did patients who had no or trace regurgitation.

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

In PARTNER IB study, the patients with severe AS and no option for surgery, and candidate for medical therapy or TAVI were followed for one year. There was significant reduction in death and stroke in TAVI patients. The results of two-year follow up also showed reduction of mortality in TAVI vs medical therapy. According to this study, TAVI is the procedure of choice for patients with severe AS who are not candidate for surgery and have life expectancy for at least one year.

Indications and Contraindications

In extremely high-risk patients, TAVI is superior to surgery (class I). In high risk patients(I) and moderate (IIa)risk patients TAVI is non-inferior or even superior to surgery (with transfemoral approach). In two large studies on moderate risk patients, the mean age of patients was more than 80 years and STS were more than 4. In low risk patients and patients younger than 75 years, the surgery is the method of choice [6]. History of CABG, sequel of chest radiation or scliosis, and porcelain aorta favour for TAVI, whereas, short coronary ostia, annulus out of range , septal hypertrophy more than 18mm, aneurysme of aorta, bicuspid AV or severe calcification of AV and pattern of calcification (arch form with commissure to commissure),LV apical clot ,aortic root morphology unfavorable for TAVI, severe mitral or tricuspid disease or need for CABG fovor for surgery. For symptomatic severe AS with prohibitive surgical risk and survival more than 1 year, TAVI is class I indication. For symptomatic severe AS with high surgical risk and survival more than 1 year, TAVI and surgical AVR are class I indication. For symptomatic severe AS with intermediate surgical risk, surgical AVR is class I and TAVI is class IIa indication [7].

In Low Risk Patients with Severe Symptomatic AS, Surgical AVR Is Classi

In the PARTNER II (Placement of Aortic Transcatheter Valve II) RCT , which enrolled symptomatic patients with severe AS at intermediate risk (STS score ≥4%), there was no difference between TAVR and surgical AVR for the primary endpoint of all-cause death or disabling stroke at 2 years (HR: 0.89; 95% CI: 0.73 to 1.09; p=0.25). All-cause death occurred in 16.7% of those randomized to TAVR, compared with 18.0% of those treated with surgical AVR. Disabling stroke occurred in 6.2% of patients treated with TAVR and 6.3% of patients treated with surgical AVR. MSCT is the preferred technique for assessing the aortic root and size and shape of aortic annulus, the distance of coronary ostia from aortic annulus and shape of calcification. TEE 3D is an alternative tool for evaluating anatomy but is operator and image-quality dependent. Paravalvular leakage, need for pacemaker and vascular complications was more with TAVI and acute kidney injury, bleeding and AF was more with surgery, risk of stroke equal.

TAVI for Pure AI

David Roy A et al reported 43 cases of severe native valve aortic regurgitation underwent TAVI, men ST score was 10%,TAVI was successful in 42 patients, Implantation of a TAVI was performed in 42 patients (97.7%), and 8 patients (18.6%) required a second valve during the index procedure for residual aortic regurgitation. In all patients requiring second valves, valvular calcification was absent (p = 0.014). Post-procedure aortic regurgitation grade I or lower was present in 34 patients (79.1%). At 30 days, the major stroke incidence was 4.7%, and the all-cause mortality rate was 9.3%. At 12 months, the all-cause mortality rate was 21.4% (6 of 28 patients) [8].

Complications

i. Migration

ii. Paravalvular Leakage

iii. CVA

iv. Death

Paravalvular Leakage

Redilation (5%) and second valve (4%) are used for paravalvular leak after TAVI. 52% of patients have no AI, 25% trivial and 23% mild AI and 2% have moderate AI. AI was paravalvular in 32%, transvalvular in 13% and both in 3% of patients. Male sex, NYHA IV and no previous aortic valve replacement are predictors of AI after TAVI. Transapical Aortic Valve Implantation [9]. Moderate to severe paravalvular leakage has been reported in up to 24% of patients.

Paravalvular Leakage was Graded as

Trivial: only pinpoint regurgitation jet in short-axis view of aortic valve,

Mild: Less than 10% of arc length/ circumference of AV,

Moderate: Between 10-30% arc length/ circumference of AV,

Severe: More than 30% of arc length/ circumference of AV.

In Partner trial, 12% had moderate to severe AI and 66% had no, trace or mild AI. With cor-valve paravalvular leak (9-21%) was slightly higher than Edward-Sapien valves. In FRANCE 2 registry, it has been confirmed that moderate to severe paravalvular leak at discharge was higher with self-expandable (19.8%) vs Balloon-expandable (12.8%). One of the major concerns about paravalvular leak is about its progression over time. While Webb et al reported that paravalvular leak is stable at one year follow up, Ussia et al repotted regression of paravalvular leak over time (3 year follow up) and no patient has changed from mild

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to moderate or severe PVL. Data from PATNER trial showed that at 2 year follow up, in 22.4% of patients, paravalvular leak is worsened more than 1 grade, in 46% remained unchanged and 31% it has been improved at least one grade. For Balloon-expandable valves, PVL should be assessed below the skirt of the valve. For central jet, it should be assessed at coaptation point of the leaflets.

Paravalvular leak occurs in 4% of patients post-surgical AVR.

Predictors of Paravalvular Leak Post TAVI

i. Malpositioning of valve,

ii. Undersizing of valve,

iii. Extent and pattern of calcification and eccentricity.

A smaller aortic valve area was associated with more paravalvular leak and smaller aortic valve area is due to larger calcification. In Cor-valve lower depth of implantation and larger LVOT aortic angle is associated with more paravalvular leakage. In one study by Cor valve implantation, larger annulus size, low implantation and peripheral vascular disease were the factors predicting equal or more than moderate paravalvular leak after TAVI,40.5% patients showed ≥ 2+ AI after TAVI which the majority respond to post dilation (2011). Eccentricity Index was reported as a predictor for paravalvular leak, Eccentricity index is calculated by dividing Min D/Max D of aortic annulus and EI>0.25 is reported as a predictor for PVL after TAVI in some reports whereas other cannot find a relationship between EI and PVL. Amount of calcification in the landing zone is reports as a predictor of PVL in some reports but in German Registry of TAVI, it has not been found. In a study by Luigi et al, Agaston score was the only predictor of paravalvular leak after TAVI and the aortic annulus eccentricity index was not a predictor of PVL. Maximal annulus diameter and cover index as predictors of more than mild PVL in univariate analysis but did not remain in the multivariate analysis [10].

Predictors of Early and Late Stroke After TAVI Are Categorized in Two Groups

i. Patient related: female gender, peripheral vascular disease, kidney disease, new onset atrial fibrillation, history of previous stroke and fall, angina, no previous CABG and low body mass index.

ii. Procedure related: annulus size, pure AS, time of procedure, rapid atrial pacing and Balloon predilation, valve repositioning and post dilation.

In a recent meta-analysis, in multivariate analysis, prior stroke and renal impairment were found as the only independent predictors for stroke complicating TAVI [11,12].

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