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# Predicting Device Success and Early Clinical Outcome after Transapical Aortic Valve Implantation

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## Abstract

**Objective:** Pre-procedural evaluation of aortic valve patients is based on the prediction of perioperative risk for a conventional aortic valve replacement (AVR) utilizing standardized risk scores. However, in in the era of transcatheter aortic valve implantation (TAVI) the specific prediction of procedural outcome of an interventional approach seems of growing importance. We aimed to isolate patient- and approach-related factors, predicting procedural outcome of transapical aortic valve implantation (TA-TAVI), especially focusing on parameters not included in standard risk scores (e.g. BMI, intracardiac anatomy, preoperative NT-proBNP).

**Methods:** A cohort of 60 patients suffering from severe aortic stenosis and receiving TA-TAVI at our institution was analyzed (mean age was 77.7 ± 6.3 years, 50% male). All patients exhibited a high risk for conventional AVR (EuroScorelog ≥ 20 or porcelain aorta) and were scheduled for a TA approach using an Edwards Sapien valve following heart-team discussion. Prior the procedure, all patients underwent multi-slice computed tomography examination. In order to evaluate the procedural and clinical outcome after TA-TAVI, three endpoints were defined: More than mild postoperative paravalvular leak (PVL), postoperative mean transvalvular gradient > 14 mmHg and a composite endpoint of 30-day mortality, stroke and myocardial infarction. For isolation of outcome predictors, fourteen different potential predictors were included into primary univariate regression analyses, seven of which entered subsequent multivariate analyses.

**Results:** A BMI ≥ 30 was found in multivariate logistic regression to double the risk for both more than mild PVL and higher postoperative transvalvular gradients, however without reaching statistical significance (OR 2.57 95% CI 0.69-9.52; p=0.157 and OR 2.32 95% CI 0.57-9.45; p=0.242, respectively). Male gender and COPD were both associated with a decreased risk for elevated postoperative gradients. Of the analyzed approach-related parameters, especially a LVOT-aorta angle <120° was associated with an increased risk of the composite end-point (OR 6.65 95% CI 0.93-47.4; p=0.059). Furthermore preoperative NT-proBNP levels <400 ng/ml were found to predict a trend towards higher postoperative transvalvular gradients (OR 5.15 95% CI 0.32-81.9; p=0.246).

**Conclusion:** Standardized risk scores for conventional AVR are limited in terms of predicting the early outcome of TAVI procedures. The current study provides evidence that specific parameters such as the LVOT-aorta angle are likely to improve outcome prediction of patients undergoing TAVI procedures.

**Keywords:** Transapical TAVI; Device success; Outcome; LVOT-aorta angle; Risk scores

## Introduction

For patients suffering from severe aortic valve stenosis, surgical aortic valve replacement is considered the gold-standard and first line therapy [1].

However, since the patient cohort affected by aortic valve stenosis is continuously aging, relevant comorbidities are frequently increasing the risk of a surgical aortic valve replacement (AVR). In order to address this issue of high risk or even non-operable patients, transcatheter aortic valve implantation (TAVI) procedures were developed during the last decade [2] and have been implemented successfully into the therapeutic repertoire for patients suffering from aortic valve stenosis [3]. Until today, feasibility has been proven for both, the antegrade transapical (TA) as well as retrograde (transfemoral (TF), transaortic (TAO) and transsubclavian (TS)) approaches. The main advantages of TAVI procedures include the avoidance of cardiopulomonary bypass and aortic cross clamping as well as the possibility to perform the procedure without general anesthesia in case of a transfemoral approach.

Since long-term results comparable with those available for surgical AVR have not been gathered so far, TAVI is currently restricted to non-operable and surgical high-risk patients [4]. The risk evaluation is based on standardized scoring systems, such as the STS score [5] or the EuroScore [6]. However, both scoring systems have been standardized for conventional surgical procedures and are not validated to predict the procedural outcome and mortality after TAVI. Therefore this kind of procedural allocation based exclusively on surgical risk scores is likely to fall short of valid outcome prediction in case of TAVI.

Furthermore the decision on a TA vs. TF approach, currently representing the two predominant TAVI approaches, is often driven by a rather subjective, non-standardized evaluation of an underlying vascular disease. As there is continuously growing experience on the advantages and drawbacks of either major TAVI approach [7], the process of patient evaluation as well as the overall outcome after TAVI might profit from the application of more specific, patient- and approach-related outcome predictors as primary evaluation parameters. In the current study we therefore aimed at evaluating specific parameters, such as indicators of a difficult intracardiac anatomy as potential outcome predictors in patients undergoing TA-TAVI. In this context data have already been provided for example regarding the impact of total aortic calcification burden on mortality after TAVI [8]. Unlike other recent studies evaluating the early outcome after TA-TAVI [9] we did not compare different transcatheter valve systems but focused on the impact of patient related parameters.

## Methods

### Characteristics of the study and main objective

This is a single center cohort study (University Heart Center Rostock, Germany). The aim of the current study was to isolate patient- and approach-related predictors of adverse procedural outcome in terms of limited device success and early mortality following transapical TAVI.

### Study population

Sixty consecutive patients treated by a TA-TAVI procedure after heart team consent on a high surgical risk (EuroScorelog ≥ 20 or porcelain aorta) between January 2010 and November 2011were included into the analysis.

### Data collection and endpoints

All procedural and clinical data as well as data on 30-day outcome were collected from the interventional and/or clinical protocols as well as the discharge letters and the letters from the hospitals/physicians responsible for the secondary care. In order to analyze for both, limited device success and an unfavorable early clinical outcome of TA-TAVI, three endpoints were defined: More than mild postoperative paravalvular leak (PVL), postoperative mean transvalvular gradient >14 mmHg assessed by transthoracic echocardiography and a composite endpoint of 30-day mortality, stroke and myocardial infarction. Two independent investigators quantified parameters describing the intracardiac anatomy by evaluation of preoperative multi-slice computed tomography (MSCT) examinations.

### Statistics

All data were stored and analyzed using the IBM® SPSS® Statistics 22.0. Data are expressed as frequencies/proportions (%) for categorical variables or as mean ± standard deviation (SD) for continuous variables. A logistic regression model was applied for the analysis to assess the independence of procedural outcome and early clinical outcome from predictors. Odds ratios (OR's) and the respective 95% confidence intervals (CI's) were calculated. The potential predictor variables for the primary univariate analysis were patient related, such as: male gender (vs. female), age ≥ 80 years (vs. <80 years), BMI ≥ 30 kg/m$^2$ (vs. <30 kg/m$^2$), obstructive pulmonary disease (COPD) (vs. none), presence of a chronic kidney disease ≥ stage 2 (glomerular filtration rate <60 ml/min/1.73 m$^2$) (vs. none or<stage 2) , history of stroke (vs. none), history of malignant tumor (vs. none), prior cardiac surgery (vs. none), frailty (according to the Johns Hopkins Frailty Criteria) (vs. none), preoperative NT-proBNP level <400 pg/ml (vs. ≥ 400 pg/ml), as well as parameters describing the valvular pathology and approach-related intracardiac anatomy such as more than moderate calcification of the ascending aorta (based on a semi-quantitative scoring of preoperative CT images) (vs. none or mild), diameter of the intraventricular septum ≥17 mm (vs. <17 mm) , LVOT-aorta angle <120° (vs. ≥ 120°) and left ventricular enddiastolic diameter ≥ 55mm (vs. <55 mm).

Statistical significance was assumed for p <0.05. Predictor candidates showing p <0.25 by univariate analysis entered a subsequent multivariate regression model, and the adjusted ORs (ORadj) with the respective p-values and CIs were calculated. Those candidates are referred to as predictors here, if they at least double (ORadj >2) or halve (ORadj <0.5) the risk, respectively.

## Results

### Baseline characteristics

All 60 patients were treated using the Edwards Sapien device. Baseline characteristics, as wells as patient-and approach-related risk factors are summarized in Table 1. Baseline data confirm the presence of a surgical high-risk cohort.

| | Frequency (proportion %)/mean ± SD |
|---|---|
| Sex category male | 30 (50%) |
| Age | 77.7 ± 6.3 |
| More than mild aortic calcification | 22 (43.1%) |
| Intraventricular septum ≥ 1.7 cm | 35 (68.6%) |
| LVEDD (mm) | 51.1 ± 9.5 |
| LVOT-aorta angle (°) | 132.2 ± 10.2 |
| NTproBNP | 7427.7 ± 11724.4 |
| COPD | 19 (31.7%) |
| Prior cardiac surgery | 9 (15%) |
| Chronic kideny disease >stage 2 | 33 (55%) |
| Prior malignancy | 8 (13.3%) |
| Prior stroke | 11 (18.3%) |
| BMI >=30 kg/m$^2$ | 20 (33.3%) |
| Frailty | 20 (33.3%) |

**Table 1:** Baseline characteristics of the patient cohort (N=60). Baseline characteristics of the study population. BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; LVEDD: Left Ventricular End Diastolic Diameter; LVOT: Left Ventricular Outflow Tract; SD: Standard Deviation.

## Predictors of more than mild paravalvular leak

The observed rate of more than mild paravalvular leak in the study cohort was 3.7%. Univariate logistic regression analysis was performed to assess the influence of patient and approach-related risk factors with more than mild postoperative paravalvular leak. The results of the univariate and subsequent multivariate analyses are displayed in Table 2. The presence of a BMI ≥ 30 (OR 2.57 95% CI 0.69-9.52; p=0.157) was found to double the risk in terms of postoperative PVL.

| | Univariate model | | | Multivariate model | | |
|---|---|---|---|---|---|---|
| Potential predictor variable | OR | 95% CI | p-value | $OR_{adjusted}$ | 95% CI | p-value |
| BMI ≥ 30 kg/m$^2$ | 2.76 | 0.76-10.1 | 0.124 | 2.57 | 0.69-9.52 | 0.157 |
| Chronic kidney disease > stage 2 | 1.95 | 0.64-5.95 | 0.241 | 1.77 | 0.57-5.55 | 0.327 |
| More than moderate aortic calcification | 1.72 | 0.53-5.66 | 0.369 | | | |
| Intraventricular Septum ≥ 17 mm | 1.58 | 0.47-5.35 | 0.459 | | | |
| LVEDD > 55 mm | 1.42 | 0.37-5.47 | 0.613 | | | |
| Prior Cardiac Surgery | 1.33 | 0.31-6.03 | 0.709 | | | |
| COPD | 1.25 | 0.38-4.12 | 0.714 | | | |
| Frailty | 1.23 | 0.39-3.85 | 0.721 | | | |
| Prior Malignancy | 1.31 | 0.22-7.87 | 0.768 | | | |
| Male Sex | 1.17 | 0.39-3.49 | 0.78 | | | |
| Pre OP NTproBNP <400 pg/ml | 1.38 | 0.12-16.3 | 0.798 | | | |
| Age ≥ 80 years | 1.09 | 0.36-3.27 | 0.876 | | | |
| LVOT-aortic angle<120° | 1.1 | 0.25-4.76 | 0.898 | | | |
| Prior Stroke | 1.06 | 0.26-4.31 | 0.936 | | | |

**Table 2:** Predictors of more than mild paravalvular leak (Logistic Regression Analysis). BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; LVEDD: Left Ventricular End Diastolic Diameter; LVOT: Left Ventricular Outflow Tract; SD: Standard Deviation.

## Predictors of an unfavorable postoperative gradient

The observed mean postoperative transvalvular gradient was 12.1 ± 5.5 mmHg. Regression analysis suggests associations of two patient and approach-related risk factors with unfavorable (mean gradient >14 mmHg) postoperative gradients (Table 3). A BMI ≥ 30 (OR 2.32 95% CI 0.57-9.45, p=0.242), as well as a preoperative NT-proBNP level <400 pg/ml (OR 5.15 95% CI 0.32-81.9, p=0.246) predicted a trend towards a mean postoperative gradient beyond 14 mmHg, however without reaching statistical significance. In contrast male gender (OR 0.50 95% CI 0.13-1.91, p=0.309) and the presence of COPD (OR 0.45, 95% CI 0.10-2-13, p=0.315) were found to be associated with a decreased risk of elevated postoperative gradients.

| | Univariate model | | | Multivariate model | | |
|---|---|---|---|---|---|---|
| Potential predictor variable | OR | 95%-CI | p-value | OR | 95%-CI | p-value |
| Male Sex | 2.64 | 0.75-9.31 | 0.131 | 2.01 | 0.52-7.76 | 0.309 |
| Pre OP NTproBNP <400 pg/ml | 4.77 | 0.40-57.31 | 0.218 | 5.15 | 0.32-81.9 | 0.246 |
| BMI ≥ 30 kg/m$^2$ | 2.23 | 0.6-8.28 | 0.231 | 2.32 | 0.57-9.45 | 0.242 |
| Intraventricular Septum ≥ 17 m | 2.22 | 0.51-9.79 | 0.291 | | | |
| LVEDD ≥ 55 mm | 2.05 | 0.51-8.12 | 0.309 | | | |
| Chronic kideny disease > stage 2 | 1.75 | 0.52-5.83 | 0.365 | | | |
| Prior Stroke | 1.87 | 0.43-8.19 | 0.408 | | | |
| Frailty | 1.56 | 0.46-5.29 | 0.479 | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Prior Malignancy | 2.07 | 0.21-20.19 | 0.532 | | | |
| LVOT-aortic angle <120° | 1.38 | 0.24-7.93 | 0.722 | | | |
| Age ≥ 80 years | 1.21 | 0.36-4.02 | 0.756 | | | |
| More than moderate aortic calcification | 1.22 | 0.32-4.63 | 0.766 | | | |

**Table 3:** Predictors of unfavorable post-procedural transvalvular gradients (Logistic regression analysis). BMI: Body Mass Index; LVEDD: Left Ventricular End Diastolic Diameter; LVOT: Left Ventricular Outflow Tract; SD: Standard Deviation.

### Predictors of 30-day mortality, stroke and myocardial infarction

The total event rate in terms of the composite endpoint (30-day mortality, stroke and myocardial infarction) was 13.6%. Patient and approach-related predictors for poor early postoperative outcome according to the defined composite endpoint were investigated (Table 4). Of all analyzed parameters only male gender (OR 5.88 95% CI 0.50-69.6, p=0.160) as well as a steep LVOT-aorta angle <120° (OR 6.65 95% CI 0.93-47.4, p=0.059) were found to influence the risk for an unfavorable early postoperative outcome, however with only the latter one coming close to statistical significance.

| | Univariate model | | | Multivariate model | | |
|---|---|---|---|---|---|---|
| Potential predictor variables | OR | 95%-CI | p-value | OR | 95%-CI | p-value |
| Male Sex | 9.23 | 1.06-80.60 | 0.044 | 5.88 | 0.50-69.63 | 0.16 |
| LVOT aortic angle < 120° | 5.29 | 0.88-31.74 | 0.069 | 6.65 | 0.93-47.36 | 0.059 |
| Frailty | 4.16 | 0.47-36.43 | 0.198 | 1.65 | 0.12-22.6 | 0.706 |
| COPD | 2.4 | 0.53-10.88 | 0.256 | | | |
| Intraventricular Septum ≥ 17 mm | 2.33 | 0.25-21.89 | 0.458 | | | |
| Prior Stroke | 1.56 | 0.27-9.00 | 0.622 | | | |
| Chronic kideny disease > stage 2 | 1.48 | 0.32-6.87 | 0.615 | | | |
| More than moderate aortic calcification | 1.52 | 0.25-9.19 | 0.648 | | | |
| Prior Cardiac Surgery | 1.3 | 0.14-12.08 | 0.816 | | | |
| BMI ≥ 30 kg/m$^2$ | 1.2 | 0.26-5.63 | 0.817 | | | |
| Age ≥ 80 years | 1.31 | 0.25-5.63 | 0.877 | | | |
| Prior Malignancy | 1.11 | 0.12-10.48 | 0.925 | | | |

**Table 4:** Predictors of the composite outcome; 30-day mortality. stroke. myocardial infarction (Logistic Regression analysis). BMI: Body Mass Index; LVEDD: Left Ventricular End Diastolic Diameter; LVOT: Left Ventricular Outflow Tract; SD: Standard Deviation.

## Discussion

After several years of transcatheter aortic valve therapy there is growing evidence that standardized risk scores, for example the logistic EuroScore and the STS-score-utilized to evaluate patients prior an aortic valve procedure are limited in terms of predicting the early procedural and clinical outcome following TAVI [10].

The current study provides evidence, that specific approach-related outcome predictors, such as parameters reflecting the intracardiac anatomy, might be able to predict procedural and early clinical outcome following TA-TAVI more accurately than risk scores standardized for conventional AVR alone.

The EuroScore failed to predict outcome following TAVI in the SOURCE Registry [11]. Additionally, the EuroScore overestimates the periprocedural risk even for conventional surgery [12]. Although the STS score has been shown to outperform the logistic EuroScore as well as the new EuroScore 2 in terms of predicting long and short-term survival following TAVI [13,14], it recently failed to predict in 30-day mortality after TAVI [10]. Altogether, there is currently no scoring system available predicting specifically the procedural outcome and early survival following TAVI and patient selection still relies on the application risk scores standardized for conventional AVR.

However in the modern era of aortic valve therapy patient evaluation prior TAVI should specifically predict clinical outcome and the chance of device success according to the VARC criteria [15] -i.e. excellent valve performance with no paravalvular leak and low gradients - in every single patient. This seems of outstanding importance, especially when evaluating patients exhibiting a

"borderline" risk, which could be candidates for either a transcatheter or a conventional procedure.

The current study was designed to provide evidence, that specific patient and approach-related parameters are capable to predict the early outcome and valve performance following TA-TAVI.

Although obtained from a rather small cohort, our results are applicable to everyday clinical decisions, as they derive from a real-life scenario, utilizing the most common valve type (Edwards Sapien) for the TA approach.

From all analyzed parameters especially a steep LVOT-aorta angle, reflecting a rather difficult intracardiac anatomy for the TA approach, was found to predict unfavorable early clinical outcome. Interestingly, for example preoperative frailty did not predict early mortality in a comparable extent. This finding is in line with the underlying hypothesis that specific approach-related parameters might outperform a rather global risk categorization in terms of outcome prediction after TA-TAVI. Besides the LVOT-aorta angle, obviously representing a key anatomic parameter in TA procedures, for example the calcification of the device landing zone has been shown to predict unfavorable procedural outcome in terms of paravalvular leak [16] and postoperative pacemaker dependency [17]. Similarly, the total aortic calcification burden has been recently described as an integrative predictor of mortality after TAVI [8]. However, since the importance of these variables has already been demonstrated, we did not include them in the current analysis.

Another potentially relevant patient related parameter for outcome prediction after TA-TAVI elaborated by our study is serious obesity reflected by the BMI. Limited device success following a TA procedure characterized by a more than mild PVL or elevated postoperative gradients was predicted by serious obesity, obviously representing a possibly complicating factor of a TA approach. However, as others [18], we did not find an association of obesity and worse clinical outcome after TA TAVI.

The association between a low preoperative NT-proBNP level and elevated postoperative gradients is not so obvious. However, it is conceivable to estimate that patient exhibiting a rather good preoperative LV function reflected by a low NT-proBNP level might be more prone to generate higher postoperative gradients after TAVI. On the other hand plasma B-type natriuretic peptide has been identified previously as a predictor of all-cause mortality after TAVI [19].

Accordingly, the demonstrated association of male gender and the presence of COPD with a decreased risk of elevated postoperative gradients cannot be explained definitely from the current data, although it seems at least plausible to hypothesize that both patient subgroups are probably more likely to receive a larger prosthesis thereby decreasing the risk of elevated post-procedural gradients.

After decades of experience the integration of approach-related parameters represents a mainstay of patient evaluation for conventional cardiac surgery. The growing experience in transcatheter aortic valve therapy should lead to the integration of similar parameters also into the evaluation process for TAVI procedures. This kind of integration should support the further development of new risk scores, such as the recently proposed TAVI2-SCORe [20] designed specifically for the evaluation of candidate patients for TAVI.

We strongly believe, that the effort of implementing dedicated patient- and approach-related parameters within the algorithm of patient evaluation prior TAVI procedures is worthwhile, since it has become increasingly clear that the common calculation of surgical risk alone is unsatisfactory for an elaborated patient and approach selection prior TAVI.

In conclusion the current analysis provides additional evidence that the integration of specific patient- and approach-related parameters such as the LVOT-aorta angle into the preoperative patient evaluation would most likely improve outcome prediction of patients undergoing TAVI procedures. However, the analysis of larger patient cohorts is mandatory in order to consolidate this preliminary evidence.

## Limitations

This is a pilot study from an ongoing single-center TAVI registry, including a cohort of 60 patients. The study was designed with the objective to provide sufficient preliminary evidence in order to prepare the ground for subsequent larger studies validating specific predictors. The focus here was on descriptive statistics and estimations, and our study results may rather indicate whether an impact of the investigated predictor candidates is to be expected or not. Since pilot studies are usually underpowered, all results of no statistical significance are to be interpreted in a strictly explorative way.

## Conflict of Interest

Author declare no conflict of interest.

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