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Catheter-Based Valve-Implantations Using CoreValve and Edwards-Sapien Devices

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Background: Transcatheter valve implantation (TAVI) is an alternative for surgery in patients with severe aortic-stenosis at high risk. We describe our experience with TAVI.

Methods: 131 patients were treated and followed prospectively: 62 trans-femoral Corevalve; 12 trans-axillary Corevalve; 1 trans-aortic Corevalve 1; 28 trans-femoral Edwards and 28 trans-apical Edwards. This patient group (60.7% women) was characterized by relatively older age (mean 81.5 years), and high prevalence of severe co-morbidities: 31.5% diabetes mellitus, 27% post thoracotomy, 33.8% chronic renal failure, 28.4% pulmonary disease. The mean logistic EuroSCORE was 22.9% and STS 9.8%. Six cases (4.8%) were performed in degenerated bioprosthetic valves.

Results: The rate of acute procedural success was 97.0%. Six patients (4.6%) died within 30-days after the procedure and 7 patients died after that period to one year (95.4% survival @30-days and 87.0% @360-days). There were 2 cases (1.5%) needed urgent cardiac surgery due to tamponade. Vascular complications were noted in 22 patients (16.9%) mostly treated percutaneously. Six patients sustained stroke (4.6%). Permanent pacemaker implantation was required in 20 patients (15.3%): 24.3% in Corevalve and 3.7% in Edwards. Significant (grade >2) post-procedural aortic-regurgitation was noted in 4 patients (3.1%); acute renal failure in 4 patients (3.1%), blood transfusion in 23 patients (17.7%). Two patients (1.5%) needed additional valve due to misplacement. The median length of hospital stay was 5 days. Mean valve gradients decreased from 52mmHg to 8.6mmHg ($p<0.001$). At follow-up Symptomatic improvement was evident in 98% of patients.

Conclusions: TAVI is a feasible and effective procedure for the treatment of patients with severe aortic stenosis who are at high-surgical risk. Complication rate should be considered in the risk vs. Benefit assessment of patients and by a multidisciplinary 'heart team'.

The Additive Value of CT Prior to Transcatheter Aortic Valve Implantation (TAVI) Procedure

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Background: Trans-catheter aortic valve implantation (TAVI) has been recently introduced as an alternative to conventional open heart surgery for selected patients with symptomatic severe aortic stenosis.

Purpose: To evaluate the additive value of CT performed prior to TAVI procedure.

Subjects and Methods: Forty one patients with severe aortic stenosis underwent 256-slice CT for assessment of the aortic annulus and peripheral vessels before TAVI. In 35 patients the scan volume ranged from the thoracic inlet to the level of mid-thigh region and in six patients the scan volume ranged from the carina to below the diaphragmatic face of the heart.

Results: According the results of the CT studies TAVI was not performed in 2 patients due to aortic annulus dilatation (>29 mm) and in another patient due to the presence of lung malignancy. Change from trans-femoral to trans-apical approach was decided in 7/41 patients because of severe peripheral vascular disease and vessel tortuousity ,avoiding vascular access, including aortic dissection. Major non-cardiac finding included (a) thoracic: pulmonary findings in 65% (27/41), out of which 2 were malignant, and mediastinal adenopathy in 21% (12/41); (b) abdominal: adrenal, renal, gastrointestinal and hepatic pathology in 17% (6/35), 40% (14/35), 40% (14/35), 20% (7/35), respectively; 8/35 (23%) required further investigation or treatment. Skeletal findings were demonstrated in 8/41 (19%), one patient was suspected for metastatic spread.

Conclusions: Pre TAVI gated CT can improve patient selection. Gated CT allows better per patient tailoring prior to the procedure, including accurate vascular access evaluation. Non vascular findings which are frequent in this patient population, should not be underestimated since major findings changing or canceling the procedure can occur.

Percutaneous Coronary Intervention and TAVI as a Combined Procedure

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Background: Coronary artery disease (CAD) has been reported in ~50% of elderly patients with severe aortic stenosis (AS). Concomitant CAD may increases the procedural risk of transcatheter aortic valve implantation (TAVI). In light of the evolution of TAVI and ongoing improvements in techniques of PCI, a combined approach using PCI and TAVI can be proposed for patients with complex coronary artery and AS.

Aims: We report herein our experience with combined PCI and TAVI in elderly patients with severe AS.

Methods: Patients who underwent TAVI at our department were retrospectively analyzed. Study endpoints included procedural success and 30-day survival.

	TAVI+PCI Combined [n=18]
Age [year]	81±7
Male	33%
NYHA>2	100%
Anginal pain	39%
DM	33%
CAD	100%
EuroScore	20±3
STS score	9±5
Femoral/Apical/Axillery	78%/22%/0%
CoreValve/Edwards	39%/61%
Procedural success	94%
One month mortality	5.6%

Conclusion: We conclude that in carefully selected cases, combining PCI and TAVI is feasible and associated with acceptable clinical outcomes in selected cases. Further experience is needed to evaluate this expanded strategy

Transcatheter Aortic Valve Replacement for Low Gradient Severe Aortic Stenosis: Clinical Outcomes

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Background: Aortic stenosis (AS) characterized by aortic valve <1.0cm2 , mean aortic pressure gradient (MPG) <40 mmHg and left ventricular (LV) ejection fraction > 50% is referred to as low gradient severe aortic stenosis (LGSAS). Symptomatic LGSAS may be a form of a more advanced stage of AS with poorer prognosis. Trenscatheter aortic valve replacement (TAVR) is an effective treatment in patients with typical severe AS (defined as aortic valve are <1.0cm2, MPG>40mmhg), however the role of TAVR in patients with LGSAS and high operative risk in uncertain.

Methods: In this study we retrospectively compared clinical outcome of TAVR in patients with symptomatic LGSAS to those with typical severe AS.

Results: Echocardiography among 104 consecutive TAVR patients, revealed typical severe AS in 72(69%) patients where as 32(31%) patients were classified as LGSAS. The New York Heart Association functional class improved by the same extent in patients with severe AS (3.1±0.4 to 1.3±0.3, p<0.001) and in patients with LGSAS (3.2±0.4 to 1.4±0.3, p<0.001). The one-year survival rate was not different between patients with LGSAS, and patients with typical AS (89.5±5.8% vs. 92.4±3.7%; p=0.95). The one-year freedom from death or re-admission for heart failure was not different between the groups (86.3±6.5% vs. 84.0±5.0%; p=0.25), nor the one-year freedom from the combined cardiac outcome (all cause mortality, or heart failure or new onset atrial fibrillation, or AV block requiring pacemaker implantation, or re-admission for syncope) (75.7±8.2% vs. 75.4±5.6%; p=0.34).

Conclusion: Transcatheter aortic valve replacement in patients with high operative risk provides similar clinical benefit in patients with LGSAS to that of patients with typical severe AS.

Left Main Stenting in Patients with Severe Aortic Stenosis Prior to Percutaneous Valve Interventions

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Patient #	Logistic Euroscore	Vascular access	Balloon pump	Lesion location	Stents	AS therapy
1	40	Femoral	Yes	Distal	Xience 3.5X18 mm	BAV
2	13	Femoral	No	Distal	Endeavor 3.0X30 mm	BAV
3	60	Brachial	Yes	Ostial	Promus 3.0X10 mm	BAV
4	13	Femoral	Yes	Ostial	SKS: Promus 3.5X15 mm, Promus 4.0X15 mm	TAVI
5	9	Radial	No	Ostial	Resolute 4.0X9 mm	TAVI
6	20	Femoral	No	Ostial	Driver 4.5X9 mm	TAVI
7	49	Femoral	No	Distal	Cypher 3.5X18 mm	TAVI
8	35	Radial	No	Distal	Culotte: Cypher 3.5X18 mm, Cypher 3.5X18 mm	TAVI
9	45	Radial	No	Distal	Culotte: Resolute 3.5X22 mm, Resolute 3.0X16 mm	TAVI
10	35	Radial	No	Distal	Cypher 3.5X18 mm	TAVI

Aims: High-risk patients with severe aortic stenosis (AS) who are candidates for transcatheter valve implantation (TAVI) or balloon aortic valvuloplasty (BAV) may additionally require revascularization of the unprotected left main coronary artery (UPLM). We aimed to assess the feasibility and acute procedural safety of UPLM stenting in such patients.

Methods and results: Ten cases of UPLM stenting prior to BAV or TAVI at three medical centers over a two year period were identified. Mean age was 84±4 years, aortic-valve area 0.70±0.12 cm2, left ventricular ejection fraction 58±3% and logistic EuroScore 32±17. Intra-aortic balloon counterpulsation was used in 3 patients. A single stent was used in 7 patients and two stents in 3 patients. One patient received a bare-metal stent and the others drug-eluting stents. No procedural complications occurred and the patients were hemodynamically stable. Three patients subsequently underwent BAV and 7 underwent TAVI. During 6 months of follow-up 2 patients died; one due to AS restenosis 6 months after BAV and one due to vascular complications 18 days after TAVI (34 days after UPLM stenting).

Conclusions: Stenting of the UPLM in patients with severe AS prior to percutaneous valve intervention seems feasible and safe. This approach may enable more patients to achieve comprehensive percutaneous therapy for severe coronary and valvular disease.

Phantom of the Opera of TAVI: The Point of No Return

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Background: Diastolic dysfunction and pulmonary artery hypertension (PAH) are frequent findings in patients with severe aortic stenosis (AS) and their influence on clinical features and outcome is recognized. The question is whether TAVI can reverse this and lead to better survival.
Methods: Parameters of diastolic dysfunction as well as PAH were assessed with transthoracic echocardiography before TAVI, month and year after TAVI in 58 consecutive patients with severe AS and high risk for surgical aortic valve replacement. Tricuspid valve gradient was used as surrogate of PAH.
Results: Mean age was 80.6 years (range 58-91) and mean EuroSCORE was 24±14.7SD. E to A ratio at the baseline was 1.26±0.86, month after TAVI was 1.37±1.26 and 1.02±0.79 year after TAVI. Deceleration time (DT) at baseline was 190±86 ms at baseline, 207±80 ms month after TAVI and 215±58 ms year after TAVI. Peak e' lateral annular velocity was 5.7±1.2 cm/s at the baseline, 5.8±1.5 cm/s month after TAVI and 7.2±3.4 cm/s year after TAVI. Tricuspid valve gradient declined from 43±15 mmHg at baseline to 35±13 mmHg moth after TAVI an remains the same year after TAVI, 34±10 mmHg. General linear model multivariate test of repetitive measures did not show significant decrease of E to A ratio ($p=0.15$), no significant increase of DT ($p=0.51$), no significant increase in lateral e' velocity ($p=0.13$). Tricuspid valve gradient fall significantly month after TAVI ($p<0.05$) without further decline and without influence on one year survival ($p=0.08$).
Conclusion: Diastolic left ventricular performance did not change over time after TAVI and has no impact on overall survival. Tricuspid valve gradient was reduced significantly month after TAVI without further decline and without influence on one year survival.

Surgical Aortic Valve Replacement for Aortic Stenosis in the Era of Transcatheter Implantation

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Background: Open aortic valve replacement (AVR) is the standard of care for severe aortic stenosis (AS) with excellent results, yet the peri-operative morbidity and mortality among high-risk patients remains significant. The introduction of transcatheter aortic valve implantation (TAVI) as an alternative for high-risk surgical patients is thought to change clinical characteristics and outcomes of the remaining AVR patients in the TAVI era.
Methods: This is a single center analysis comparing two cohorts of consecutive patients undergoing isolated AVR for severe AS, in the 4 years before (period 1) and 3 years after (period 2) the introduction of TAVI to our heart center. Baseline characteristics were prospectively gathered to a registry. The logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was calculated for each patient. Primary endpoint was 30-day mortality; secondary endpoints included 1-year mortality and major adverse peri-operative events.
Results: After exclusion of patients with bicuspid aortic valve and prior mechanical aortic prosthesis (not being TAVI candidates), study population consisted of 231 pts. in period 1 and 162 pts. in period 2. Mean age was 74 years in both periods with 45% and 50% male, respectively. Mean logistic EuroSCORE was 12.7±12 (period 1) vs. 9.7±9 (period 2), p=0.006. We found a trend for lower 30-day mortality (2% vs. 5%, p=0.1), in period 2, while one-year mortality was dramatically improved (6% vs. 15%, p<0.01). Interestingly, while EuroSCORE was an independent predictor of 30-day and 1-year mortality in period 1, it was not found to predict mortality in period 2 patients. The major complication rate didn't differ significantly between the two periods (p=0.19).
Conclusion: We show a significant improvement in baseline characteristics and mortality in patients undergoing surgical AVR for severe AS during the recent years. This change must be explained by the patients' selection process in the new TAVI era.

Transcatheter Aortic Valve Implantation in Israel 2011: Preliminary Results of the National Israeli Ongoing Registry

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Background: transcatheter aortic valve implantation (TAVI) is a novel emerging technology for the treatment of severe and symptomatic aortic stenosis patients that are considered to be of high surgical risk. Israel adopted TAVI relatively early with first cases performed at 2008. We report the national extent and characteristics of TAVI use and its outcome at 30 days and 1 year.
Methods & Results: I-TAVI is a national ongoing registry, established by the Israeli Workgroup for Interventional Cardiology, that includes all 10 Israeli TAVI centers. From August 2008-November 2011 there were 826 TAVIs in Israel. Mean patients age was 81.8±À7 and Logistic Euroscore 20.8±À11%. 522 implantations were performed using the Medtronic-Corevalve self expandable valve system and 304 with the Edwards-Sapien balloon expandable valve system. 673 implantations were performed via a transfemoral approach, 63 trans-axillary, 80 trans-apically and 10 via a direct aortic approach.
Clinical Improvement and reduction of 1≤ functional capacity level were observed in >90%. Mortality at 30 days was 5.4% and at 1 year 17.5%. Detailed analysis will be presented at the IHM meeting.
Conclusions: TAVI is widely expanding in Israel. The technology appears safe and effective for the treatment of severe aortic stenosis in patients at high-surgical risk.