PCR London Valves 2012 Abstracts

PCR london valves | Transcatheter therapies in patients with mitral regurgitation or poor left ventricular function

Transcatheter aortic valve replacement for severe aortic stenosis in elderly patients with severely depressed left ventricular function

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Aims: A low ejection fraction is a predictor of morbidity and mortality after surgical aortic valve replacement but little is known about its effect on clinical outcomes after TAVI. We sought to assess early risks and benefits of TAVI with SAPIENT XT (Edwards Lifesciences LLC, Irvine, CA, USA) in elderly patients with aortic stenosis and severely depressed EF.

Methods and results: SOURCE XT is a multicentre, prospective, post-approval study which enrolled >2,600 consecutive patients at 94 sites in 17 countries. A total of 157 patients, 81.3±5.4-years-old, were with severely depressed EF≤30% (EF≤30), and 2,142 patients, 81.7±5.8-yrs-old, with EF>30% (EF>30) served as controls. Compared to patients with EF>30, patients with EF≤30 were more likely to be male (68.8% vs. 42.9%, p<0.0001) with NYHA III/IV (90.4 vs. 77.0%, p<0.0001) and greater STS score (9.5±6.1 vs. 8.4±7.0, p=0.042). Patients with EF≤30 had significantly higher incidence of CHF, previous MI or insulin-dependent diabetes. Effective orifice area was similar for the two groups (0.7±0.2 vs. 0.7±0.2 cm², p=0.41); however, mean gradient was significantly lower (34.1±12.4 mmHg vs. 47.5±16.3 mmHg, p<0.0001) and pulmonary pressure was significantly higher (51.2±13.1 mmHg vs. 44.7±14.9 mmHg, p<0.0001) in EF≤30 vs. EF>30. At 30-day follow-up, overall mortality (10.2% vs. 6.1%, p=0.044), cardiac death (5.3% vs. 2.1%, p=0.017) and stroke (4.6% vs. 2.0%, p=0.036) were significantly higher in EF≤30 as compared to EF>30. There were no significant differences between EF≤30 and EF>30 in terms of MI (1.3% vs. 0.6%, p=0.27), major vascular complications (1.9% vs. 1.7%, p=0.79), major bleeding events (9.0% vs. 7.3%, p=0.42) or new onset atrial fibrillation (6.7% vs. 5.1%, p=0.42). NYHA Class improved significantly at 30 days with majority of patients being in NYHA I/II (92.7% for EF≤30 and 89.6% for EF>30, p=0.36).

Conclusions: Severely depressed EF in patients with aortic stenosis undergoing TAVI was associated with significant comorbidity at baseline and increased mortality and stroke at 30 days; however, periprocedural complications were similar to patients with EF>30% and functional improvement was significant. A careful consideration of all risk factors is necessary to optimise outcomes after TAVI in low-EF patients.

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PCR london valves | Transcatheter therapies in patients with mitral regurgitation or poor left ventricular function

Prognostic implications of moderate and severe mitral regurgitation in contemporary clinical care

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Aims: The impact of surgical or percutaneous mitral valve repair in patients with severe mitral regurgitation (MR), particularly with significant left ventricular dysfunction (LVD) and comorbidities is difficult to predict. We examined the long-term prognostic impact of severe MR and the putative benefits of surgical or device therapy.

Methods and results: This was a case control study. From a single-centre echocardiographic database, 432 patients were identified and matched in a 1:1 fashion adjusting for age, gender, LV function and echocardiogram date. Two hundred and sixteen patients had moderate to severe MR while 216 patients had none or mild MR. Baseline clinical and echocardiographic characteristics were compared between both groups. The association between significant MR and event-free survival was plotted using Kaplan-Meier methods. To estimate the average number of years lost due to MR and the putative years gained through mitral valve repair, 15-year outcomes were predicted using the Royston-Parmer survival model. The years of life lost due to moderate or severe MR was estimated by the median life expectancy of patients with MR compared with patients of similar age and LV function without MR. Both groups were well matched for age, gender, LV function, ischaemic heart disease, hypertension and diabetes. Moderate or severe MR was associated with more atrial fibrillation (no/mild MR: 30.7% vs. moderate/severe MR:51.6%, p<0.001) and heart failure (13.2% vs. 27.9%, p<0.001). Significant MR was not associated with increased rate of death at 30 days (6.0% vs. 9.3%, p=0.13), but was associated with increased 12-month and overall mortality (18% vs. 31%, p=0.012 and 35.6% vs. 46.4%, p=0.015 respectively). There was also a higher rate of 12-month and overall rehospitalisation for heart failure in the MR group (18.5% vs. 23.1%, p=0.013 and 8.8% vs. 17.1%, p=0.007 respectively). Cox proportional hazard analysis demonstrated increased risk of death with significant MR (hazard ratio [HR] 1.66; 95% confidence interval [CI] 1.04-2.62, p=0.031), ejection fraction <30% (HR;1.61; 95% CI; 1.03-2.16, p=0.039), COPD (HR 1.95; CI 1.35-2.85, p<0.001) and renal dysfunction (HR 2.11; CI 1.45-3.07, p<0.001). Royston-Parmer plots were well matched with observed mortality from this and published studies over 12-month periods. A Royston-Parmer plot of 65-year-olds with normal LV function and severe MR predicted a median survival of 4.87 years with the potential to gain 1.6 life-years over 15 years following surgical intervention of MR. Royston-Parmer plots of 70-year-olds with severe MR, LVD and renal dysfunction predicted a median survival of 2.6 years with the potential to gain 1.0 life-year.

Conclusions: Mitral regurgitation remains undertreated and is associated with independent prognostic significance. The Royston-Parmer model represents a potentially useful risk stratification tool, which may have significant implications for patient selection and funding discussions for the future application of novel devices for the treatment of MR.

PCR london valves | Transcatheter therapies in patients with mitral regurgitation or poor left ventricular function

Thirty-day outcomes after TAVI in patients with severe aortic stenosis and moderate or severe mitral regurgitation

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Aims: Moderate and severe mitral regurgitation (MR) is associated with higher mortality in patients with CHF, but little is known about its impact on outcomes in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI). Isolated surgical aortic valve replacement usually has a positive impact on functional MR but the effect of TAVI is not well understood. We sought to assess the effect of MR on early clinical outcomes after transcatheter SAPIEN XT valve (Edwards Lifesciences LLC, Irvine, CA, USA) implantation, and the impact of TAVR on MR.

Methods and results: SOURCE XT is a multicentre, prospective, post-approval study which enrolled >2,600 consecutive patients at 94 sites in 17 countries. Total of 968 patients (36.8%) did not have any MR at baseline, 1,144 patients (43.5%) were with mild MR, 461 patients (17.5%) were with moderate MR, and 56 patients (2.1%) were with severe MR. Patients with moderate or severe MR were included in the MR Group (MR-Gr, n=517) and those with none or mild MR were included in the control group (C-Gr, n=2,112). Compared to the C-Gr, patients in the MR-Gr were more likely to be older (82.3±5.4 vs. 81.6±5.9, p=0.0148), female (63.1% vs. 56.5%, p=0.0073) with NYHA III/IV (81.4 vs. 75.9%, p=0.0073) and greater STS score (10±8.3 vs. 8.1±6.6, p<0.0001). MR-Gr patients had significantly higher incidence of CHF, atrial fibrillation or renal insufficiency. Mean gradient was similar for the two groups (47.5±17.0 vs. 47.3±20.1 mmHg, p=0.81); however, EF was significantly lower (50.1±12.0% vs. 53.0±11.2%, p<0.0001) and pulmonary pressure was significantly higher (50.5±16.0 mmHg vs. 43.3±14.1 mmHg, p<0.0001) in MR-Gr vs. C-Gr. There were no significant differences between MR-Gr and C-Gr in terms of overall mortality (7.2% vs. 5.9%, p=0.28), cardiac death (2.5% vs. 2.2%, p=0.64), stroke (1.2% vs. 2.6%, p=0.0627), major vascular complications (1.4% vs. 1.9%, p=0.41) or major bleeding events (7.4% vs. 7.8%, p=0.81). One month after TAVI, MR had improved by at least 1 degree in 30.4% of patients with any MR at baseline and in 44% of patients with moderate or severe MR.

Conclusions: Despite significant comorbidity, TAVI in patients with severe aortic stenosis and concomitant moderate or severe MR was not associated with an increased mortality. Furthermore, MR was improved in 44% of patients but longer follow-up is needed to understand the potential benefit of TAVI in this subset of patients.

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Real-world European experience with the transcatheter treatment of significant mitral regurgitation: demographics and procedural outcomes

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Aims: Use of the MitraClip System as a transcatheter therapeutic option for treating significant mitral regurgitation (MR) continues to expand throughout Europe. As of June 15, 2012, a total of 4,534 patients have been treated with the MitraClip devices in Europe in a real-world setting in both the ACCESS-EUROPE studies and in commercial use.

Methods and results: Baseline demographics, device time and post-procedural reduction in MR severity are reported from patients treated between September 17, 2008 and June 15, 2012. A total of 4,534 patients were treated at 144 institutions in 17 European countries. Patients were elderly, with a median age of 75 years. At baseline, 67% of patients had functional MR (FMR). Left ventricular (LV) dysfunction was categorised as severe in 34% of patients, with LV ejection fraction <30% reported in 30% of patients. Pre-procedural MR severity was reported as MR ≥3+ in 99.6% of patients. The MitraClip device implant rate was 95.6% with the following distribution of devices: 201 patients (4.4%) underwent the procedure but received no device, 2,873 patients (63.4%) received one device, 1,350 patients (29.8%) received two devices and 110 patients (2.4%) received three or more devices. The median device time was 80 minutes. Post-procedural MR severity was reported as MR ≤2+ in 90% of patients, with 58% of all patients achieving MR ≤1+. Approximately 93% of patients achieved at least a 1-grade reduction in MR severity. No change in MR severity was reported in 5.6% of patients and <1% of patients had worsening MR severity.

Conclusions: As reported, patients treated with the MitraClip device in the real-world use setting are elderly and present with a significant incidence of FMR and impaired LV function. Reduction of MR severity was achieved via the MitraClip therapy in the majority of these patients, demonstrating adoption of the MitraClip therapy in a predominantly high-surgical-risk patient population.

PCR london valves | Treatment and consequences of regurgitation during transcatheter valve therapies

Transcatheter aortic valve implantation for pure severe native aortic regurgitation

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Aims: Transcatheter aortic valve implantation (TAVI) is an established treatment for patients with severe aortic valve stenosis and prohibitive or high surgical risk. There is limited data and experience for TAVI in the treatment of patients with pure severe native valve aortic regurgitation. We aimed to evaluate the off-label treatment of pure native aortic regurgitation (NAR) with TAVI for patients with prohibitive surgical risk by examining the procedural and clinical results from a retrospective worldwide registry of patients with NAR treated with TAVI.

Methods and results: Data on baseline patient characteristics, device and procedural parameters, echocardiographic parameters and outcomes up to June 2012 were collected retrospectively in a uniform spreadsheet from 14 centres that have performed TAVI for pure NAR. A total of 43 patients underwent TAVI with the CoreValve prosthesis (Medtronic, Minneapolis, MN, USA) in 14 centres (mean age 75.3±8.8 years, 53% female, mean logistic EuroSCORE 26.9±17.9%, mean STS score of 10.2±5.3%, n=35 transfemoral, n=4 subclavian, n=3 direct aortic, n=1 carotid). The mean annulus size was 23.7±2.1 mm and the 29 mm prosthesis was most commonly used (n=21 29 mm, n=14 26 mm, n=1 31 mm). Implantation was successful in 42 patients (97.7%) and 8 (18.6%) patients required a second valve during the index procedure for residual aortic regurgitation. In all cases where a second valve was needed, annular calcification was absent (p=0.014). Post-procedure aortic regurgitation ≤ grade I was present in 34 patients (79.1%). All-cause mortality at 30 days was 9.3% (4 patients) and the incidence of major strokes was 4.7% at 30 days. At 12 months, the all-cause mortality was 21.4% (6/28 patients) with a cardiovascular mortality of 10.7% (3 patients).

Conclusions: This represents the first registry analysis of patients being treated with TAVI for the indication of pure severe NAR. TAVI for severe NAR is feasible and can be an effective treatment for patients with prohibitive surgical risk.

PCR london valves | Treatment and consequences of regurgitation during transcatheter valve therapies

Predictors of post-procedure paraprosthetic aortic regurgitation following self-expanding valve implantation: a multicentre registry analysis

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Aims: The mechanisms of paraprosthetic aortic regurgitation (PPAR) in transcatheter valve intervention is related to patient and procedural factors. We studied the association of balloon valvuloplasty and implant depth with PPAR.

Methods and results: We conducted a multicentre (Rotterdam, Brompton, Harefield) analysis of 295 patients undergoing Medtronic CoreValve implantation with prior CT annular sizing. Significant PPAR was defined as moderate or severe angiographic regurgitation. Implant depth was measured as the mean distance from the nadir of the non- and left coronary sinuses to the distal valve frame angiographically. Pre-implantation nominal and achieved balloon size during valvuloplasty were recorded. The majority of patients had mild (35.5%), trivial (20.7%) or no (7.6%) PPAR with significant PPAR observed in 36% of patients. Significant PPAR was associated with a larger mean native annular diameter (p=0.01) and annulus to valve size ratio (p=0.03). Significant PPAR was also associated with increased depth of implantation (p=0.035). Although nominal balloon and native valve sizes were well matched, underexpanded balloon size was associated with significant PPAR (p=0.04). 13.7% of patients had post-dilatation of the implant.

Conclusions: Significant paraprosthetic aortic regurgitation following Medtronic CoreValve implantation is associated with larger native valve dimensions and increased depth of implant. Adequacy of balloon valvuloplasty may also predict PPAR.

PCR london valves | Treatment and consequences of regurgitation during transcatheter valve therapies

Impact of post-procedural aortic regurgitation on mortality after TAVI

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Aims: Post-procedural aortic regurgitation (post-AR) is known to be associated with poor short-term to mid-term outcome after transcatheter aortic valve implantation (TAVI). The aim of this study was to clarify the impact of mild post-AR on clinical outcomes.

Methods and results: We compared clinical outcomes in 400 consecutive TAVI recipients according to post-AR grade: none (group 1=74.8%), mild (group 2=22.2%) or moderate to severe (group 3=3.0%). The mean age was similar in the three groups (83.4±6.1 years) as well as logistic EuroSCORE (22.5±11.4, 24.5±11.6 and 21.5±9.4%, p=0.28) and annulus size (22.0±1.8, 22.2±2.1 and 22.5±2.1 mm, p=0.53). The Edwards valve was the most frequently used in group 1 compared to groups 2 and 3 (89.3, 78.7 and 83.3%, p=0.03) and the implanted valve size was similar in all groups (25.6±2.0, 25.4±2.2 and 25.5±2.2 mm, respectively, p=0.69). Post-dilatation was required more frequently in group 3 (4.7, 24.1 and 50.0% respectively, p<0.01). Post-procedural increase in mitral regurgitation was in line with the post-AR grade (0.78±0.73, 1.22±0.80 and 1.89±0.78, respectively, p<0.01). Despite the absence of difference in 30-day mortality, longer-term outcome was significantly poorer in patients with mild AR than in those with no AR (log-rank p<0.01), albeit better than in patients with moderate to severe AR regardless of TAVI type and left ventricular function. In group 2 (mild, post-AR), patients with no pre-procedural AR had worse outcome compared to those who had pre-procedural AR (log-rank p=0.01). Post-AR was also identified as an independent predictor of mid-term to long-term mortality (HR1.68, 95% CI: 1.21-1.44, p<0.01).

Conclusions: Mild AR post TAVI is associated with a worse outcome when compared to no AR. Careful valve selection and post-dilatation when required to avoid mild post-AR might contribute to improved clinical outcome after TAVI.

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Percutaneous closure of paravalvular aortic leaks with the Amplatzer Vascular Plug III ®, late clinical follow-up

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Aims: Percutaneous closure of aortic paravalvular leaks (APL) has been presented as an alternative to reoperation. Our objective was to describe our population undergoing percutaneous repair of APL with the Amplatzer Vascular Plug III® (AVP III) device and describe clinical events.

Methods and results: All patients were considered who underwent percutaneous repair of at least one APL where the AVP III device was used. Results are reported as medians and differences in chi-square. There were 12 patients aged 67±14 years. The number of aortic valve surgeries was 2.03±0.96. Interval time from the last surgery to percutaneous closure of the APL was 7.61±7.66 years. Nine patients had mechanical valve prosthesis, four patients also had a mechanical mitral valve and presented a mitral paravalvular leak. Clinical presentation: 30% had heart failure, 10% haemolytic anaemia and 60% both. The NYHA functional Class 3±0.58, haematocrit 28.7±4.9%, LDH 1,219±928 UI/L. Echocardiography: LVEF 60±9%; systolic PAP: 55±28 mmHg; numbers of APL 16; degree of regurgitation 3.2±0.8; EuroSCORE 14±4. In 13 procedures, 13 APL were attempted; the wire was crossed retrograde in 12 APL, an arterial venous loop was established in 4 patients where the delivery sheath was advanced anterograde. The procedure was successful in 11 patients and 11 APL with 1.09 AVP III devices implanted. Simultaneous mitral and aortic closure was accomplished in three patients. Functional outcome of the procedure decreased APL regurgitation in 1±0.8 grades. Periprocedural events: pacemaker one patient (the pacemaker electrode moved while making the arteriovenous loop), femoral pseudoaneurysm: one patient, and mortality one patient (he did not have AVP III deployed and died three days later of heart failure). Follow-up 642±397 days. Ninety-one per cent of patients with AVP III show improvement of functional class by at least 1 grade, NYHA functional Class at follow-up was 2±0.9 p=0.004, haematocrit 35±4.3% p=0.03, LDH 438±353 UI p=0.04 and APL regurgitation 1±1.1 p=0.01. Late clinical events: new intervention for moderate to severe residual APL regurgitation in two patients (one patient at surgery at 246 days and one patient with new percutaneous repair with new AVP III at 727 days). Hospitalisation for aortic regurgitation: two patients; late mortality in one patient at 831 days of coronary artery disease.

Conclusions: Percutaneous closure of APL using an AVP III device is safe with high rate of immediate procedural success. Patients presented late clinical improvement in both functional classes and haematocrits, and a significant decrease in aortic periprosthetic regurgitation.

PCR london valves | Treatment and consequences of regurgitation during transcatheter valve therapies

Effects of preoperative tricuspid regurgitation on mitral regurgitation treatment with the MitraClip device in high-risk patients

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Aims: Purpose of the study is to characterise high-risk patients with mitral regurgitation (MR) treated with the MitraClip device (Abbott Vascular, Abbott Park, IL, USA) and to assess the impact of preoperative TR≥3+ on the outcomes at mid-term follow-up after MitraClip treatment.

Methods and results: From November 2008 to March 2012, 106 consecutive patients with degenerative and functional moderate to severe or severe MR underwent MitraClip implantation at our institution. All the patients were assessed by a preoperative standardised protocol, which included TEE, angiography and evaluation of the surgical risk. The functional status was assessed by 6 MWT, while quality of life was evaluated by MLHFQ and SF-36 questionnaires. Short and mid-term outcomes of patients with and without concomitant TR≥3+ (TR group and no-TR group, respectively) were compared. Preoperative TR≥3+ was present in 21/106 patients (19.8%). Patients of the two groups were similar for age, comorbidities and expected surgical risk. Functional aetiology was present in 71.4% of the TR group and in 70.6% of the no-TR group (p=0.9). Preoperative echocardiography showed similar LVEDD (p=0.5) and LVEF (p=0.4). Patients of the TR group had worse quality of life (MLHFQ 44.7 vs. 36.9- p=0.04; SF-36 physical domain 30.4 vs. 36.6 –p=0.004). In-hospital mortality was 0% in TR group and 1.2% in no-TR group (p=0.6). Similar reduction of MR to ≤2+ before discharge was achieved in the two groups (TR group=90.5%, no-TR group=91.6%, p=0.8). At one-year follow-up, actuarial survival was 79.4±10.6% for TR group and 91.1±3.9% for no-TR group (p=0.5) while freedom from MR≥3+ was 67.7±12.1% for TR group and 85.1±5.1% for no-TR group (p=0.04). At last follow-up (mean 9.2 months, range 1-41 months), overall freedom from death, MR≥3+ and rehospitalisation for HF was 47.6% for TR group and 69% for no-TR group (p=0.06). Significant reduction in LV dimensions was observed at follow-up in no-TR group: LVEDD decreased from 66.1±9.4 mm to 62.9±9.1 (p=0.04); LVEDD did not significantly change in TR group (from 66.2±10.6 mm to 69.4±6.5; p=0.3). The presence of preoperative TR≥3+ was identified as predictor of recurrence of MR≥3+ (OR 3.75).

Conclusions: The presence of preoperative TR is associated with more impaired quality of life in MitraClip candidates. Moreover, in patients with significant TR, the recurrence of MR≥3+ and the incidence of composite outcome of death, MR recurrence and rehospitalisation for HF results were higher at mid-term follow-up. Reverse remodelling at follow-up is more likely to occur in patients without preoperative TR.

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MitraClip repair for severe mitral regurgitation: initial Asian experience

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Aims: Percutaneous mitral valve repair for severe mitral regurgitation (MR) is now possible utilising the MitraClip valve repair system. The aim of this study is to describe the initial experience in Asia with the MitraClip device.

Methods and results: Twenty-eight patients underwent treatment with the MitraClip between April 2011 and April 2012 in two tertiary academic medical centres in Singapore. Data on demographic, clinical and procedural characteristics, as well as outcomes were collected prospectively in a registry and analysed. Of the 28, 14 (50%) had functional MR, 12 (42.9%) had degenerative MR and two (7.1%) had mixed pathology. The median age was 66 years, 13 (46.4%) were male, and 22 (78.6%) were Chinese. The mean BMI was 23.7, seven (25%) were in NYHA Class II and 21 (75%) were in NYHA Class III-IV. Ten (35.7%) had diabetes mellitus and eight (28.6%) had prior coronary bypass surgery. The median LVEF was 40% and the median logistic EuroSCORE II was 2.8. Seventeen (60.7%) patients had one clip while 10 (35.7%) had two clips. Acute procedural success was achieved in 26 patients (92.9%). Of the two patients who were technically procedural failures, one was a clinical success. In this patient, with severe MR from Barlow's disease, prior breast cancer with radiation therapy, cardiac cirrhosis, chronic renal failure and a body weight of 37 kg, the goal of therapy was to reduce MR from 4+ to 3+. This was achieved and the patient had dramatic clinical improvement. Of the two major adverse events, one was from single leaflet attachment, urgent surgery and eventual death in a patient with functional MR; and the other was from oesophageal laceration from the transoesophageal echo probe resulting in blood transfusions.

Conclusions: The MitraClip has been successfully used in North America and Europe for the percutaneous treatment of severe MR. This case series demonstrates that percutaneous mitral valve repair using the MitraClip can be safely and successfully performed in an Asian population for both degenerative and functional MR.

PCR london valves | Treatment and consequences of regurgitation during transcatheter valve therapies

Percutaneous closure of paravalvular mitral prosthetic regurgitation with the Amplatzer Vascular Plug III®

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Aims: Percutaneous closure of mitral valve periprosthetic leak (MPL) is being investigated as an alternative to repeated surgery. Different devices have been used to attempt percutaneous repair. Our objective is to describe our population undergoing percutaneous closure with the Amplatzer Vascular Plug III ® (AVP III), and assess clinical events.

Methods and results: All patients were treated percutaneously for at least one MPL. Clinical characteristics and details of the procedure were recorded prospectively. AVP III device was used. Procedural success was defined when the device was implanted and the MPL regurgitation decreased by at least one grade. Device failure was defined as death or a new intervention on the same MPL at 30 days. Fifty-four patients aged 67±12 years. 94% with mechanical mitral valves; number of surgeries on the mitral valve was 2.08±0.94. The time from surgery to percutaneous intervention was 9.8±7.81 years. The EuroSCORE log 19.3±13.23. Clinical heart failure was 11.1%; haemolytic anaemia: 11.1% and both 77.8% was the clinical indication. The NYHA functional Class 3.3±0.58, haematocrit 28.7±4.79%, LDH 1,099±965 UI/L and MPL regurgitation 3.25±0.81. Sixty MPL (1.52±0.72/p), 59 MPL initially were attempted for closure in 63 procedures. A second procedure was done on nine MPLs and a third attempt in one MPL, with AVP III implant success in 96.2% of patients. In three patients, simultaneous closure of MPL and aortic leak were done. Seventy AVP III were initially implanted in 52 patients (1.36 AVP III/patients). MPL regurgitation decreased 1.3±0.65 grades. Complications of the procedure: embolisation AVP III one patient (captured percutaneously and implanted in the same procedure), impingement of the mitral prosthetic disc in four patients (emergency surgery two patients) and permanent pacemaker in one patient. Procedural success was 92.5%. Clinical events at 30 days: percutaneous reintervention, residual regurgitation in three patients, mitral valve replacement surgery in one patient, stroke one patient, hospitalisation for heart failure six patients and death in two patients. Clinical success was 85.1%. Follow-up: improvement of NYHA functional Class by at least 1 grade occurred in 80% (p=0.03). Compared with baseline: NYHA functional Class 2.53±0.97 p=0.034, haematocrit 34.1±5.02% p=0.002 and MPL regurgitation 2.2±1.3 p=0.047.

Conclusions: Percutaneous repair of MPL is a feasible alternative with a high immediate technical success rate and few complications. At follow-up, recovery of both functional class, haematocrits and decrease of at least 1 degree regurgitation was observed. Patients can undergo reintervention for residual or new leak.

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PCR london valves | Risk assesment in TAVI including valve-in-valve

Transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: results from the global valve-in-valve registry

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Aims: Transcatheter aortic valve-in-valve (VIV) implantation is an emerging therapeutic alternative for patients with failed surgical bioprosthesis and may obviate the need for a redo surgery. We aimed to evaluate the clinical results of this technique using a large worldwide registry.

Methods and results: The registry included 416 patients with degenerated aortic bioprosthetic valves (age 77.7±9.7 years; 55.3% men) from 54 cardiac centres. The mode of failure was stenosis (n=168, 40.4%), regurgitation (n=125, 30%), and combined stenosis and regurgitation (n=123, 29.6%). Implanted devices were Edwards SAPIEN (n=225), CoreValve (n=190) and Melody (n=1). Adverse procedural outcomes included 11.1% device malposition and 1.9% ostial coronary obstruction. Post procedure, valve maximum / mean gradients were 28.5±14.3 mmHg / 16.1±9.0, respectively. Independent predictors for high post-procedural gradients (mean ≥20 mmHg) were baseline bioprosthesis stenosis (vs. regurgitation, odds ratio [OR], 6.33, p<0.001) and the use of the Edwards SAPIEN device (OR 2.1, p=0.008). At 30-day follow-up, all-cause mortality was 7.8% and 87.5% of patients were at New York Heart Association functional Class I/II. One-year survival was 82.6%. Using multivariate analysis, the strongest independent predictor for one-year mortality post-VIV was baseline bioprosthesis stenosis (vs. regurgitation, OR 3.7, p=0.003).

Conclusions: The VIV procedure is clinically effective in most patients, with one-year results comparable with other TAVR cohorts. Baseline bioprosthetic stenosis is the strongest predictor for both elevated post-procedural gradients and one-year mortality.

PCR london valves | Risk assesment in TAVI including valve-in-valve

Impact of experience on TAVI outcome: a propensity-matched analysis from the pragmatic plus initiative

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Aims: To evaluate the impact of growing experience and technological refinements with transfemoral transcatheter aortic valve implantation (TF-TAVI) on clinical outcome in patients with symptomatic severe aortic stenosis (AS).

Methods and results: We retrospectively analysed 793 consecutive TF-TAVI patients from four European centres and evaluated experience in three propensity-score-matched cohorts subcategorised based on enrolment date. Three propensity-score-matched cohorts of 214 TF-TAVI patients were identified. With mounting experience and moving from the initial to the last cohort, all-cause 30-day mortality tended to be lower (7.0% in T1 vs. 3.7% in T3, p=0.16) but with improved 1-year survival (79% vs. 86%, p=0.016). Over time there were significantly fewer major vascular complications (15% vs. 7.9%, p=0.023), life-threatening (17.8% vs. 7.9%, p=0.003) and major bleedings (22.4% vs. 12.1%, p=0.007). Major vascular complications and life-threatening bleedings due to closure device failure decreased significantly (9.2% vs. 3.1%, p=0.01 and 5.7% vs. 1%, p=0.01, respectively).The combined safety endpoint dropped from 31.3% in T1 to 17.8% in T3 (p<0.001). By multivariable analysis (including adjustment for arterial sheath size) the last cohort as compared to the initial cohort was associated with significant reductions in 30-day mortality (OR 0.35, 95% CI 0.12 - 0.96), stage 3 AKI (OR 0.12, 95% CI 0.29 - 0.93) and the combined safety endpoint (OR 0.52, 95% CI 0.29 - 0.93).

Conclusions: Growing TAVI experience results in significant reductions in major vascular complications, including life-threatening bleedings as well as the combined clinical safety endpoint and improved 1-year survival.

PCR london valves | Risk assesment in TAVI including valve-in-valve

Is EuroSCORE II better than EuroSCORE in predicting mortality after transcatheter aortic valve implantation?

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Aims: The European System for Cardiac Operative Risk Evaluation II (ESII) has been developed recently to improve the predictive value of the original logistic EuroSCORE (LES). The purpose of this study was to examine the performance of the ESII in patients undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: Between October 2006 and November 2011, 453 consecutive patients with severe aortic stenosis undergoing TAVI using both the Edwards valve and CoreValve were included in the current analysis. The performance of ESII, LES and Society of Thoracic Surgeons Predicted Risk of Mortality score (STS) were evaluated. Mean age was 83.1±6.4. The Edwards valve was used in 382 (84.3%) of the cohort. Observed 30-day mortality was 12.8%. The mean ESII, LES and STS were 8.1±5.2, 22.4±12.1, 8.1±6.0, respectively. Moderate correlation was observed in both ESII vs. LES (R=0.65, p<0.01), ESII vs. STS (R=0.47, p<0.01). ESII best predicted 30-day mortality compared to LES and STS (the area under the receiver operating characteristic curve [AUC]: 0.68, 0.65 and 0.60 respectively). In the TF cohort, ESII was better in predicting 30-day mortality compared to LES and STS (AUC=0.74, 0.61, 0.60, respectively).

Conclusions: Although the ESII was inadequately calibrated for predicting 30-day mortality, the ESII demonstrated better predictive performance after TAVI compared to the LES and STS especially in the TF cohort.

PCR london valves | Risk assesment in TAVI including valve-in-valve

Comparison of new EuroSCORE II with logistic EuroSCORE and STS score in predicting 30-day and one-year mortality in patients undergoing TAVI

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Aims: The validity of the logistic EuroSCORE (LES) and STS score for risk stratification in patients undergoing TAVI is questionable. The purpose of this study was to compare the newly created EuroSCORE II (ES II) with the LES and STS score in patients undergoing TAVI by Medtronic CoreValve or Edwards SAPIEN after formal turn-down for surgical AVR.

Methods and results: Eighty-two consecutive patients in a single institution underwent TAVI via the transfemoral, trans-subclavian, transapical and direct aortic approaches. Estimated LES, ES II and STS score were calculated retrospectively. The 30-day mortality was 7.3% (6/82) and the one-year mortality was 23.2% (19/82). The mean LES of patients who did not survive at 30 days was 33% and among survivors it was 23.5% (p=0.8; RR 1.4, 95% CI 0.44-4.46). The ES II at 30 days was 20.1% in non-survivors and 10.3% in survivors (p=0.62, RR 1.96, 95% CI 0.61 - 6.32). The STS score was 9.1% and 7.6% (p=0.87; RR 1.2, 95% CI 0.5-2.89) in non-survivors and survivors respectively. At one-year, the mean LES in non-survivors was 28.2% and 22.9% in survivors (p=0.84; RR 1.23, 95% CI 0.51-3.0). ES II was 13.9% and 10.2% (p=0.79; RR 1.36, 95% CI 0.5-3.71). The STS score was 8% and 7.6% (p=0.95; RR 1.05, 95% CI 0.52-2.14). Overall there was no difference in the relative risk between the non-survivors and survivors based on any of the three risk scores. We then classified the patients into low, intermediate and high risk groups (LES <10, 10-20, >20%, ES II <5, 5-10, >10% and STS <5, 5-10, >10% respectively) and analysed the 30-day and one-year mortality. Patients in the high ES II risk group (>10%) had higher mortality compared with both low-risk and intermediate-risk groups at 30 days and one year following TAVI, although this failed to reach statistical significance. In contrast the LES and STS score did not show any consistent trends among the three risk groups.

Conclusions: ES II was no better than LES or STS score in predicting 30-day or one-year mortality in patients undergoing TAVI after formal surgical turn-down. ES II may predict mortality better in the highest risk group. This study highlights the deficiencies of all three surgical risk scores in predicting mortality in patients undergoing TAVI and thus the need to develop a dedicated TAVI risk score system.

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PCR london valves | Risk assesment in TAVI including valve-in-valve

Comparison of EuroSCORE and EuroSCORE II in predicting short-term mortality in patients undergoing TAVI

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Aims: The logistic EuroSCORE was designed to estimate the risk of 30-day mortality in surgical patients, especially those undergoing coronary artery bypass grafting. However, when applied to isolated surgical aortic valve replacement (AVR) or transcatheter aortic valve implantation (TAVI), it is believed to overestimate the real risk. We sought to determine whether the newly proposed EuroSCORE II scale is better calibrated with absolute risk of mortality in an unselected cohort of patients treated with TAVI.

Methods and results: The EuroSCORE and EuroSCORE II were assessed in 49 high-risk patient with aortic valve stenosis treated with TAVI from March 2010 to February 2012. The majority of cases were performed via the transfemoral route (n=36, 74%) followed by the left transsubclavian (n=8, 16%), transapical (n=3, 6%) and transaortic access (n=2, 4%). Mortality was assessed at 30 days. The study population consisted of 23 females (47%) and 26 males (53%). The mean age was 79.9±6.2 years. The expected mortality according to the EuroSCORE was 17.5% (95% confidence intervals [CI] 14.3%-20.7%), whereas in EuroSCORE II it was 5.9% (95% CI 4.2%-7.6%). After a 30-day follow-up, the observed mortality was 4.1% (two out of 49). The patients who died were only characterised by low-to-medium mortality risk in both scales (11.6% and 13.6% by EuroSCORE, 3.5% and 4.4% by EuroSCORE II).

Conclusions: EuroSCORE II more accurately predicts mean mortality in patients after TAVI. However, both current risk scores do not provide a reliable estimate of exact operative mortality in an individual patient treated with TAVI.

PCR london valves | Risk assesment in TAVI including valve-in-valve

Comparison of effectiveness and safety of TAVI in patients ≥90 years of age versus <90 years of age

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Aims: In a fraction of patients aged ≥90 years, less invasive transcatheter aortic valve implantation (TAVI) has been considered as a therapeutic option for aortic stenosis (AS) under careful clinical screening. However, the safety and effectiveness of using TAVI in such a population has not been fully elucidated. The aim of this study was to investigate the feasibility of TAVI in nonagenarians.

Methods and results: We prospectively enrolled 136 consecutive patients with severe AS who were referred for TAVI. Procedural, early- and mid-term clinical outcomes were compared between patients aged <90 (n=110; average age, 82.3±8.3) and ≥90 (n=26; average age, 91.6±1.9) years old. Comparison of baseline characteristics revealed that among patients ≥90 years, prevalence of females was higher (50% vs. 81%, p<0.001) and mean aortic valve gradient was greater (45.5±15.4 mmHg vs. 56.3±23.4 mmHg, p=0.005) than those in patients <90 years. Major vascular complications occurred more frequently in patients ≥90 years (5% vs. 19%, p=0.022), while the rate of procedural success, 30-day and six months, mortality were not different between the two age groups (96% vs. 100%, p=0.58; 6% vs. 15%, p=0.22; 14% vs. 27%, p=0.14, respectively). Mortality rates were higher among patients ≥90 years. At six-months, both groups of survivors were similar in symptom status, having New York Heart Association classifications below Class II (89% vs. 84%, p=0.68). The cumulative survival (median 13.4±8.0 months of follow-up) was not significantly different between the two age groups (p=0.22, log rank test).

Conclusions: Even very elderly nonagenarians might experience acceptable clinical results and benefits after TAVI.

PCR london valves | Single and multicentre TAVI registries

Transcatheter mitral valve-in-valve/valve-in-ring implantations for degenerative post-surgical valves: results from the global valve-in-valve registry

BEST 2012 ABSTRACT

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Aims: Transcatheter mitral valve-in-valve / valve-in-ring implantation is an emerging therapeutic alternative for patients with failed mitral valves after surgical intervention and may obviate the need for a redo operation. We aimed to evaluate the clinical results of this technique using a large worldwide registry.

Methods and results: The registry included 70 patients with degenerated mitral valves after surgical intervention (11.4% ring only, median of nine years post procedure) from 17 centres. Mean age 74.0±11.3 years; 70% female (STS score 16.2±10.4%). The mode of failure was regurgitation (n=36, 51.4%), stenosis (n=13, 18.6%), and combined stenosis and regurgitation (n=21, 30%). Transcatheter Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA) implantation was performed in all cases (23 mm in 22.9%, 26 mm in 58.6%, and 29 mm in 18.6%). Procedural access was transapical in 60 cases (85.7%); transseptal in seven (10%), and through the left atrium via right mini-thoracotomy in three (4.3%). Combined procedures included three aortic valve-in-valves, transapical aortic valve replacement, tricuspid valve-in-ring implantation, and transapical paravalvular leak closure. Device malposition appeared in 4.3% of cases and post-implantation valvuloplasty was utilised in 12.1%. Post procedure, mitral valve area was 2.1±0.6 cm^2, valve maximum / mean gradients were 13.6±6.4 mmHg / 6.4±2.7, respectively, and significant mitral regurgitation (≥+2) was observed in 5.7% of patients. Median length of hospital stay was seven days. At 30-day follow-up, all-cause mortality was 10.3% and 82.3% were at New York Heart Association functional Class I/II.

Conclusions: Mitral valve-in-valve/ valve-in-ring implantations, performed in very high-risk patients, were clinically effective in most patients with degenerative mitral valves after surgery. The safety and efficacy of this approach should be further examined.

PCR london valves | Single and multicentre TAVI registries

The Swedish TAVI registry: all 566 procedures in 2008-2011

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Aims: To describe the total nationwide experience of TAVI including follow-up to one year.

Methods and results: The Swedish TAVI registry is a part of the Swedeheart group of registries. It covers all seven centres and all procedures since the first TAVI case in our country in 2008. Procedural and clinical data are entered into a central database prospectively. Mortality is collected from the national civil registry, with 100% coverage. Five hundred and sixty-six TAVI procedures were performed in 565 patients from 2008 to 2011. Mean age was 82 years, and mean logistic EuroSCORE was 26%. There is no trend for younger patients or a lower EuroSCORE from 2008 to 2011. Most patients had NYHA Class III symptoms before the procedure. The aortic mean pressure gradient was on average 50 mmHg before the procedure and 10 mmHg two to three months later. Transfemoral access was used in 385 cases, transapical access in 159 cases and subclavian access in 22 cases. The Medtronic CoreValve system was used in 314 cases and the Edwards SAPIEN system in 252 cases. The mortality at 30 days was 6.4%, and at one year (in patients treated in 2008-2010) 14%. In-hospital stroke was 2.2% (2008-2011). The median hospital stay was six days. In transfemoral cases, the 30-day and one-year mortality was 5.5% and 12%, respectively, compared to 8.8% and 19% in transapical cases (unadjusted). In CoreValve cases, the 30-day mortality and one-year mortality was 5.4% and 13%, respectively, compared to 7.5% and 17% in SAPIEN cases (unadjusted). Forty patients aged 90 or over were treated, with a 5% 30-day mortality and 4% one-year mortality (the latter in the 23 patients treated 2008-2010). Among the 209 cases performed in 2011, in-hospital complications included stroke (1.5%), vascular complication (11%), major bleeding (8%), new permanent pacemaker (8%) and new need for dialysis (1%). The technical success rate was 97%. General anaesthesia was used in 99% of the SAPIEN cases compared to 13% of the CoreValve cases. The mean procedural time was 1:35 with the CoreValve system and 1:59 with the SAPIEN system. On the postoperative echocardiogram, grade 0-1 aortic regurgitation was found in 86%, grade 2 regurgitation in 10% and grade 3 regurgitation in 3%. Comparing different counties in the country, there was a fourfold difference in the number of treated patients per 100,000 inhabitants in 2011.

Conclusions: A nationwide TAVI registry is feasible and is able to give valuable data. For Sweden, we found a rather low short-term and long-term mortality and a low stroke rate.

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PCR london valves | Single and multicentre TAVI registries

The Ibero-American Transcatheter Aortic Valve Implantation Registry: acute and long-term results

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On behalf of the RIVAT Investigators, 1. Spain; 2. Portugal; 3. Argentina

Aims: To evaluate immediate and long-term results of transcatheter aortic valve implantation (TAVI) with the CoreValve system in consecutive "real world" patients with severe aortic stenosis.

Methods and results: This is a retrospective analysis of 1,170 consecutive patients who underwent TAVI in 42 centres from Spain, Portugal and Latin America from December 2007 to March 2012. Statistical analysis was performed with PAWS 18. $p<0.05$ was used for statistical significance. Percentages, χ^2 and the Fisher test are presented for categorical variables, and mean±SD or median (range) and Student's T-test for continuous variables. Kaplan-Meier curves are presented for estimates of long-term outcomes. Age was 81.4±6.3 years, mean logistic EuroSCORE was 17.8±13.1, and 55% of the patients were male. Baseline comorbidities: 33% of the patients were diagnosed with diabetes mellitus, 30% had prior coronary revascularisation, 11% myocardial infarction, 11% stroke or transient ischaemic attack, 13.5% extra-cardiac arteriopathy, 22% chronic renal failure, 35% chronic obstructive pulmonary disease (COPD), 18% had moderate or severe mitral regurgitation, 19% severe pulmonary hypertension and 14.5% had an LVEF <40%; 79% of the patients were in NYHA functional Class III or IV. TAVI was performed through a femoral access in 95% of the patients, and planned vascular closure was successful in 88%. Procedural success was reported in 96% and post-procedural aortic regurgitation was ≤2 in 95% of the patients. In-hospital mortality was 7.3%, and the in-hospital combined safety endpoint according to the Valve Academy Research Consortium (VARC) definition was 85.8%. A second valve-in-valve was implanted in 4% of the patients and a permanent pacemaker in 25%. 131 patients were lost to follow-up. Of the remaining patients, 88% were in NYHA Class I or II at one month, 91% at 12 months and 94% at 24 months. Kaplan-Meier estimates of freedom from total and cardiac mortality at two years were 53% and 73%, respectively, and mortality was related to the baseline logistic EuroSCORE (mortality at two years of 19% for those with a logistic EuroSCORE <10%, 46% for logistic EuroSCORE between 10% and 20% and 53% for those with logistic EuroSCORE >20%, $p<0.001$; cardiac mortality of 10%, 17% and 29% for the same subgroups, $p<0.001$). Mortality after hospital discharge was related to prior extracardiac arteriopathy ($p=0.048$), insulin treatment ($p<0.001$), severe COPD ($p=0.011$), coronary artery disease ($p=0.012$), known severe pulmonary hypertension, liver cirrhosis ($p=0.007$) and the occurrence of post-procedural complications ($p=0.003$), stroke ($p<0.029$) or renal failure stage 3 ($p=0.002$). Freedom from hospital admission for cardiac causes was 63%, with no differences between logistic EuroSCORE groups.

Conclusions: TAVI with the Medtronic CoreValve system in the "real world" is feasible, safe and associated with a marked improvement in functional status and a low mortality rate at follow-up. Death after hospital discharge is related to baseline comorbidities and to in-hospital complications.

PCR london valves | Single and multicentre TAVI registries

Initial experience with transfemoral implantation of the prosthesis Edwards SAPIEN XT without previous valvuloplasty in patients with severe aortic stenosis

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Aims: Balloon valvuloplasty (BV) before transcatheter aortic implantation of the prosthesis has been considered a mandatory step before valve implantation. However, BV has been associated with complications such as atrioventricular block, aortic insufficiency and stroke. We report on 10 patients with severe aortic stenosis in whom direct transfemoral implantation of the SAPIEN XT was performed.

Methods and results: From November 2011 to April 2012, 10 patients (33% of the patients treated with the Edwards SAPIEN XT during that period) were selected who met the following criteria: moderate calcification, homogeneous distribution of calcium, symmetrical opening of the valve and some degree of aortic insufficiency. The valve positioning was guided by TEE in all cases. All patients had symptomatic aortic stenosis of a native valve and were high-risk for surgery. Echocardiographic characteristics: aortic annulus diameter ranged from 17 to 24 mm (determined by TEE). Six patients had mildly calcified valves; in four patients the degree of calcification was moderate. All patients had symmetric opening of the stenotic aortic valve. Mild aortic regurgitation was present in seven patients, moderate in two and trivial in one. The native valve was crossed and the prosthetic aortic valve was properly positioned in all cases and implanted in the correct position in all cases. No patient underwent post-dilatation and only one patient had mild periprosthetic regurgitation. There were no adverse events (death, need for pacemaker, myocardial infarction or stroke). At 30 days post procedure, all patients had significant clinical improvement.

Conclusions: The direct implantation of an Edwards SAPIEN XT without prior balloon valvuloplasty in selected cases is feasible and safe. The number of patients in whom this technique is applicable and their impact on reducing complications has yet to be determined.

PCR london valves | Single and multicentre TAVI registries

Transcatheter valve-in-valve implantation in degenerated aortic bioprostheses via transfemoral access with the Edwards SAPIEN XT transcatheter heart valve

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Aims: Surgical treatment of degenerated aortic bioprostheses is associated with an increased risk of morbidity and mortality, especially in elderly patients with significant comorbidities. Therefore, transcatheter aortic valve implantation (TAVI) performed as valve-in-valve (VIV) technique appears as an attractive alternative treatment option. We report on a case series of seven patients with dysfunctional bioprosthetic aortic heart valves who have been treated with TAVI via transfemoral access.

Methods and results: Valve-in-valve implantation using the Edwards SAPIEN XT bioprosthesis (Edwards Lifesciences LLC, Irvine, CA, USA) was performed in eight patients (three men, five women, mean age 85.3±6.1 years) with a high operative risk (logistic EuroSCORE 27.2±7.3). Six patients underwent TAVI because of high-grade stenosis of the aortic bioprosthesis, whereas two patients presented with a high-grade regurgitation. All patients suffered from NYHA Class III-IV dyspnoea during admission. TAVI was successfully performed via transfemoral access under local anaesthesia with mild analgesic medication in all cases. Mild aortic regurgitation occurred in three patients while no permanent pacemaker implantation was required. Major cardiac events or cerebrovascular events did not occur. One aneurysm spurium, with the need of one blood transfusion, occurred. All patients improved at least one NYHA Class within 30 days.

Conclusions: TAVI for degenerated aortic bioprostheses, using the Edwards SAPIEN XT valve via transfemoral access is a feasible option for patients at high surgical risk.

PCR london valves | Single and multicentre TAVI registries

TAVI for patients with severe bicuspid aortic valve stenosis

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Aims: A bicuspid aortic valve (BAV) is regarded as a relative contraindication to transcatheter aortic valve implantation (TAVI) due to the risk of uneven expansion of the bioprosthesis. The purpose of this study was to evaluate the efficacy and safety of TAVI in patients with BAV.

Methods and results: Of 470 patients included in our prospective TAVI database (October 2006 to January 2012), 229 consecutive patients undergoing both echocardiography and multidetector computed tomography (MDCT) were analysed. We compared clinical outcomes in patients with vs. without BAV. In this series of 229 patients, BAV was detected by MDCT in 21 patients (9.2%). BAV was identified by transthoracic and/or transoesophageal echocardiography in 9/21 patients only. The BAV group consisted of type 1 L-R (16 cases), type 1 R-N (1), type 1 L-N (1) and type 2 L-R and L-N (3). The mean length of raphe measured by CT was 12.7±2.7 mm (range: 7-16 mm). Patients were 83.1±6.6 years old and EuroSCORE 20.0±11.4%. The BAV group was similar to the non-BAV group except for diabetes (4.8 vs. 24.0%, p=0.04). The aortic annulus diameter was not significantly larger by MDCT (24.7±3.0 vs. 23.7±1.9 mm, p=0.14) in BAV patients. CoreValve was used more frequently in the BAV group (47.6 vs. 16.3%, p<0.01). There was no significant difference in device success (100 vs. 92.8%, p=0.23), risk of annulus rupture (0 vs. 1.4%, p=0.75) or valve migration (0 vs. 1.4%, p=0.75) in BAV vs. non-BAV patients. Post-procedural mean gradient (10.0±3.4 vs. 9.7±4.1 mmHg, p=0.78), aortic regurgitation ≥2/4 (19.0 vs. 14.9%, p=0.54), 30-day mortality (4.8 vs. 8.2%, p=0.49) and 30-day combined safety point (14.3 vs. 13.5%, p=0.56) were also similar in both groups. In the BAV group there were no significant differences in post-procedural mean pressure gradient (9.3±3.2 vs. 10.8±3.6 mmHg, p=0.36) and post-procedural AR grade ≥2 (9.1 vs. 30.0%, p=0.31) between Edwards valve and CoreValve.

Conclusions: In patients with BAV, TAVI is associated with high rates of success, low complication rates, similar efficacy and acceptable outcomes as in non-BAV patients.

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PCR london valves | Single and multicentre TAVI registries

Percutaneous transfemoral transcatheter aortic valve implantation (pTAVI): a single-centre experience comparing general with local anaesthesia

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Aims: Transcatheter aortic valve implantation (TAVI) is the treatment of choice for high-risk patients with aortic stenosis. Percutaneous transfemoral vascular access is the preferred and least invasive approach (pTAVI) and may be performed under local anaesthetic (LA) in suitable patients. Other vascular approaches are surgical (sTAVI) and require general anaesthesia (GA). We aim to describe the vascular approaches and modes of anaesthesia used in our CoreValve TAVI programme and evaluate, as well, the vascular outcomes of pTAVI using the Prostar pre-closure device.

Methods and results: Consecutive TAVI procedures (n=106) between October 2008 and April 2012 were analysed and data pertaining to baseline characteristics, delivery approaches, anaesthesia and hospital stay were examined. All patients who had TAVI via the percutaneous femoral approach were specifically asked about new claudication symptoms on follow-up and those who had successful device (Prostar) closure of femoral arteriotomy had quantitative assessment of femoral angiographic stenosis (QFA). Vascular access was assessed routinely by aorto-ilio-femoral angiography; vessel diameter (minimum 6 mm), tortuosity and calcification were the key determinants of suitability. Each case was reviewed by a multidisciplinary team (MDT) involving cardiologists, surgeons and anaesthetists. The transfemoral approach was preferred wherever appropriate. LA was considered for all transfemoral cases taking into account the body habitus and patient psychology. The delivery approach was transfemoral in 84 (79%), subclavian in 17 (16%) and direct aortic in five (5%) cases. Of the 84 transfemoral cases 47 (56%) were performed with GA and the remaining 37 (44%) under LA. The mean logistic EuroSCORE in the GA group (22%) was significantly higher than in the LA group (16%) (p=0.019). Other variables like age, gender and body mass index (BMI) were comparable as was the duration of hospital stay (11.3 [GA] vs. 9.8 [LA]). Closure of the femoral arteriotomy using the Prostar device was successful in all but five cases (79/84, 94%). In one case, emergency bypass grafting was necessitated by avulsion of the iliac artery during removal of the sheath. QFA was performed in 69 of these 79 patients. This revealed a mean angiographic stenosis of 30±17% (2-72%). Greater than 50% stenosis was found in 13 (13/69; 33%) patients. Importantly however, there was no incidence of new claudication on follow-up (median 17 months).

Conclusions: Our data suggest that in selected patients determined by an MDT, pTAVI under local anaesthesia is feasible, safe and probably desirable, particularly in the older patients. Surprisingly, lower logistic EuroSCORE and not BMI was a significant factor favouring the use of local anaesthesia. The percutaneous transfemoral approach and subsequent pre-closure using the Prostar device appear to have satisfactory acute and long-term vascular outcomes even in patients who had a significant degree of angiographic stenosis after device closure.

PCR london valves | Vascular access in TAVI

The European experience with the direct-aortic approach for a self-expandable transcatheter aortic bioprosthesis implantation

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Aims: The self-expanding CoreValve prosthesis is implanted retrogradely usually via the femoral or subclavian arteries. However, the transcatheter aortic valve implantation (TAVI) population of elderly patients with severe aortic stenosis is also often affected by severe iliac-femoral vasculopathy or deemed to carry a high risk of vascular injury.

Methods and results: All European centres with experience of CoreValve implantation through a direct aortic approach were surveyed. All 15 centres with three or more implants were invited to contribute procedural data and outcomes onto a dedicated database. We enrolled 151 patients treated in 15 centres in nine countries in Europe and Israel. Mean patient age was 80.8±6.4 years, 46% of patients were female. The mean logistic EuroSCORE was 26.6±16; 85% of patients were in NYHA functional Class ≥III. Echocardiographic maximum transvalvular gradient was 80 mmHg and left ventricular ejection fraction was 50%. Peripheral vascular disease was present in 86% of cases and was the main reason for femoral TAVI exclusion. Of the patients, 55% had coronary artery disease and 28% of the patients had undergone previous coronary artery bypass surgery. The procedure was performed in 62% of cases via a mini-sternotomy and in 58 patients through a right anterior mini-thoracotomy in the 2nd intercostal space. In 50% of cases the CoreValve 29 mm was implanted. In all patients after valve deployment, the mean aortic gradient immediately dropped to ≤5 mmHg. Procedural success was achieved in 97% of cases. There were no procedural deaths and 30-day mortality was 8.6%. The incidence of stroke was 3.9% and 20% of patients required a new permanent pacemaker. Median post-operative hospitalisation was 10 days.

Conclusions: Direct aortic access is a feasible approach for TAVI with the self-expanding CoreValve prosthesis. These initial results with this technique are encouraging given the high-risk patient cohort (with a particularly high incidence of concomitant vascular disease).

PCR london valves | Vascular access in TAVI

Transseptal antegrade transcatheter aortic valve replacement for no-access option patients. A contemporary experience

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Aims: Antegrade transseptal (TS) was the first approach for TAVR. However, due to the complexities and complications with this technique, it was replaced by the retrograde transfemoral, transaortic or antegrade transapical approaches. We aimed to assess feasibility and procedural outcomes of TS TAVR in patients with no access options.

Methods and results: Observational consecutive case series of inoperable patients with aortic stenosis (AS) with iliofemoral arterial diameter <7 mm and contraindications for either transaortic or transapical access who underwent TAVR with the Edwards SAPIEN (ES) valve via an antegrade transvenous TS approach at a single high-volume centre. Over three months, seven patients (four men and three women) with inoperable severe symptomatic AS underwent antegrade TS TAVR with 26 mm (n=4) and 23 mm (n=3) ES valves. Mean age was 86.4±9.4 years, Society of Thoracic Surgeons (STS) score 7.5±3.8% and aortic valve area 0.66±0.4 cm^2. Comorbidities included severe COPD (n=3), coronary artery disease (n=6), peripheral arterial disease (n=5), cerebrovascular disease (n=7), porcelain aorta (n=4), two prior sternotomies (n=2). One patient had prior radiation to the chest. Antegrade deployment of the ES TAVR was technically feasible in six patients and post-procedural ECHO did not show significant aortic regurgitation or damage to the mitral valve. Vascular complications occurred in two patients as a consequence of retrograde balloon aortic valvuloplasty, one patient suffered transient complete heart block and haemodynamic collapse requiring pacing and IABP insertion. Median (25^{th}, 75^{th}) length of hospital stay was five (4, 11) days. The median (25^{th}, 75^{th}) follow-up period was 39 (23, 60) days. There were no cerebrovascular events, rehospitalisations or deaths and mean NYHA Class improved from 3.3 to 1.6.

Conclusions: Our experience suggests that antegrade transvenous-TS approach using currently available equipment is a technically feasible option and still has a place in the current TAVR era for patients with contraindications for transarterial or transapical access.

PCR london valves | Vascular access in TAVI

Transcutaneous aortic valve implantation using the left carotid access: feasibility and early clinical outcomes

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Aims: In some patients, transfemoral or transaxillary percutaneous aortic valve implantation is not possible. Thus, carotid artery access may represent a safe alternative to the femoral and subclavian access even offering certain advantages. In this article, we describe aortic valve implantation using the left carotid arterial approach and report our experience.

Methods and results: Using a self-expandable nitinol-based device (CoreValve ReValving System, Medtronic Ltd, Luxembourg) we exposed the left carotid artery through a small incision. Arterial puncture and initial 6 Fr sheath introduction were achieved through a contra-incision. The same implantation technique used for transaxillary implantation was used. Progressive artery dilatation was achieved using sheaths of increased diameter. Rapid ventricular pacing was used to reduce cardiac output while performing a routine aortic balloon valvuloplasty. Only then was an 18 Fr sheath inserted into the carotid artery and pushed down into the ascending aorta. The patients were monitored using cerebral oxymetry to assess cerebral perfusion. Thirty-two consecutive patients at high surgical risk were implanted and studied prospectively. Transfemoral and subclavian catheterisation were considered unfeasible or at risk of severe complications. Carotid arterial injury did not occur in any patient. A transient ischaemic attack (TIA) occurred in one patient contralateral to the carotid access. Paravalvular leak, as assessed by angiography and echocardiography controls, was trivial (grade 0-1) in all patients. There were no intraprocedural deaths. One patient needed a pacemaker implantation (3.1%).

Conclusions: This initial experience suggests that left carotid transarterial aortic valve implantation in selected high-risk patients is feasible and safe with satisfactory, short-term outcomes. No death occurred in the 30-day follow-up period.

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PCR london valves | Vascular access in TAVI

Is the percutaneous femoral approach for TAVI always better? A comparison with a femoral surgical cut-down

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Aims: Percutaneous transfemoral transcatheter aortic valve implantation (TAVI), with a pre-closure suture-mediated device, represents the most widely used invasive approach, even if a high rate of major vascular complications has been reported in all TAVI studies. We analysed our TAVI experience comparing standard arterial surgical cut-down (SF) to percutaneous femoral access (PF) in terms of complications and costs.

Methods and results: From May 2008, one hundred and sixty patients have been treated with TAVI at our centre. One hundred and nineteen patients were treated through the femoral arteries, the remainder by an alternative approach (direct aortic, subclavian, transapical). In this present analysis we consider only the last 40 consecutive patients (mean age 79.3 years) treated with the CoreValve bioprosthesis through the femoral approach from January 2011. This would be after our initial learning curve of 80 percutaneous femoral approaches. In both groups 20 patients were treated, no major difference in pre-TAVI characteristics was evident, mean age in the PF group 80.8 years (10 females) vs. 77.2 years (11 females) in the SF group. The incidence of major vascular complications was significantly different between the two groups (p=0.008): six patients experienced major vascular complications in the PF group was requiring endovascular treatment with covered stent placement, while none of the patients in the SF group had major vascular complications. The amount of contrast used was superior in the PF group 233±53 cc vs. 148±60 cc in the SF patients (p<0.01). This led to a different procedural cost (excluding the prosthesis): mean cost of the material was 4,589±2,992 euros in the PF vs. 2,204±1,071 euros in the SF group. One patient died at 30 days in the PF group. There was no difference in post-implant hospital stay: 13.4 in PF vs. 11.2 in SF.

Conclusions: Approaching TAVI as a heart team - having cardiologists and cardiac surgeons always involved together also in transfemoral cases - makes it easy to perform a femoral surgical cut-down which in our experience was safer and more cost-effective in comparison to the percutaneous femoral approach.

PCR london valves | Vascular access in TAVI

One single centre's short- and long-term outcomes after TAVI: no differences between the transfemoral and transapical approach

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Aims: We present the clinical outcomes of a single Italian centre - performing both the transarterial (TF/TI) and transapical (TA) approaches in high-risk patients with severe symptomatic aortic stenosis (AS) and with special emphasis on efficacy and safety over the mid- to long-term.

Methods and results: Between March 2008 and December 2011, transcatheter aortic valve replacement (TAVI) was attempted in 290 patients (mean age 81±6 years) unsuitable for conventional surgery based on a holistic assessment incorporating patient's frailty, presence of comorbidities and operative risk. Data were collected prospectively and mortality tracking was achieved in 100% of patients with mortality status reported as of June 2012. Data from the patients who survived over 12 months were used for comparisons of the baseline and follow-up results. Logistic EuroSCORE was 20±11% in the TF/TI group and 22±12% in the TA group. A retrograde transarterial approach was used in 67.2% of cases, 181 transfemoral and 14 transiliac. In the other 32.8% of patients, TAVI was performed by the transapical approach due to severely diseased femoroiliac accesses or severely calcified aorta. Thirty-day mortality was 3.6% after TF/TI versus 2.1% after TA (p=0.723). During the course of this experience, we encountered 12 cases of vascular complications in the TF/TI group vs. none in the TA group (p=0.02). All of them were successfully managed by surgical or endovascular treatment. Widely feared stroke complications occurred at a low incidence within both the TF/TI and TA groups (four and two cases, respectively). TAVI accomplished significant mean aortic gradient reduction and improvement in valve area, which were sustained from perioperative to last echocardiographic assessment in both groups. Of the TAVI patients, 25.5% had a mild paravalvular leak (PVL), 3.1% a moderate PVL and none a severe PVL. More than 80% of them improved, or at least remained stable at one-year follow-up. Among patients who survived at least 30 days, 12-month survival was 88.6% for TF/TI and 81.7% for TA (p[log-rank]=0.1). At closing date, postoperative NYHA Class improved one class at least in both groups (p<0.001), although NYHA Class improvement at 30 days was significantly higher in TF/TI patients.

Conclusions: Our four-year experience confirms balloon-expandable TAVI efficacy and safety in high- risk candidates with end-stage AS. It further shows that both transarterial and transapical approaches are safe, although the transarterial technique is associated with certain access-site-specific complications that require highly qualified management, and early subjective clinical improvement is worse after transapical approach.

PCR london valves | Vascular access in TAVI

Balloon-expandable sheath for borderline vascular access in transfemoral TAVI

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Aims: The percutaneous approach for TAVI is conditioned by the need for large-bore introducer sheaths with a diameter greater than 18 Fr and burdened by a high access-related complication rate (4-13%), due to advanced atherosclerosis of the iliofemoral axis. SoloPath™ (Onset Medical Corp., Irvine, CA, USA) is a balloon-expandable vascular sheath, hydrophilic and low-profile, that approaches the vessel as a 13 Fr device and reaches its nominal inner diameter of 18 Fr after dilatation, being less traumatic during insertion than standard sheaths. The aim of this study is to present the results of the employment of SoloPath™ for TAVI in borderline vessels in terms of procedural success and the incidence of vascular complications.

Methods and results: Based on angiography and CT scan imaging, we have defined as "borderline access" every ilio-femoral axis with at least one of these features: a) small vessel size (>5 <6 mm); b) focal stenoses; c) diffuse calcified atheromasia; d) tortuosity. We have evaluated procedural results and vascular complications according to VARC definitions in consecutive patients with difficult access, treated with the 18 Fr Medtronic CoreValve system and in whom we used the balloon-expandable sheath (SoloPath). The sheath was introduced after fluoroscopy-guided puncture and placement of Prostar as recommended. At least one of the mentioned anomalies was encountered in 27 patients. Specifically, we found 11 diffusely small vessels, nine focal stenoses, 19 diffuse and calcified atheromasia and 13 severe tortuosities (nine kinking, four loop). In all patients the transfemoral approach was selected and the prosthesis was implanted. In one case, the prosthesis was recovered successfully, while in another the prosthesis and the introducer were damaged during recovery without vascular complications. Procedural success was obtained in 26/27 patients, as one CoreValve was implanted in a low position causing a worsening of the underlying mitral insufficiency and, consequently, refractory heart failure and death at the third month. We observed five vascular events that required urgent surgical repair: three incomplete arteriotomy closures with the Prostar device; one common femoral artery perforation and iliac artery dissection during Prostar introduction, before SoloPath insertion; one common femoral artery perforation due to percutaneous puncture in an improper site (bifurcation). All five patients experienced a haemoglobin drop requiring RBC transfusion (>4 packed cells). Mean length of in-hospital stay was 14.3 days. We did not observe any minor vascular complications.

Conclusions: The balloon-expandable vascular sheath may be helpful in the management of the borderline iliac-femoral axis. Observed major vascular complications are not directly related to the sheath. When the introduction site shows diffuse disease, surgical cut-down of the vessel would be a better option than percutaneous puncture, while alternative access sites can be considered despite higher invasiveness and morbidity.

PCR london valves | Pot-pourri

Predictive factors of successful repeat percutaneous mitral commissurotomy for mitral restenosis after previous percutaneous commissurotomy

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Aims: Several studies suggest that repeat percutaneous mitral commissurotomy (PMC) for mitral restenosis after a first successful intervention is safe and effective. It thus remains as a good treatment for this indication. The aim of this study was to identify the predictive factors of immediate results for repeat PMC to categorise the best candidates for this technique.

Methods and results: We retrospectively analysed data of 84 consecutive patients (mean age=30.88±12.24 years, female=81%) who have undergone a second PMC 48±23 months after a first successful PMC procedure. Among them, twenty-two (26.2%) were in atrial fibrillation. Echocardiography showed that 32.1% of the group had a Wilkins score ≤8 and 67.9% had a score >8, mean mitral valve area=1.09±0.2 cm² and mean of the mean gradient=14.8±6.6 mmHg. Mitral insufficiency ≤2 was noted in 44.6% of the cases. A good result of PMC was defined as a final valve area post PMC ≥1.5 cm² without a mitral insufficiency ≥2. A good result was achieved in 84.5% of the cases with an Inoue balloon. Valve area increased from 1.09±0.2 cm² to 1.79±0.3 cm². A severe mitral regurgitation occurred in six patients (7.1%). All of them required an urgent surgical valve replacement. Univariate analysis showed that the Wilkins score, mitral valve area and time of restenosis were the strongest factors associated with the immediate result. A Wilkins score >8 was associated with an odds ratio (OR) of 5.68 (95% CI, 0.78 to 41.5; p=0.034) for poor results. A mitral valve surface area <0.9 cm² was associated with an OR of 3.14 (95% CI, 1.2 to 8.19, p=0.028) for poor results. Compared with early restenosis, late restenosis, which is defined as a restenosis that occurs more than three years after the first PMC, was linked with an OR of 4.12 (95% CI, 0.97 to 17.46, p=0.027) with insufficient results. Finally, patients with pulmonary hypertension ≥55 mmHg tend to have less chance of a success rate than patients without (71.4% vs. 89.8%, p=0.052, OR=2.8, 95% CI, 1.01 to 7.76).

Conclusions: In conclusion, the anatomical criteria and the evolution of the disease were the strongest factors associated with the immediate result after repeat PMC. Patients in an unfavourable form and with advanced disease have less chance of benefiting from PMC. This should be taken into account when selecting candidates for repeat PMC.

PCR london valves | Pot-pourri

Concept of the central clip: when to use one or two Mitraclips®

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Aims: Percutaneous edge-to-edge mitral valve repair with the MitraClip® was shown to be a safe and feasible alternative compared to conventional surgical mitral valve repair. We analyse the concept of the central clip and the predictors of the need for more than one Mitraclip® in our high-risk surgical population with severe mitral regurgitation (MR).

Methods and results: Patients with severe MR (3 or 4+) and high operative risk (as defined by logistic EuroSCORE) declined for conventional mitral valve repair were considered for the MitraClip®. The procedure was performed under general anaesthesia with transoesophageal echocardiographic guidance. Device success was defined as placement of one or more MitraClips® with a reduction of MR to ≤2+. Patients were followed up clinically and with transthoracic echocardiography at one month and at one year. From September 2009 to March 2012, 43 patients with severe MR with a mean age of 74.8±10.7 years (30 males and 13 females; mean log EuroSCORE 24.1±11, mean LVEF 47.5±18.5%; mean±SD) were treated. Median follow-up was 385 days (104-630; Q1-Q3). Device implantation success was 93%. All patients were treated following the central clip concept. Concerning the MR itself, 52.5% was degenerative in aetiology and 47.5% was functional. The degree of MR was reduced from 3.6±0.4 to 1.4±0.6 ($p<0.001$); NYHA Class improved from 3.1±0.4 to 1.8±0.7 ($p<0.001$). Nineteen patients (47.5%) received two or more clips. Vena contracta ($p<0.001$) and the presence of two broad jets ($p<0.001$) were correlated with the need for a second clip. The presence of a restricted posterior mitral valve leaflet (PML) was inversely correlated with the need for more than one clip ($p=0.02$). A cut-off value of ≥7.5 mm for vena contracta predicted the need for a second clip (sensitivity 83%, specificity 90%, $p=0.01$).

Conclusions: The central MitraClip® concept achieved a significant reduction in the degree of mitral regurgitation in the majority of patients treated. The presence of a broad jet (quantified by a vena contracta greater than 7.5 mm) significantly predicted the need for more than one clip.

PCR london valves | Pot-pourri

Incidence of permanent pacemaker implantation after TAVI and re-evaluation of the indications after the periprocedural period

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Aims: Transcatheter aortic valve implantation (TAVI) has evolved to be an efficient treatment for surgical extreme and high-risk patients with aortic stenosis. However, using the CoreValve (CV) system carries a risk of atrioventricular (AV) conduction system abnormalities requiring permanent pacemaker (PPM) implantation (PPMI) in up to 30% of the patients. The aims of the study were to examine the incidence of PPMI after TAVI using the CV system at the Rigshospitalet and evaluate the patients' indication for PPM after the periprocedural period.

Methods and results: Data were analysed for the first 258 consecutive patients (149 males [58%] mean age 80.3±7 years) who underwent TAVI at Rigshospitalet University Hospital of Copenhagen. The indications for PPM were divided into periprocedural or not (≤30 days or >30 days), as well as TAVI-related indications and non-TAVI-related indications (AV block or not). In addition, the TAVI-related indications were divided into absolute indications (3rd degree AV block and 2nd degree AV block type II and advanced) and relative indication for PPM (2nd degree AV block type I and 1st degree AV block with left bundle branch block). Patients who received a PPM were re-evaluated for the indication >30 days after their TAVI procedure. Twenty-four (9%) of the patients who underwent TAVI were excluded from the study due to PPM or indication for PPM prior to TAVI. Seventy-five (32%) of the patients received a PPM after TAVI; 63 (26.9%) patients within 30 days after TAVI and 12 (5%) patients after 30 days. Of the 63 patients who received a new PPM <30 days, 53 (84%) had a TAVI-related indication, and 46 of these patients (88%) had an absolute indication. However, at the F/U only 50% still had an absolute indication for PPM, whereas the 3rd degree AV block or the 2nd degree AV block type II or advanced was resolved in the rest of the patients.

Conclusions: Our data confirm that the incidence of PPM after TAVI is high (26.9%), but only 19.7% received a PPM on an absolute indication within 30 days after the procedure. Furthermore, after the periprocedural period, only 9.8% of the TAVI patients without a pre-existing device had an absolute indication for PPM. This suggests that the PPMI may be reduced by postponing the decision to ≥10 days after TAVI, as is the practice after surgical aortic valve replacement.

PCR london valves | Pot-pourri

Achieving a low pacing rate with CoreValve TAVI: high implantation, new delivery catheter, or both?

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Aims: Permanent pacemaker implantation (ppm) post transcatheter aortic valve implantation (TAVI) is a well recognised complication and the greater requirement after CoreValve TAVI compared with surgery (33% vs. 8%). Pre-existing bundle branch block (BBB), larger valve size, post-dilatation and low implantation have been shown to increase independently the risk of ppm requirement. Implantation below the aortic annulus can result in compression of conduction tissue and heart block. A modified delivery catheter (ACCUTRAK) may allow a more controlled release expansion of the prosthesis, preventing low implantation and reducing ppm need. We evaluated the ppm requirement in all our TAVI patients treated before and after the introduction of the Accutrak catheter.

Methods and results: TAVI was performed in 107 patients: transfemoral (84 patients), left subclavian (17 patients) and direct aortic approach (six patients). A high valve deployment strategy of 3-5 mm below the aortic annulus was routinely employed. Thirteen of these had a pre-existing ppm and were excluded from analysis. Forty-six patients had TAVI with a pre-Accutrak delivery catheter and 48 patients underwent TAVI using the Accutrak catheter. Procedural outcomes were analysed with a detailed evaluation of pre-TAVI ppm, pre-procedure ECG, annulus size, predilation balloon size, CoreValve size and post-dilatation in the two different groups. Recognised predictors of ppm requirement post TAVI were similar in both groups and were not significant. A total of 11 patients required a new ppm (11.7%) post TAVI. There were five ppm implantations in the pre-Accutrak group and six patients in the Accutrak group. In the pre-Accutrak group with new ppm implantations, two patients had sinus rhythm (SR) plus LBBB, one atrial fibrillation (AF) with LBBB, one SR with RBBB and one SR. In the Accutrak group, one had SR with RBBB, three patients had SR with first degree heart block and RBBB, three with AF and RBBB, and three with SR and first degree heart block. There was no significant difference in ppm requirement between the TAVI group pre and post-Accutrak (10.9% vs. 12.5%; p=1.0).

Conclusions: In our well characterised cohort, the need for ppm is lower than previous reports (11.7% vs. 33%) and appears to be independent of the Accutrak delivery catheter. We would advocate a high deployment strategy of 3-5 mm below the annulus to reduce the pacing rate. We also observed an apparent reduction in the incidence and severity of the paravalvular leak after high implantation of the device. Further evaluation of the effect of Accutrak catheter on ppm requirement in "middle to low" implanting centres is required.

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How does inflammation influence left ventricular function after TAVI?

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Aims: Transcatheter aortic valve implantation (TAVI) is an emerging treatment option for inoperable or high-risk patients. After the procedure, most patients show significant improvement of left ventricular function. However, the recovery of the left ventricle is not immediately observed in all patients, while in some there is a temporary deterioration. Furthermore, elevated levels of CRP and white blood cells (WBC) are observed in some patients after TAVI. Elevated CRP has been associated with reduced left ventricular function. Therefore, we hypothesised that inflammatory parameters may influence left ventricular recovery after TAVI.

Methods and results: Data from 76 consecutive patients (80.37±5.36 years, 33 males (48.8%), AVA: 0.63±0.15 cm^2) who underwent TAVI were evaluated from an existing database. Blood samples were obtained before TAVI, three hours and daily for five days after the procedure. CRP as well as WBC were recorded. In addition, transthoracic echocardiogram was performed and obtained before TAVI and daily for five days after the procedure. Patients were separated into three groups according to left ventricle improvement (improved, declined, unaffected). From these groups, LVEF improved in 29 patients (39.7%), declined in 11 patients (15.1%) and remained unaffected in 33 patients (45.2%). We performed the ANOVA statistical test among the three groups and found significant differences between them for CRPmax ($p<0.01$) and WBC1st day after ($p<0.01$). In particular, *post hoc* analysis showed higher levels of CRPmax (70.2±49.28 vs. 120±22.36, $p<0.01$) and WBC1st day after (16,333±4,685 vs. 11,748±3,512, $p<0.01$) in patients with declined LVEF compared to those with unaffected LVEF, respectively. Similarly, *post hoc* analysis recorded greater value for CRPmax (120±22.36 vs. 61.99±36.9, $p<0.01$) and WBC1st day after (16,528±4,890 vs. 10,800±2,687, $p<0.01$) in patients with declined LVEF when compared with those with improved LVEF.

Conclusions: In conclusion, inflammation as detected by simple indices such as WBC and CRP may be associated with left ventricular function after TAVI.

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Early and late changes in quality of life following TAVI using the transfemoral and transapical approaches

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Aims: Balloon-expandable transcatheter aortic valve implantation (TAVI) has been shown to improve health-related quality of life (QoL) in PARTNER participants at one and 12 months for all employed measures. The aim of our study was to evaluate the effects of access route upon clinical results and QoL in patients undergoing either transfemoral TAVI (TF-TAVI) or transapical TAVI (TA-TAVI).

Methods and results: A retrospective analysis was performed upon data from 264 consecutive patients receiving TF-TAVI or TA-TAVI at two European centres. QoL was assessed using the self-reported EQ-5D questionnaire, as well as a visual analogue scale of overall health state (EQ-VAS). 179 patients underwent TF-TAVI (mean age 81.7±6.1 years, 66% female) and 85 patients underwent TA-TAVI (mean age 79.6±9.0 years, 62% female). Patient characteristics in the two cohorts were similar except for higher logistic EuroSCORE in the TA-TAVI patients (p=0.014), greater incidence of peripheral artery disease (p=0.002), porcelain aorta (p=0.002), prior surgical aortic valve replacement (SAVR) (p=0.002) and prior cardiac surgery (p<0.001). Procedural success was comparable between the two cohorts (98.3% for the TF-TAVI group vs. 100% for the TA-TAVI group, p=0.553). At 30 days, both groups demonstrated significant increases in aortic valve area and mean transvalvular gradient (p<0.001 for both). Post-procedural ICU/CCU and overall in-patient stay were shorter in the TF-TAVI group (p<0.001 and p<0.001). The 30-day mortality rate was 3.9% for the TF-TAVI group and 2.4% for the TA-TAVI group, respectively (p=0.723). At baseline, TA-TAVI patients reported more significant problems (EQ-5D score ≥2) in mobility (p<0.001), self care (p<0.001) and usual activities (p=0.002). They also reported lower overall health with EQ-VAS median 15 points (interquartile range [IQR] 10-30) vs. 50 points ([IQR 20-60]; p<0.001). At 30 days, the TF-TAVIs reported fewer problems with usual activity (p=0.013) and pain/discomfort (p<0.001). Overall health was improved in both groups but to a greater magnitude in the TF-TAVI patients (EQ-VAS 85 [IQR 75-90] vs. 70 points [IQR 60-80], p<0.001) compared to baseline. Despite this, the absolute improvement in EQ-VAS (ΔEQ-VAS) at 30 days was most marked in TA-TAVI patients (55 [IQR 30-61.3] vs. 40 points [IQR 30-56.3], p=0.022) By one year there were no differences between TF-TAVI and TA-TAVI patients in any EQ-5D domain nor in EQ-VAS, but the greater absolute improvement in the TA-TAVI group remained (60 [IQR 50-70] vs. 55 points [IQR 40-70], p=0.031).

Conclusions: TAVI is effective in improving QoL with both TA-TAVI and TF-TVI approaches in patients not eligible for SAVR. Overall health-related QoL is greater at the earlier time point of 30 days in the TF-TAVI cohort. By one year the improvements are similar in both groups. However, the magnitude of improvement in QoL is greater in the TA-TAVI patients at both 30 days and one year.

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Emergency and prophylactic use of miniaturised veno-arterial extracorporeal membrane oxygenation (vaECMO) in transcatheter aortic valve implantation (TAVI)

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Aims: In transcatheter aortic valve implantation (TAVI) short-term mortality closely relates to life-threatening procedural complications. Veno-arterial extracorporeal membrane oxygenation (vaECMO) can be used to stabilise the patient in emergency situations. However, for the prophylactic use of vaECMO in very-high-risk patients undergoing TAVI there is no experience. We report our centre's experience using vaECMO in TAVI.

Methods and results: From January 2009 to August 2011, we performed 131 TAVI. Emergency vaECMO was required in eight cases (7%), due to ventricular perforation (n=3), haemodynamic instability/cardiogenic shock (n=4) and haemodynamic deterioration due to ventricular tachycardia (n=1). From August 2011 onwards, prophylactic vaECMO was systematically used in very-high-risk patients (n=9, 11%) during 83 procedures and emergency vaECMO in one case (1%) due to ventricular perforation. Median logistic EuroSCORE in prophylactic vaECMO patients was considerably higher compared to the remaining TAVI population (30% vs. 15%, p=0.0003) while in patients with emergency vaECMO it was comparable (18% vs. 15%, p=0.08). Comparing prophylactic to emergency vaECMO, procedural success, procedural-related death, and 30-day mortality were 100% vs. 78% (p=0.5), 0% vs. 33% (p=0.2) and 0% vs. 44% (p=0.08), respectively. Major vascular complications and rate of life-threatening bleeding did not differ in both groups (11% vs. 11%, p=0.99 and 11% vs. 33%, p=0.6) and were not vaECMO-related.

Conclusions: Life-threatening complications during TAVI can be managed using emergency vaECMO but mortality remains high. Systematic use of prophylactic vaECMO in very-high-risk patients is safe and might be advocated in selected high-risk patients.