Valve Replacement: Importance Of Stroke Volume and the Left Ventricular Outcomes, Paravalvular leak, TAVR

RESULTS

N=142 consecutive patients who underwent TAVR using SAPIEN device were included in the study (n=76 SAPIEN XT and n=66 SAPIEN 3). There was no difference between groups regarding age, Euroscore, gender, previous medical history and left ventricle ejection fraction. However, SAPIEN 3 patients had a higher prevalence of peripheral arterial disease (65.2% vs. 36.8%, p=0.001) and ilio-femoral axis calcifications on scan (47.9 vs. 26.5%, p=0.008) than the others. Moreover, SAPIEN 3 patients had a smaller aortic valve area than SAPIEN-XT subjects (0.67±0.9 vs 0.76 ± 0.14 cm²/m², p=0.007), yet there was no significant difference in aortic annulus diameter (25.2±4.5 vs 23.6±2.2 mm, p=ns). TAVR was performed through transfemoral access in 96% in both groups. Device implantation success rate was higher (100% vs. 99%, p=0.002) in the SAPIEN 3 than in the SAPIEN-XT group. The prevalence of moderate to severe paravalvular leak was lower in SAPIEN 3 than in SAPIEN-XT patients (0% vs 9.2%, p=0.01). We observed fewer hemorrhagic events in the SAPIEN 3 group than in the other, as assessed by the lower incidence of life-threatening events (0% vs 9.2%, p=0.01). There was no difference either to the 20 days of MACCE (major cardiovascular & cerebrovascular events) between patients, including no difference in terms of death (3% vs. 5%), stroke (3% vs. 2.6%) and major vascular complications (6% vs. 13%). Finally, the rate of permanent pacemaker implantation was comparable in both groups (10.8% vs. 14.5%, p=0.49).

CONCLUSIONS

The use Edwards SAPIEN 3 allows TAVR in patients with more severe peripheral artery disease. Moreover, this device provides excellent short-term outcome and lower rates of paravalvular regurgitations compared to the previous generation SAPIEN-XT valve.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS

Outcomes, Paravalvular leak, TAVR

TCT-627

Left Ventricular Mass Regression After Transcatheter Or Surgical Aortic Valve Replacement: Importance Of Stroke Volume And The Left Ventricular Mass Formula

Jae K. Oh,1 Grace Lin,2 Sahar S. Abdelmoneim,3 Ana Kada khodayan,1 Stephen H. Little,1 David Adams,3 Michael J. Reardon,4 David A. Orsinielli,5 Jeffrey Popma6

BACKGROUND

Prospective randomized trials have demonstrated that transcatheter aortic valve replacement (TAVR) is an effective alternative to surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis at increased surgical risk, but reasons why left ventricular (LV) mass regresses more rapidly to a greater extent after SAVR than TAVR despite a higher AV gradient after SAVR is unknown. We sought to determine why LV mass regression is greater after SAVR.

METHODS

Baseline and serial echocardiography studies of patients randomized to SAVR with a bioprosthetic valve vs TAVR with a self-expanding CoreValve were analyzed by an Echo Core Lab blinded to treatment and outcomes. Echocardiography measurements including LV area were performed according to established guidelines and LV mass was calculated using the formula of Devereaux et al: 0.83 x ([LVEDD + LPWT + IVS]3 - [LVEDD]3) + 0.6. LVEDD = LV end-diastolic dimension, LPWT= posterior wall thickness, and IVS=interventricular septal thickness.

RESULTS

Data were available in 389 TAVR and 533 SAVR patients. SAVR, LVIDD, PWT, IVS, LV mass, and SV were similar in TAVR and SAVR at baseline. These variables were unchanged at discharge with TAVR. However, after SAVR at discharge, LV mass decreased from 227.4±65.02 to 215.08±59.02 gm (p=0.002), and LVEDD from 65.21±66.64 to 4.81±6.65 cm (p=0.0001), although PWT and IVS were unchanged. 2D derived stroke volume (SV) also declined at discharge from 72.64±27.04 mL to 58.93±21.10 mL (p=0.01) after SAVR, but not after TAVR (70.42±27.21 mL to 70.36±24.48 mL; p=0.46). Similar changes were observed with Doppler derived SV. At 1 year, LV mass, SV and LVEDD remained smaller following SAVR vs. TAVR, a difference that persisted after exclusion of those with moderate aortic regurgitation (AR).

CONCLUSIONS

Greater LV mass regression after SAVR is due to smaller post-operative LVEDD associated with lower SV after SAVR than TAVR. Further study is needed to identify the reasons for reduced SV after SAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS

Aortic valve replacement, Echocardiographic assessment, Transcatheter aortic valve replacement

TCT-628

Prospective Non-randomized Comparison Between Three Transcatheter Aortic Valve Replacement Devices: Accurate vs Corevalve vs Sapien XT. A Single Heart Team Experience in Patients With Severe Aortic Stenosis

Tannas Jatene,1 Antonio d Castro Filho,2 Rafael A. Meneguz-Moreno,3 Dimytri A. Siqueira,4 Alexandre Abizaid,4 Auristela I. Ramos,5 Magaly Arrais,5 David Le Bihan,6 Rodrigo B. Barreto,6 Adriana Moreira,6 J. Eduardo Sousa,7 Amanda Sousa7

1Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Sao Paulo;2Dante Pazzanese Institute of Cardiology, Sao Paulo, Brazil;3Institute Dante Pazzanese of Cardiology, Sao Paulo, Sao Paulo/SP;4Institute Dante Pazzanese de Cardiologia, Sao Paulo, Brazil;5Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Sao Paulo;6Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil;7Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Sao Paulo, ICor, Sao Paulo, Bouvet Island;8Instituto Dante Pazzanese de Cardiologia, Sao Paulo, CA;9Dante Pazzanese, Sao Paulo, Brazil

BACKGROUND

This is the first study comparing outcomes after transfemoral transcatheter aortic valve replacement (TAVR) with Accurate, CoreValve and Edwards Sapien XT (SXT).

METHODS

We prospectively evaluated patients with severe aortic stenosis undergoing transfemoral TAVR at two centers coordinated by the same Heart Team. Study objectives were echocardiography findings and Valve Academic Research Consortium (VARC) at 30 days.

RESULTS

We evaluated 162 patients (ACT n=48, MCV n=57, SXT n=57). Baseline clinical and imaging features are resumed in Table 1. Immediately after the procedure, Device Success were lower with MCV (97.9% vs 86% vs 94.7%; p=0.049), as well as Aortic Valve Area (1.90±0.26 vs 1.81±0.32 vs 2.01±0.28; p=0.002), with no differences in Mean Gradient (p=0.752) or Moderate/Severe Aortic Regurgitation (p=0.272). At 30 days, there were no significant difference in all-cause mortality (p=0.298), cardiovascular mortality (p=0.222), myocardial infarction (p=0.776) and stroke (p=0.999). Additionally, no differences were found in major vascular complications (p=0.594), life-threatening bleeding (0.378) and stage 3 acute kidney injury

Table. Echocardiographic Parameters by Treatment Over Time

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TAVR</th>
<th>SAPIEN 3</th>
<th>SAPIEN XT</th>
<th>ACT</th>
<th>MCV</th>
<th>MCV</th>
<th>SXT</th>
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<tbody>
<tr>
<td>LVEDD (cm)</td>
<td>4.97</td>
<td>4.76</td>
<td>4.78</td>
<td>4.74</td>
<td>4.76</td>
<td>4.76</td>
<td>4.80</td>
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<td>IVST (mm)</td>
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<td>11.46</td>
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<tr>
<td>LV mass (g)</td>
<td>277.21</td>
<td>274.65</td>
<td>274.65</td>
<td>272.43</td>
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<tr>
<td>SV (ml)</td>
<td>70.36</td>
<td>69.25</td>
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<td>68.90</td>
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<tr>
<td>Mean Gradient (mmHg)</td>
<td>42.28</td>
<td>42.28</td>
<td>42.28</td>
<td>42.28</td>
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</tbody>
</table>

Note: All values are mean ± standard deviation.
CONCLUSIONS Although the three devices have shown good device success rates and hemodynamic improvement on echocardiogram, CoreValve use lead to higher combined early safety endpoints, mainly because of more permanent pacemaker usage. Larger cohorts or randomized trials are needed do corroborate these findings.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Calcification, TAVR

TCT-630 Transfemoral aortic valve implantation (TAVI) with the balloon-expandable Edwards Sapien 3 valve compared with the self-expanding Medtronic CoreValve

Julia Seeger, Birgid Gonska, Christoph Rodevald, Dominik Scharnbeck, Sinisa Marcovic, Wolfgang Rottbauer, Jochen Wöhrlé
1University of Ulm, Ulm, Germany

BACKGROUND In patients with severe aortic stenosis undergoing transfemoral aortic valve implantation (TAVI) device success was significantly higher with the balloon-expandable Edwards XT valve (EXT) compared with the self-expanding CoreValve (CV) in the randomized CHOICE trial. The second generation Edwards Sapien 3 valve was designed to reduce paravalvular aortic regurgitation. Absence of post-procedural aortic regurgitation was associated with a lower acute and long-term mortality in the Partner trial. We compared the outcome of the ES3 with the CoreValve in patients undergoing TAVI.

METHODS The first 100 consecutive patients treated with the ES3 were compared with the last 100 consecutive patients treated with the CoreValve (Clinical Trial Registration: NCT02162069). Mean STS-Score was 10.2±7.9%. Post-procedural aortic regurgitation, rate of permanent pacemaker implantation, and device success were analyzed according to VARC criteria. Device size was based on multislice computer tomography performed with a 256 Philips Brilliance ICT scanner. Measurements of aortic annulus, left ventricular outflow tract (LVOT) were performed with a dedicated software (Medtronic Structural Heart, version 7.0).

RESULTS Baseline characteristics were mostly similar between the CoreValve and ES3 population: age 81±6 vs. 82±6 years (p=0.24), female 49% vs. 52% (p=0.67), diabetes mellitus 34% vs. 38% (p=0.56), coronary artery disease 61% vs. 60% (p=0.89), history of cardiac surgery 14% vs. 9% (p=0.27), pulmonary disease 36% vs. 60% (p<0.01). Also the computer tomography acquired parameters did not differ significantly between the EXT and ES3 population. Post dilatation was necessary in 11% after CoreValve implantation and in no patient after ES3 implantation (p=0.01). Rate of device success according to case of valve embolization in the mild AVCS group. Thirty-day mortality and major complications were similar between groups (Table). One year mortality was 13.2% vs. 16.4% in the AVCS<1500 vs. AVCS>1500, respectively (p=0.61).

CONCLUSIONS Balloon-expandable TAVR can be performed safely in patients with extremely low AVCS. We demonstrated excellent acute procedural outcome, lower rates of postprocedural PVR and no case of valve embolization.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Calcification, TAVR