Chew, N., et al. (2017). "Mid-term study of transcatheter aortic valve implantation in an Asian population with severe aortic stenosis: two-year Valve Academic Research Consortium-2 outcomes." Singapore Med J 58(9): 543-550.

INTRODUCTION: Transcatheter aortic valve implantation (TAVI) is an effective treatment for high-risk or inoperative patients with severe aortic stenosis. Given the unique characteristics of Asian populations, questions regarding mid-term outcomes in Asians undergoing TAVI have yet to be addressed. We evaluated the two-year clinical outcomes of TAVI in an Asian population using Valve Academic Research Consortium-2 definitions. METHODS: This prospective study recruited 59 patients from a major academic medical centre in Singapore. The main outcomes were two-year survival rates, peri-procedural complications, symptom improvement, valvular function and assessment of learning curve. RESULTS: Mean age was 76.8 years (61.0% male), mean body surface area 1.6 m(2) and mean logistic EuroSCORE 18.7%. Survival was 93.2%, 86.0% and 79.1% at 30 days, one year and two years, respectively. At 30 days post TAVI, the rate of stroke was 1.7%, life-threatening bleeding 5.1%, acute kidney injury 25.0%, major vascular complication 5.1%, and new permanent pacemaker implantation 6.8%. 29.3% of TAVI patients were rehospitalised (47.1% cardiovascular-related) within one year. These composite outcomes were measured: device success (93.2%); early safety (79.7%); clinical efficacy (66.1%); and time-related valve safety (84.7%). Univariate analysis found these predictors of two-year all-cause mortality: logistic EuroSCORE (hazard ratio [HR] 1.07; p < 0.001); baseline estimated glomerular filtration rate (HR 0.97; p = 0.048); and acute kidney injury (HR 5.33; p = 0.022). Multivariate analysis identified non-transfemoral TAVI as a predictor of cardiovascular-related two-year mortality (HR 14.64; p = 0.008). CONCLUSION: Despite the unique clinical differences in Asian populations, this registry demonstrated favourable mid-term clinical and safety outcomes in Asians undergoing TAVI.

Chieffo, A., et al. (2015). "Impact of Mixed Aortic Valve Stenosis on VARC-2 Outcomes and Postprocedural Aortic Regurgitation in Patients Undergoing Transcatheter Aortic Valve Implantation: Results From the International Multicentric Study PRAGMATIC (Pooled Rotterdam-Milan-Toulouse in Collaboration)." Catheter Cardiovasc Interv 86(5): 875-885.

OBJECTIVES: We sought to evaluate the impact of mixed aortic stenosis (MAS) on postprocedural aortic regurgitation (PPAR) and clinical outcomes after transcatheter aortic valve implantation (TAVI). BACKGROUND: The impact of MAS of TAVI outcomes is unknown. METHODS AND RESULTS: Data from a multicenter registry were retrospectively analysed. Outcomes were compared between patients with pure aortic stenosis (PAS; associated AR<1+/3+) and MAS (associated AR>/=1+/3+). Study objectives were PPAR incidence and short- and long-term mortality. Overall, 1,062 patients were included: 419 (39.4%) with MAS and 643 (60.5%) with PAS. At 30 days, there were no differences in mortality, however, a higher incidence of major bleeding (22.7% vs. 16.8%; P=0.016), PPAR>/=1+/3+ (42.6% vs. 26.5%; P<0.001) and lower device success (89.3% vs. 93.3%; P=0.019) was observed in patients with MAS. Of note, MAS was an independent predictor of PPAR>/=1+/3+ at multivariable analysis (OR: 2.882; CI: 1.851-4.488; P<0.001). At 2 years of follow-up, no survival differences were present between MAS and PAS groups. Similarly, following stratification for PPAR>/=1+/3+, MAS had no protective effect on survival as compared with PAS. CONCLUSIONS: MAS was associated with lower device success and higher PPAR incidence. However, despite these findings, it had no influence on long-term postoperative outcomes.

Miura, M., et al. (2017). "Early Safety and Efficacy of Transcatheter Aortic Valve Implantation for Asian Nonagenarians (from KMH Registry)." Int Heart J 58(6): 900-907.

As Japan has one of the most rapidly aging populations in the world, transcatheter aortic valve implantation (TAVI) is likely to be performed in increasing numbers of older people. There is little information on either the efficacy or the safety of TAVI in nonagenarians in Asia.From October 2013 to June 2015, 112 consecutive patients underwent TAVI with Edwards SAPIEN XT valves in our institution. We compared 25 patients aged at least 90 years (mean 91.6 +/- 1.7 years) with 87 patients aged under 90 years (mean 82.5 +/- 6.0 years) at the time of TAVI. All definitions of clinical endpoints and adverse events were based on the Valve Academic Research Consortium 2 definitions.The median follow-up interval was 561.5 days (the first and third quarters, 405.0 and 735.8 days). Nonagenarians had a higher logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE), Euro II score, and the Society of Thoracic Surgeons predictive risk of mortality (STS) score, and a prevalence of clinical frailty scale >/= 4. The rate of device success, and the 30-day and 6-month mortalities were not different between patients aged >/= 90 years and < 90 years (96.0% versus 92.0%, P = 0.68; both 0%, P = 1.00; 4.0% versus 3.5%, P = 0.32, respectively). At six months, clinical efficacy and time-related valve safety were also similar in the two groups (12.5% versus 13.4%, P = 1.00; 4.5% versus 10.3%, P = 0.68, respectively). The cumulative 1-year mortalities were not significantly different between the two groups (8.4% versus 9.4%, P = 0.94, respectively).TAVI can contribute to acceptable clinical results and benefits in a carefully selected group of nonagenarians in Asia.

Mollmann, H., et al. (2021). "The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes." Clin Res Cardiol 110(12): 1912-1920.

BACKGROUND: Transcatheter aortic valve implantation (TAVI) has become standard treatment for elderly patients with symptomatic severe aortic valve stenosis. The ACURATE neo AS study evaluates 30-day and 1-year clinical and hemodynamic outcomes in patients treated with the ACURATE neo2 valve. METHODS: The primary endpoint of this single-arm multicenter study is 30-day all-cause mortality. Other key endpoints include device performance, echocardiographic measures assessed by an independent core laboratory, and VARC-2 clinical efficacy and safety endpoints through 12 months. RESULTS: The study enrolled 120 patients (mean age 82.1 +/- 4.0 years; 67.5% female, mean baseline STS score 4.8 +/- 3.8%). The VARC-2 composite safety endpoint at 30 days occurred in 13.3% of patients. All-cause mortality was 3.3% at 30 days and 11.9% at 1 year. The 30-day stroke rate was 2.5% (disabling stroke 1.7%); there were no new strokes between 30 days and 12 months. The rate of permanent pacemaker implantation was 15.0% (18/120) at 30 days and 17.8% (21/120) at 1 year. No patients required re-intervention for valve-related dysfunction and there were no cases of valve thrombosis or endocarditis. Patients demonstrated significant improvement in mean aortic valve gradient (baseline 38.9 +/- 13.1 mmHg, 1 year 7.8 +/- 3.5 mmHg; P < 0.001 in a paired analysis). In the overall population, paravalvular leak was evaluated at 1 year as none/trace in 60.5%, mild in 37.0%, and moderate in 2.5%; no patients had severe PVL. CONCLUSIONS: One-year outcomes from the ACURATE neo AS study support the safety and performance of TAVI with the ACURATE neo2 valve.

Pellegrini, C., et al. (2019). "One year VARC-2-defined clinical outcomes after transcatheter aortic valve implantation with the SAPIEN 3." Clin Res Cardiol 108(11): 1258-1265.

AIMS: To evaluate 1-year outcome after transcatheter aortic valve implantation (TAVI) using the SAPIEN 3 (S3) prosthesis with emphasis on the composite endpoints "clinical efficacy after 30 days" and "time-related valve safety" proposed by the updated Valve Academic Research Consortium (VARC-2). METHODS AND RESULTS: Four hundred and two consecutive patients undergoing transfemoral TAVI with the S3 were enrolled. Mean age was 81 +/- 6 years, 43% were female and median logistic EuroSCORE I was 12% [8-19]. Device success was achieved in 93% (374/402) with moderate or severe paravalvular leakage (PVL) in 2%. At 1 year all-cause mortality was 8.9% [95% CI 6.4-12.2] and new permanent pacemaker implantation rate was 16% [95% CI 12.7-20.4]. The composite endpoint time-related valve safety occurred in 29% with structural valve deterioration, defined as elevated gradients or more than moderate PVL, occurring in 13%. The clinical efficacy endpoint after 30 days was observed in 37% of patients with the main contributor symptom worsening with New York Heart Association functional class III + in 17% of cases. CONCLUSIONS: For the first time, VARC-2-defined composite endpoints at 1 year are reported and reveal a considerable proportion of patients experiencing the endpoint of time-related valve safety (29%) and clinical efficacy after 30 days (37%).

Pellegrini, C., et al. (2019). "One-year clinical outcome with a novel self-expanding transcatheter heart valve." Catheter Cardiovasc Interv 94(6): 783-792.

OBJECTIVES: To evaluate 1-year outcome using the ACURATE neo (Symetis S.A., a Boston Scientific Company, Ecublens, Switzerland) according to the updated Valve Academic Research Consortium (VARC-2) with emphasis on the composite endpoints "clinical efficacy after 30 days" and "time-related valve safety". BACKGROUND: Initial reports on the clinical performance of patients treated with the ACURATE neo are promising; however, information regarding one-year outcome is scarce, especially with regard to the composite endpoints proposed by the VARC-2. METHODS: One hundred and fifty one consecutive patients undergoing transfemoral transcatheter aortic valve replacement (TAVR) with the ACURATE neo for severe aortic valve stenosis were enrolled. Data were prospectively collected and event rates during follow-up were calculated as the Kaplan-Meier estimates. RESULTS: Mean age was 81.1 +/- 5.9 years and 49.7% (75/151) were female with a median logistic EuroScore of 13.8% [8.2-20.5]. Device success was achieved in 88.1% (133/151) and procedure related mortality was 0.7% (1/151). At one-year, all-cause mortality was 3.3% (5/151), while permanent pacemaker implantation occurred in 12.7% (19/151) of patients. The "clinical efficacy after 30 days" was observed in 24.8% (37/151), where the main contributor was symptom worsening in 14.8% (22/151) of cases. "Time-related valve safety" occurred in 22.0% (33/151) with structural valve deterioration as main contributor in 10.7% (16/151) of cases. CONCLUSIONS: Using the ACURATE neo, we found a favorable safety profile with low all-cause mortality at 1 year. The reported VARC-2 defined composite endpoints at 1 year reveal low rates of "clinical efficacy after 30 days" and "time-related valve safety".

Vontobel, J., et al. (2015). "Early safety outcome following transcatheter aortic valve implantation: is the amount of contrast media used a matter of concern?" Swiss Med Wkly 145: w14238.

QUESTIONS UNDER STUDY: The study objective was to evaluate the impact of the amount of contrast medium used for transcatheter aortic valve implantation (TAVI) on short-term outcome. Patients undergoing TAVI are exposed to repeat contrast medium application both for preprocedural screening and during the TAVI procedure itself. Whether the amount of contrast media is associated with worse outcome is unclear. METHODS: A total of 257 patients were included (median age 82.7 years) and divided into two groups with preserved and reduced kidney function (glomerular filtration rate <60 ml/min/1.73 m2), respectively. Total volume of contrast media administered during and within 5 days prior to TAVI was analysed. A combined early safety endpoint at 30 days was evaluated. RESULTS: The early safety endpoint was reached by 31 patients and acute kidney injury occurred in 22 patients. The median total volume of contrast media administered was 144 ml (interquartile range 81-225 ml). The amount of contrast did not independently predict the early safety endpoint in the overall population (odds ratio [OR] 0.93, 95% confidence interval [CI] 0.56 to 1.53, p = 0.774) and in subgroups with preserved and reduced kidney function. Change in creatinine was an independent strong predictor of the early safety endpoint in the overall population (OR 18.13, 95% CI 4.70 to 69.99, p <0.001), as well as in subgroups with preserved and reduced kidney function. The amount of contrast did not predict a change in creatinine within 72 hours following TAVI (r = 0.02, 95% CI -0.02 to 0.07, p = 0.368). CONCLUSION: Decreased kidney function after TAVI influences outcome. When rather small amounts of contrast media are used for screening and the TAVI procedure itself, the amount of contrast media seems not to be an independent predictor of outcome, further suggesting that decreased kidney function after TAVI is multifactorial.

Zhang, Y., et al. (2015). "Propensity-matched comparison between Direct Flow Medical, Medtronic Corevalve, and Edwards Sapien XT prostheses: Device success, thirty-day safety, and mortality." Catheter Cardiovasc Interv 85(7): 1217-1225.

AIMS: To compare 30-day performance of three different type of transcatheter aortic valve implantation (TAVI) prosthesis: Direct Flow Medical (DFM), Medtronic Corevalve (MCV), and Edwards Sapien XT (ES). METHODS AND RESULTS: Forty consecutive patients treated with DFM for severe aortic stenosis were matched to an equal sample of patients undergoing TAVI with MCV and ES (1:1:1 propensity score-matching). Primary end-point was 30-day safety, defined according to the valve academic research consortium (VARC-2) criteria. Secondary end-points were: (i) immediate post-TAVI transaortic gradient reduction, (ii) device success, and (iii) 30-day mortality. Patients treated with DFM had higher 30-day safety rate compared to MCV and ES (respectively: 95.0% vs. 67.5% vs. 82.5%; P=0.006). Immediate post-TAVI, transaortic gradient reduction was similar for DFM, MCV, and ES subgroups (respectively: 8.3 +/- 5.2 mm Hg vs. 5.3 +/- 3.7 mm Hg vs. 5.6 +/- 5.1 mm Hg; P=0.15); likewise, device success did not differ significantly (respectively: 100% vs. 92.5% vs. 92.5%; P=0.19). Mortality rates were also similar (respectively: 0% vs. 7.5% vs. 7.5%; P=0.190). In the pooled binary logistic regression analysis, blood transfusion was associated to 30-day safety (HR 0.156, 95% CI 0.049-0.500, P=0.002), while a significant trend was observed for the vascular closure device type (favoring Proglide vs. Prostar: HR 0.239, 95% CI 0.049-1.160, P=0.076). CONCLUSIONS: In high-risk patients with aortic stenosis undergoing TAVI, device success and short-term mortality were comparable between DFM, MCV, and ES. In contrast, the 30-day VARC-defined safety primary end-point was met significantly more frequently in patients treated with DFM. This result was mainly driven by differences in major vascular complications, associated to differences in vascular closure devices between the different valve subgroups.