Impact of diabetes on outcomes after TAVI procedure: a multicentre registry

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Aims: Several factors have been identified as predictors of early and midterm events after TAVI, but incidence and prognostic impact of diabetes, especially if insulin dependent, on their short and mid outcomes remains to be defined.

Methods and results: A total of 511 consecutive patients undergoing TAVI at our Institutions were enrolled, and divided according to diabetes status. All-cause mortality at 30 days and at follow up was the primary end point, while periprocedural complications, rate of myocardial infarction, stroke, re-intervention at follow up in the secondary. All end points were adjudicated according to VARC. 511 patients were enrolled: 361 without diabetes, 78 with orally treated/diet controlled diabetes and 72 with insulin treated diabetes. Patients with orally treated diabetes were more frequently female and patients with insulin treated diabetes were younger. 30 days mortality was not significantly higher in patients with orally treated diabetes (6.4%) and insulin treated diabetes (9.7%) compared with non-diabetic patients (4.7% p=0.09). Bleeding, vascular complications, post procedural acute kidney injury and peri-procedural stroke were not significantly different in the three groups. At a median follow up of 400 days patients with insulin treated diabetes had a significantly higher mortality rate (33.3% Vs 18.6%; p=0.01), and higher myocardial infarction incidence (8.3% Vs 1.4%; p=0.002) if compared with patients without diabetes. Stroke and re-interventions at follow-up were similar in the three groups. After multivariable adjustment insulin treated diabetes was independently correlated with death (HR 1.75, 95% CI 1.1-2.8) and myocardial infarction (HR 5.6, 95% CI 1.5-20.5).

Conclusion: Diabetes doesn’t significantly affect rates of complications in TAVI patients. Insulin treated diabetes, but not orally treated diabetes, is independently associated with deaths and myocardial infarction at mid-term follow-up. Insulin treated diabetes should be included into dedicated scores to predict outcomes of patients after TAVI.

Measurement of the aortic annulus diameter using transesophageal echocardiography and multislice computed tomography. Are they interchangeable?

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Background: Transesophageal echocardiography (TEE) is often considered as the reference method for the measurement of the aortic annulus diameter (AAD) during transcatheter aortic valve implantation (TAVI). In the present study, we evaluated whether Multislice Computed Tomography (MSCT) could reproduce and thus substitute to TEE.

Method: We compared AAD measurements performed using TEE, MSCT and transthoracic echocardiography (TTE) in 129 consecutive patients with severe aortic stenosis (AS) referred for TAVI. Using MSCT, AAD was measured in the 3-chamber view and at the level of the virtual basal ring. We calculated the mean (MD) of the long-axis (LA) and short-axis (SA) diameters, mathematic transformations emphasizing the weight of the SA (MD2 = 2SA + LA/3), AAD derived from the cross-sectional area and from the circumference of the virtual basal ring. Comparisons between methods were assessed using single measure intra-class correlation coefficient (ICC) and agreements as regard to the TAVI strategy (decision to implant and choice of the prosthesis’ size based on manufacturer’s cutoffs recommendations) expressed using the kappa value.

Results: The 3C method (ICC=0.79, 95% interval 0.73-0.83), MD4 (ICC=0.76, 95% interval 0.69-0.81) and MD5 (ICC=0.75, 95% interval 0.67-0.81) provided the highest correlation and the best agreement to TEE (kappa value of 0.47, 0.27 and 0.31 respectively) but remained lower than TTE (ICC=0.87; 95% interval 0.83-0.91; kappa=0.66). The agreement between MSCT and TEE varied with the degree of eccentricity of the aortic annulus or the degree of aortic valve calcification but was reached using the values observed with TTE.

Conclusion: No direct or indirect MSCT method provided higher correlations to TEE than TTE. Consequently, no MSCT method could reproduce and thus substitute to TEE. Randomized prospective studies are clearly needed to evaluate which method provides the best clinical results, but we definitely demonstrate that MSCT and TEE are not interchangeable.

A novel device for antegrade percutaneous balloon aortic valvuloplasty: feasibility of the looped Inoue balloon technique in a swine model

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Objectives: The study aimed to assess the feasibility of a novel device and technique for antegrade percutaneous balloon aortic valvuloplasty (BAV) in a swine model.

Background: BAV is currently being applied more frequently compared to the past with the advent of transcatheter aortic valve replacement. Although the antegrade BAV approach offers several advantages over the retrograde approach, the antegrade approach is technically more complicated and demanding.

Methods: We developed a novel balloon catheter and a technique to simplify the antegrade BAV. The balloon catheter was designed to make a loop in left atrium by inserting two different sized styles. The balloon catheter was easily dropped into the left ventricle via the mitral valve while maintaining the loop. The balloon catheter was advanced to the ascending aorta with holding the 2 styles. Then, the balloon was inflated. We named the technique as the looped Inoue balloon technique. The feasibility of the looped Inoue balloon technique was assessed in a healthy swine with a body weight of 40kg by 4 independent operators. Every operator conducted the procedure twice.

Results: All procedures were successfully conducted; the procedural success rate was 100% in all operators. The average procedure time was 170±35 seconds. No procedure related complications were noted.

Bedside measurement of red blood cell distribution width predicts one-year mortality following transcatheter aortic valve implantation

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Purpose: Red blood cell distribution width (RDW) is a measure of heterogeneity in erythrocyte size; high levels are associated with increased long-term mortality following transcatheter aortic valve implantation (TAVI).

Methods: An observational cross-sectional study of all subjects undergoing TAVI implantation in an experienced European institution was conducted. The baseline characteristics and clinical outcomes from a series of 385 patients who underwent TAVI were collected. The study endpoints were defined according to VARC 2. All patients provided written informed consent for the procedure and data collection. Statistical analysis was performed using SPSS version 21.0. Univariate analysis followed by multivariate regression analysis was performed. The following covariates were adjusted for regression analysis: age, sex, body mass index, logistic EuroSCORE, Society of Thoracic Surgeons score, previous MI, CABG, or PTCA, coronary artery bypass grafting (CABG). The objective was to assess whether baseline RDW is predictive of outcome following transcatheter aortic valve implantation (TAVI).

Results: In univariate analysis RDW was found to be associated with 30 day-mortality (p= 0.022) and all-cause mortality at 1 year (p= 0.015). No significant comparing the past with the advent of transcatheter aortic valve replacement. Although the antegrade BAV approach offers several advantages over the retrograde approach, the antegrade approach is technically more complicated and demanding.

Methods: We developed a novel balloon catheter and a technique to simplify the antegrade BAV. The balloon catheter was designed to make a loop in left atrium by inserting two different sized styles. The balloon catheter was easily dropped into the left ventricle via the mitral valve while maintaining the loop. The balloon catheter was advanced to the ascending aorta with holding the 2 styles. Then, the balloon was inflated. We named the technique as the looped Inoue balloon technique. The feasibility of the looped Inoue balloon technique was assessed in a healthy swine with a body weight of 40kg by 4 independent operators. Every operator conducted the procedure twice.

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Results: In univariate analysis RDW was found to be associated with 30 day-mortality (p= 0.022) and all-cause mortality at 1 year (p= 0.015). No significant
association was shown between RDW, combined safety-end point, combined ef-
ficacy end-point, cardiovascular death at 30 days and cardiovascular death at 1 year. In Cox regression analysis, RDW remained a significant predictor of all-
cause mortality at 1 year (odds ratio [OR] 1.15, 95% confidence interval [CI]
1.02-1.29, p= 0.02). Other significant predictors of total mortality were previous
PTCA (OR 0.43, 95% CI 0.22-0.86, p= 0.02), BMI (OR 0.87, 95% CI 0.79-0.95,
p= 0.002) and logistic Euroscore (OR 1.02, 95% CI 1.01-1.04, p= 0.004). Post-
hoc receiver-operating characteristic (ROC) curve analysis was also performed to
further analyse the relation between RDW and all-cause mortality at 1 year. RDW
levels were found to be significant of total 1-year mortality with an area under
curve of 0.62 (95% CI 0.52-0.72, p= 0.015).

Conclusions: In the present study we showed for the first time that RDW, an
inexpensive and easily measurable laboratory variable which is used routinely in
daily clinical practice, is independently associated with all-cause mortality at one
year following TAVI implantation.

P5420 | BEDSIDE
Does atrial fibrillation influence the clinical outcome of patients with severe aortic stenosis treated by transcatheter valve implantation?
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Purpose: To analyze the influence of previous atrial fibrillation on the outcome of patients with degenerative aortic stenosis undergoing transcatheter aortic valve implantation.
Methods: Between April 2008 and December 2012, 191 patients with aortic stenosis underwent transcatheter aortic valve CoreValve implantation: 149 (78%) were in sinus rhythm (group I), and 42 (22%) had permanent (n=30) or paroxysmal (n=12) atrial fibrillation (group II). Patients were followed-up for 23±17 months. We defined major events as: death from any cause, stroke or readmission for congestive heart failure.
Results: The mean age was 78±5 years. There were no significant differences in baseline characteristics among groups in terms of age, incidence of diabetes, hypertension, coronary artery disease, chronic pulmonary disease, prior stroke, chronic renal failure or STS score. Baseline peak systolic pulmonary pressure was also higher in group II patients (50±13 vs 44±15 mmHg; P<0.05). However, there were no differences between groups in left ventricular ejection fraction, peak aortic gradient or aortic valve area. Both groups of patients underwent similar treatment procedures, with no differences in terms of valve size, need for post-
dilation or permanent pacemaker implantation. Procedural success was achieved in 137 patients (92%) in group I and in 37 (88%) in group II (p=ns). Nine patients (6%) in group I died in hospital vs. 5 (12%) in group II (p=ns). Patients in sinus rhythm were discharged with aspirin and clopidogrel, while patients with atrial fibrillation received oral anti-coagulation, plus aspirin and/or clopidogrel. During follow-up, 13 further deaths occurred in group I (6% in group II; p=ns). The incidence of stroke was lower (3.4%) in group I as compared with group II (17%; p<0.01). Readmission rates for congestive heart failure were 7.1±6.3% in group I and 4.3±4.4% (12%) in groups I and II, respectively (p<0.05). The Kaplan Meier major event- free survival rate at 3 year follow-up was 82% in group I vs. 48% in group II (p<0.001).
Conclusions: Patients with atrial fibrillation undergoing transcatheter aortic valve implantation showed a higher rate of events at follow-up compared with those observed in patients in sinus rhythm. Atrial fibrillation should be considered as an adverse condition when evaluating risk stratification for these patients.

P5421 | BEDSIDE
Implant dynamics of transcatheter aortic valve implantation in Europe
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Purpose: Transcatheter aortic valve implantation (TAVI) gained Conformité Eu-
ropéenne (CE)-mark approval in 2007, and in subsequent years the number of patients undergoing TAVI in Europe has increased exponentially. Disparate adoption
of medical technology is pervasive and results in inequitable patient access. Adoption kinetics of a novel medical technology such as TAVI has not been previ-
ously described. We sought to examine the adoption kinetics of TAVI in Western Europe
Methods: TAVI adoption was investigated across 11 European nations: Germany, France, Italy, United Kingdom (UK), Spain, The Netherlands, Switzerland, Bel-
gium, Portugal, Denmark and Ireland. Two sources of data were used: (1) lead physicians; provided national registry data; and (2) the Eurocoeur Transcatheter Cardiovascular Monitor system. The penetration of TAVI in each nation was
determined as a measure of actual TAVI use relative to potential use.
Results: Between January 2007 and December 2011, 34,317 patients under-
went TAVI in the 11 study nations. Almost half of all implants were performed in
Germany (45.9%). In 2011, the highest annual increase in procedural volume was
observed in France (81%) and Germany (48%), while Ireland (-15%) and Portugal
(-3%) experienced a decline.
We observed a wide variation in the number of TAVI implants per million of pop-
ulation. Germany (88.7) and Portugal (6.1) accounted for the highest and lowest
number of TAVI implants per million of population in 2011, respectively. Among
the 11 study nations, the mean number of TAVI implants per million was 32.9±24.9.
The number of centres performing TAVI increased 9-fold from 37 in 2007 to 342
in 2011. In 2011, Germany (90) and Italy (87) had the highest number of TAVI
centres whereas Portugal, Denmark and Ireland (3) had the lowest. Belgium had
the highest number of TAVI centres per million (2.1). On average, there were
0.9±0.6 TAVI centres per million. These numbers led to an average of 41±28
TAVI implants per centre in 2011, with estimates in individual countries ranging
from 10 in Ireland to 89 in Germany.
In 2011, we estimate that there were 28,400 living TAVI recipients and 158,371
potential TAVI candidates in the 11 study nations. Thus, the calculated weighted
average TAVI penetration rate was 17.9%. Germany (36.2%) and Portugal had
the highest and lowest TAVI penetration rates, respectively.
Conclusions: There is substantial variation in the adoption of TAVI and in the
annual number of TAVI implants per centre across nations. TAVI remains greatly
underutilised with an estimated weighted penetration rate of 17.9%.

P5422 | BEDSIDE
Is 30-day mortality after transcatheter aortic valve implantation lower than society of thoracic surgeons predicted risk of mortality? A meta-analysis and meta-regression of contemporary studies
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Purpose: Under the situation of insufficient direct-comparison data of trans-
catheter aortic valve implantation (TAVI) versus surgical aortic valve replace-
ment (AVR) for aortic stenosis (AS), we performed a meta-analysis and meta-
regression comparing observed 30-day all-cause mortality after TAVI with pre-
dicted mortality (for AVR in patients undergoing TAVI) using the Society of Tho-
racic Surgeons Predicted Risk of Mortality (STS-PROM) (not logistic EuroSCORE
[European System for Cardiac Operative Risk Evaluation]) in contemporary
studies.
Methods: MEDLINE and EMBASE were searched from January 2011 to Decem-
ber 2012 using PubMed and OVID. Eligible studies were those enrolling patients
with AS undergoing TAVI and reporting both STS-PROM and outcomes (including
30-day all-cause mortality) using the VARC (Valve Academic Research Consor-
tium) definitions. For each study, data regarding observed and predicted mortality
were used to generate mean differences (MDs) and 95% confidence intervals
(CIs).
Results: Seventeen reports enrolling >8000 patients undergoing TAVI were iden-
tified and included. Pooled analysis demonstrated significantly lower 30-day all-
cause mortality than STS-PROM (random-effects MD, -1.63%; 95% CI, -3.22%
to -0.05%; P<0.04). Random-effects meta-regression revealed significantly neg-
ative relationship between STS-PROM and MD (coefficient, -0.83; 95% CI, -1.21
to -0.45; P<0.001) and 8.7% of the x-axis intercept of the upper 95% CI curve (Figure 1), suggesting that mortality after TAVI may be significantly (P<0.05) lower than predicted mortality in patients with >8.7% of STS-PROM.

Figure 1. Meta-regression of STS-PROM on MD

Conclusions: Thirty-day all-cause mortality after TAVI appears to be lower than
STS-PROM, especially in patients with >8.7% of STS-PROM.