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## **The impact of post-procedural complications on reimbursement, length of stay and mechanical ventilation among patients undergoing transcatheter aortic valve implantation in Germany**

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## Abstract

**Background:** The impact of various post-procedural complications after transcatheter aortic valve implantation (TAVI) on resource use and their consequences in the German reimbursement system has still not been properly quantified.

**Methods:** In a retrospective observational study, we use data from the German DRG statistic on patient characteristics and in-hospital outcomes of all isolated TAVI procedures in 2013 (N=9147). The impact of post-procedural complications on reimbursement, length of stay and mechanical ventilation was analyzed using both unadjusted and risk-adjusted linear and logistic regression analyses.

**Results:** A total of 235 (2.57%) strokes, 583 (6.37%) bleeding events, 474 (5.18%) cases of acute kidney injury and 1,428 (15.61%) pacemaker implantations were documented. The predicted reimbursement of an uncomplicated TAVI procedure was €33,272, and bleeding events were associated with highest additional reimbursement (€12,839,  $p < 0.001$ ), extra length of stay (14.58 days,  $p < 0.001$ ), and increased likelihood of mechanical ventilation for more than 48 hours (OR 17.91,  $p < 0.001$ ). A more moderate complication-related impact on resource use and reimbursement was found for acute kidney injury (additional reimbursement: €5,963,  $p < 0.001$ ; extra length of stay: 7.92 days,  $p < 0.001$ ; ventilation >48h: OR 6.93,  $p < 0.001$ ) as well as for stroke (additional reimbursement: €4,125,  $p < 0.001$ ; extra length of stay: 4.68 days,  $p < 0.001$ ; ventilation >48h: OR 5.73,  $p < 0.001$ ). Pacemaker implantations, in contrast, were associated with comparably small increases in reimbursement (€662,  $p = 0.006$ ) and length of stay (3.54 days,  $p = 0.006$ ) and no impaired likelihood of mechanical ventilation more than 48 hours (OR 1.22,  $p = 0.156$ ). Interestingly, these complication-related consequences remain mostly unchanged after baseline risk-adjustment.

**Conclusions:** Post procedural complications such as bleeding events, acute kidney injuries and strokes are associated with increased resource use and substantial amounts of additional reimbursement in Germany, which has important implications for decision making outside of the usual clinical sphere.

**Keywords:** post-procedural complications, TAVR, transcatheter aortic valve replacement, excess costs, reimbursement, resource use

**JEL codes:** C01, I10

## Introduction

Degenerative aortic valve stenosis is a common heart defect among elderly patients and causes significant morbidity and mortality in this group. For a long time, the most effective therapy has been surgical aortic valve replacement (SAVR). Over the last decade, the introduction of transcatheter aortic valve replacement (TAVR) has added a valuable alternate therapeutic option [1].

Evidence for the cost-effectiveness of TAVR generally agrees that TAVR is competitive compared to standard medical therapy, with multiple studies finding the cost–benefit ratio of TAVR to be within the acceptable range for the healthcare systems examined [2–5], with one notable exception from Belgium [6]. Comparisons of TAVR and SAVR have been less conclusive, possibly due at least in part to a lack of strong clinical data underpinning the analyses, since accurate published cost data for TAVR procedures is somewhat limited due to difficulties in collecting data from most systems [7].

For TAVR procedures performed in Germany, it has previously been shown that bleeding complications are associated with increased resource use and in-hospital costs in a real-life cohort of patients [8], and complication-induced additional costs of patients undergoing TAVR were analyzed in a prospective observational study of 163 consecutive cases [7].

This latest study uses statistical and costing data from the German universal healthcare system and the German Federal Statistical Office to further improve our understanding of the economics of clinical TAVR practice. Under the German universal healthcare system, hospitals are reimbursed on the basis of a fee paid out according to the diagnosis under the German Diagnosis Related Groups (G-DRG) system. Fees are adjusted yearly based on expenditure data from a sample group of German hospitals and are subject to continuous calibration to accurately reimburse cost [9–14]. These databases represent a valuable source of national-level health economic data that has been used previously to examine other disorders [15, 16]. The data is highly detailed and includes a wide range of patient characteristics and preexisting conditions, which we have included in our analysis.

Using data from these sources on TAVI procedures performed in Germany in the year 2013 (N=9147), we examine the impact of clinical complications on reimbursement, length of stay, the likelihood of ventilation>48h, and the time of ventilation among ventilated patients >48h.

## Methods

### Data source

Since the introduction of a diagnosis and procedure-related remuneration system (German Diagnosis Related Groups, G-DRG system) in Germany in 2003 it is mandatory for all hospitals to transfer patient data on diagnoses, co-morbidities and procedures to the Institute for the Hospital Remuneration System (InEK). These data therefore include all procedures performed in German hospitals. Coding guidelines and annual adaptations by the German Institute for Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI; Cologne, Germany; <http://www.dimdi.de>) ensure uniform documentation. Diagnoses are coded according to the German Modification of the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10-GM). Similar to the ICD-classification, endovascular and surgical procedures have to be coded according to the German Operation and Procedure Classification (OPS). As described previously [1, 17], we were able to use the OPS codes (OPS codes: 5-35a.0 in 2007 and 5-35a.00, 5-35a.01 from 2008) to identify all TAVI patients relevant for our analysis. The logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation [18]) was calculated with the available information (age, gender, admission status and the ICD codes of comorbidities obtained from the Federal Bureau of Statistics), but critical preoperative state and left ventricular function were not available and were assumed as inconspicuous state (i.e. no critical preoperative state and no left ventricular dysfunction). Thus, we calculated a best-case scenario for the EuroSCORE. Patients with a baseline diagnosis of pure aortic regurgitation and those with concomitant cardiac surgery or percutaneous coronary intervention were not included in this analysis.

Bleeding was defined as requiring more than 5 units of red blood cells (RBC) for admission. For all other comorbidities and complications the existing anamnestic or acute distinctive codes were used (we have discussed OPS and ICD codes in greater detail in a previous paper [1, 17]).

Overall, we found and analyzed a total of 9,247 records of in-hospital data for isolated TAVI cases in 2013. It should be noted that these are not exclusive patient- but case-based records, so a single patient may have had multiple admissions and procedures. However, these data do include all isolated TAVI procedures in German hospitals in 2013.

### **Statistics**

The impact of post-procedural complications was analyzed with respect to the endpoints reimbursement, length of hospital stay and time of mechanical ventilation. Due to the fact that the time of mechanical ventilation was equal to zero for a considerable number of records this variable was split into a dichotomous variable ‘probability of ventilation more than 48 hours’ and a continuous variable ‘time of ventilation among those patients ventilated more than 48 hours’. In a first step, unadjusted regression analyses are carried out to assess the impact of post-procedural complications with respect to the different endpoints. Logistic and linear regression analyses are applied for dichotomous and continuous endpoints, respectively. Next, baseline risk adjustment was applied by adding all available pre-procedural patient characteristics (as defined by Reinöhl et al. [1]) as confounders.

All regression results are available in Appendix Table 1. All analyses were carried out using Stata 13.1 (StataCorp, College Station, Texas, USA).

## **Results**

In 2013, a total of 9,147 TAVI procedures were performed in Germany. Please note that these patient numbers are the result of a steadily increasing number of TAVI procedures in Germany (starting from 144 procedures in 2007) [1]. Over these 9,147 TAVI procedures, a total of 235 (2.57%) strokes, 583

(6.37%) bleeding events, 474 (5.18%) cases of acute kidney injury and 1428 (15.61%) pacemaker implantations were recorded (see Table 2). Average reimbursement was € 34,611, average length of hospitalization was 17.04 days, and a total of 482 patients (5.27%) needed to be mechanically ventilated for more than 48 hours. Among patients ventilated more than 48 hours, the average ventilation time was 293 hours.

### **Post-procedural complications and reimbursement**

As shown in Table 3, post-procedural complications are associated with additional reimbursement. Leaving differences in baseline characteristics aside (see 'unadjusted extra reimbursement' in Table 3), bleeding events are associated with the highest additional reimbursement (€12,839,  $p < 0.001$ ), followed by cases of acute kidney injury (€5963,  $p < 0.001$ ), stroke (€4,125,  $p < 0.001$ ), and pacemaker implantations (€662,  $p = 0.006$ ). The impact of these complications also remains mostly unchanged after adjustment for baseline characteristics. The impact of stroke, for instance, decreases by 6% to €3,880 after adjustment but remains significant ( $p < 0.001$ ). In contrast to the unadjusted estimates, these €3,880 may be interpreted as being independent from individual baseline risk factors. Interestingly, most of the baseline characteristics used for adjustment showed to be of high relevance for reimbursement. Reimbursement, for instance, was increased by age, high EuroSCORE values, male gender, poor heart function (NYHA III or IV), hypertension and records of atrial fibrillation (see Table S1).

### **Post-procedural complications and length of hospital stay**

The unadjusted increase in length of stay is highest for bleeding events (14.58 days,  $p < 0.001$ ) followed by cases of acute kidney injury (7.92 days,  $p < 0.001$ ), stroke (4.68 days,  $p < 0.001$ ), and pacemaker implantations (3.54 days,  $p = 0.006$ ). Again, these values decrease slightly after adjustment for baseline characteristics but remain significant ( $p < 0.001$ , see Table S2).

### **Post-procedural complications and mechanical ventilation**

The likelihood of mechanical ventilation for more than 48 hours is increased after bleeding events (OR 17.91,  $p < 0.001$ ), acute kidney injury (OR 6.93,  $p < 0.001$ ) and stroke (OR 5.73,  $p < 0.001$ ), but not for patients receiving pacemaker implantation (OR 1.22,  $p = 0.156$ ). Again, these values decrease slightly after adjustment for baseline characteristics (see Table 3 and Table S3). Among this highly selective risk group of patients undergoing mechanical ventilation more than 48 hours, bleeding complications are still associated with the longest episodes of mechanical ventilation (236.08 hours,  $p < 0.001$ ), followed by stroke (139.61 hours,  $p = 0.009$ ), and acute kidney injury (48.36 hours,  $p = 0.132$ ).

## Discussion

In Germany, DRGs are defined by the patients' diagnoses, gender and age, treatment procedures, complications or comorbidities, and further attributes. Based on this data, a predetermined reimbursement rate per case is calculated [19]. For long-stay outlier cases, however, hospitals receive additional reimbursement for every day that the patient stays above the upper length of the stay threshold [20]. Furthermore, additional reimbursement is possible in case of very complex intensive care treatments, which have to be proven by documentation of illness severity and treatment effort during ICU stay [21]. Although we cannot determine which of the above named factors led to additional reimbursement, the present study provides reimbursement details and the most relevant post-procedural complications for TAVI procedures performed in Germany in the year 2013. As shown in Table S1, the predicted reimbursement of an uncomplicated TAVI procedure was €33,272. In contrast, a previous study from our group calculated the predicted cost of an uncomplicated TF-TAVI procedure at €34,351, which would indicate reimbursement almost covering the cost of treatment for these patients [7]. This is perhaps unsurprising given the design of the German DRG system and its use of empirical data to validate and adjust the value on an annual basis.

Overall, our results correspond to evidence from the literature. We previously identified life threatening non-access site bleeding (€47,494) and stage 3 Acute kidney injury (€20,468) as having the most substantial impact on hospital costs [7]. Moreover, the study results indicate that the



additional costs of complications are predominantly found within the ICU costs, which is most likely attributable to the complexity of the case and the severity and timing of complications [7].

Finally, we believe that a particular point of interest from our findings is the differentiation between reimbursement, length of hospital stay and mechanical ventilation. These data are rarely presented and we consider the results to be of special relevance to economic modelling analyses set in Germany, where the various outcomes of our study may be used as inputs [2–6, 22].

Our study has several limitations, beyond those normally associated with a retrospective analysis [1]. First, it is based on administrative data. As a consequence, coding errors are inevitable. Second, post-procedural complications are recorded in little detail. As stated before, we used the available diagnostic and procedural codes for acute and chronic conditions (OPS and ICD-10-GM as discussed in greater detail in a previous paper [1, 17]). Other studies were able to categorize complications according to the latest definitions by the valve academic research consortium (VARC-2) [7, 23], which is far more detailed and makes our results not directly comparable for some dimensions. Third, the timing of post-procedural complications is not available from the dataset. Therefore, the presented results may be subject to time-dependent bias.

Overall our study accurately shows reimbursement, length of hospital stay and mechanical ventilation after TAVI procedures and the consequences of pre-determined and relatively well-defined post-procedural complications. We have also demonstrated that the consequences of these complications are substantial from the payer's perspective, which has important implications for decision making outside of the usual clinical sphere.

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