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Cost-comparison of third generation transcatheter aortic valve implantation (TAVI) devices in the German Health Care System☆

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has a substantial impact on daily cardiovascular care delivery based on issues such as cost effectiveness and economic value within a restricted health care budget. Until now, potential financial benefits of third generation valve models have not been evaluated in a real-world setting.

Methods and results: We identified 204 eligible patients (Jan 2014-Sep 2016) who either received the balloon-expandable Edwards Sapien 3 (ES3) or the self-expandable Medtronic Evolut R (MER). Baseline information, procedural characteristics, 30-day outcome as well as in-hospital costs and reimbursement were collected and analyzed. The major cost driver was initial valve-kit costs with a significantly higher amount in the ES3 group, which was set at 0 with the lower price (ES3/MER: +4390.0€ ± 3.807.0 vs. 0.0€ ± 734.1; $p < 0.01$). However, initial valve-kit costs were balanced by additional material costs in the MER cohort. Overall costs did not differ significantly between valve models (ES3/MER: x + 13.808.0€ ± 5.595.0 vs. x + 10.681.0€ ± 4.518.0; $p = 0.6885$) and reimbursement was moderate (ES3/MER: 1.649.7€ vs. 4776.7€).

Conclusion: Quality, success rate, and costs were comparable between third generation devices. Initial valve-kit costs were significantly higher in the ES3 group, whereas overall costs did not significantly differ between the two valve types.

1. Introduction

Aortic valve stenosis (AS) is the most common valvular heart disease in western countries with increasing prevalence [1]. Since its introduction in 2002, a paradigm shift in the management of severe AS has occurred. Currently, TAVI emerges as the treatment option of choice in high risk patients and even shows favorable outcome in an intermediate risk collective [2–4]. It is suggested that the number of implanting procedures will increase 4-fold in the next decade. Therefore, TAVI already has and will have a substantial impact on daily cardiovascular care delivery, which also raises issues like cost effectiveness and economic value within a restricted health care budget.

Technological advancements like retrievable valves, smaller sheath sizes, and new skirt techniques to prevent paravalvular leakage promise outcome optimization as well as cost effectiveness [5]. But until now there was lack of a direct cost comparison between the two market-leading devices (the balloon-expandable Edwards Sapien 3 [ES3] and the self-expandable Medtronic Evolut R [MER]) in a real-world setting. Reimbursement compared with costs is a discussion TAVI centers regularly conduct with their administration and centers are eagerly awaiting data. Therefore, we analyzed all up-coming costs during TAVI procedure–associated in-hospital stays in comparison with the leading third generation valve models at our center.

2. Methods

2.1. Study population

Between January 2014 and September 2016, 465 transfemoral TAVI procedures were performed at the Heart Center Düsseldorf. The study population consisted of 204 patients who underwent transfemoral TAVI with either the balloon-expandable third generation

Abbreviations: AS, aortic stenosis; EuroSCORE, European System for Cardiac Operative Risk Evaluation; ES3, Edwards Sapien 3; G-DRG, German-Diagnosis Related Groups; ICU, intensive care unit; IMC, intermediate care unit; MER, Medtronic Evolut R; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium.

☆ ***Clinical Trial Registration***—URL: http://www.clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/NCT01805739.

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[1] These authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation and should be considered equally. The authors have no conflict of interest to declare for this article.

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Edwards system (ES3; Edwards Lifesciences, Irvine, CA) or the third generation self-expandable Medtronic Evolut-R system (MER; Medtronic Inc., Minneapolis, MN). Patients with devices not mentioned above (e.g., Edwards Sapien XT, second generation CoreValve) and TAVI in preexisting surgical valves (planned valve-in-valve-procedures) were excluded from the study. Furthermore, the first 20 patients in each cohort were excluded to guarantee comparable learning curves without influencing the procedure and outcome. TAVI with ES3 began in 2014, but MER was first available in 2015; therefore, all second generation CoreValve and the still available CoreValve 31 mm were excluded from the study, resulting in the large difference of included (n = 204) and performed (n = 465) procedures. All transfemoral TAVI procedures were performed according to current guidelines. Best practice was strictly adhered to and all procedures were carried out with local anesthesia. A modified CONSORT flow chart (Fig. 1) gives an overview of patient population, selection process, and data analysis.

All patients provided written informed consent for TAVI and the use of clinical, procedural, and follow-up data for research. The study procedures were in accordance with the Declaration of Helsinki and the institutional Ethics Committee of the Heinrich-Heine University approved the study protocol (4080). The study is registered at clinical trials (NCT01805739).

2.2. Statistical analysis

The collected data included patient characteristics, imaging findings, periprocedural in-hospital data, and laboratory results. Clinical endpoints were reported according to the Valve Academic Research Consortium (VARC-2) consensus statement [6]. Continuous data were tested for normal distribution via Kolmogorov-Smirnov/Shapiro-Wilks test, were expressed as the mean and standard deviation, and were compared using Student's *t*-test for paired data. Categorical variables were described by the frequencies and percentages. Data analysis was performed using the statistical software GraphPad 6.0 (Prism®). All statistical tests were 2-tailed, and a value of $p < 0.05$ was considered statistically significant. General and detailed additional costs are presented as proportions of total costs with averaged calculations to preserve comparability. Costs were subdivided into categories (Table 1) based on valve-kit costs, general in-hospital costs, and additional material costs. To achieve better comparability, additional costs caused by individual patients were analyzed according to predefined subgroups (ES3 vs. MER) and displayed as a share of averaged overall costs.

2.3. Cost regulation in the German Health Care System

Since 2003, medical procedures are reimbursed as flat rates per case in the German-Diagnosis Related Groups (G-DRG) system. A yearly readjusted base rate determines an appointed amount as reimbursement for rendered services by the hospital. G-DRGs are fixed for all procedures and do not necessarily reimburse all costs. Reimbursement for TAVI procedures between 2014 and 2016 by the G-DRG system guaranteed an average refund between 33.172.7€ and 33.313.9€ for each transfemoral implanting procedure and all resulting costs. However, reimbursement was strongly adjusted towards decreasing refund since 2016.

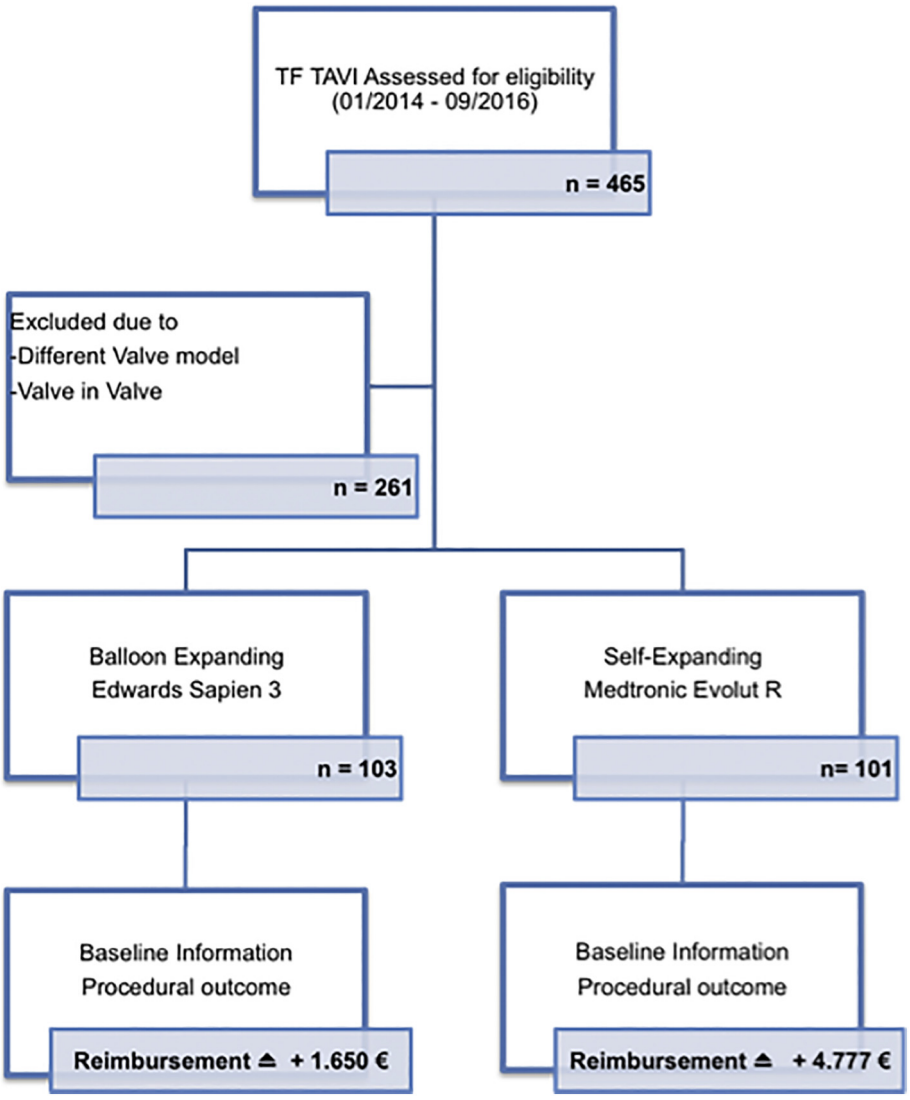

Fig. 1. Modified CONSORT Flow Diagram. Patients with different valve models (e.g., Edwards Sapien XT, second generation CoreValve) and TAVI in preexisting surgical valves (planned valve-in-valve-procedures) were excluded. TAVI with ES3 started in 2014, but MER was first available in 2015, so all second generation CoreValve and the still available CoreValve 31 mm were excluded from the study, resulting in the sizable difference of included (n = 204) and performed (n = 465) procedures.

Table 1
Overview of cost definitions.

Valve-kit costs	General in-hospital costs	Additional material costs
Initial material investment, i.e., valve and provided kit by the manufacturer with balloons, loading device, delivery catheters, sheaths, etc.	Summation of costs caused by general ward, intermediate care, and intensive care unit stay	All additional material costs, including balloons, wires, and sheaths not initially provided by the manufacturer and material/resources for complication management

3. Theory/calculation

Technological advancements like retrievable valves, smaller sheath sizes, and new skirt techniques to prevent paravalvular leakage promise outcome optimization as well as cost effectiveness. Until now, potential financial benefits of third generation valve models have not been evaluated in a real-world setting. Therefore, we analyzed all up-coming costs during TAVI-associated in-hospital stay in comparison with the leading third generation valve models. Quality, success rate, and costs were comparable between third generation devices. Initial valve-kit costs were significantly higher in the ES3 group, whereas overall costs did not significantly differ between the two valve types. Reimbursement was moderate for this complex procedure.

4. Results

4.1. Baseline characteristics

Baseline characteristics significantly differed between groups regarding sex (ES3/MER: female 44.4% vs. 77.0%; $p < 0.01$), body mass index (ES3/MER: 28.1 ± 5.2 vs. 25.8 ± 5.3; $p < 0.01$), aortic valve area (ES3/MER: 0.79 ± 0.22 cm^2 vs. 0.70 ± 0.18 cm^2; $p < 0.01$) and logistic EuroSCORE I (ES3/MER: 26.8 ± 17.5% vs. 32.2 ± 18.8%; $p = 0.03$). For further baseline information and functional data please see Supplementary material Table 1.

4.2. Procedural characteristics

There were 103 patients who underwent TAVI with the balloon-expandable third generation ES3 and 101 patients received the retrievable self-expandable MER. Due to annulus anatomy and different sizing recommendations (area vs. perimeter and oversizing vs. 1:1 sizing), distribution of valve sizes significantly differed between groups. Additionally, implantation procedure duration (defined as time period each patient spends in the hybrid operating suite) was shorter in patients receiving ES3 compared with MER (100.8 ± 28.6 min vs. 111.0 ± 29.2 min, respectively; $p = 0.01$). Further procedural characteristics and outcome data are listed in Supplementary material Table 2.

4.3. Outcome characteristics

Overall all-cause 30-day mortality was 4.4% (ES3/MER: 3.9% vs. 5.0%; $p = 0.7$); major vascular complications defined by VARC-2-criteria occurred in 2.9% cases (ES3/MER: 3.9% vs. 2.0%; $p = 0.4$). Acute kidney injury was observed in cumulative 10.7% of all patients; five patients (2.4%) needed dialysis during their hospital stay. Strongly reduced GFR < 30 ml/min did not differ significantly between groups (ES3/MER: 1.0% vs. 1.0%; $p = 0.6$). Myocardial infarction after TAVI occurred in 0.9%. New onset of atrial fibrillation was seen in 2.9% of the whole study population. ICU (Intensive and Intermediate Care Unit) length of stay was 4.1 ± 5.2 days in the ES3 group and 5.0 ± 5.2 days in the MER group ($p = 0.2$). Total length of stay did not differ significantly between groups (ES3/MER: 14.9 ± 8.8 days vs. 16.3 ± 9.5 days; $p = 0.2$). Notably, pacemaker implantation rate after TAVI did not differ significantly between groups (ES3/MER: 4.8% vs. 10.0%; $p = 0.10$).

4.4. Detailed analysis of cost drivers

The major cost driver was initial material expenditure, mostly triggered through high valve-kit prices, with a significantly higher amount in the ES3 group. The lower valve-kit costs in the MER cohort were set at zero due to internal disclosure agreements and the resulting difference in the ES3 cohort is described as "+" (ES3/MER: +4.390.0€ ± 3.807.0 vs. 0.0€ ± 734.1; $p < 0.01$, Fig. 2A).

Additional material and associated costs like additional balloon use for pre- (ES3/MER: 0.0 ± 0.0 vs. 604.7€ ± 336.9; $p < 0.01$) and post-dilatation (0.0 ± 0.0 vs. 37.3€ ± 156.9; $p = 0.01$) were significantly higher in the MER group because this equipment is already integrated in the ES3 valve-kit by the manufacturer. In general, pre- and post-ballooning was less frequently applied in the ES3 cohort (pre-ballooning ES3/MER: 61.2% vs. 86.1%; $p < 0.01$ and post-ballooning ES3/MER 2.9% vs. 11.9%; $p = 0.01$, Fig. 2B). Bleeding costs were all driven by additional implantation of covered stent grafts (CSG) but in a more frequent number in ES3 patients (ES3/MER: 15.5% vs. 9.9%; $p = 0.3$) with associated higher costs (ES3/MER: 244.7€ ± 614.7 vs. 155.9€ ± 568.1; $p = 0.3$) without any statistical significance. Detailed sub-analysis offered no relation to previous dual antiplatelet therapy, oral anticoagulation or the existence of peripheral artery disease as a relevant risk factor for bleeding complications (data not shown).

Snaring was necessary in 3 (2.9%) cases of the MER group and added averaged additional costs of 11.1€ ± 66.5 to the amount of general costs. In one patient, this maneuver led to correct positioning of the valve and in the remaining cases, a second valve was implanted because of aortic valve prosthesis insufficiency. Currently, the use of a second valve replacement is exempt from charges by the manufacturer. If this practice changes in the future, it could have a financial impact if compensation is from the hospital.

Staff costs when included in the general in-hospital costs (Table 1, Table 2) only formed a small proportion of overall costs. Total working hours of the catheter laboratory team were 11.0 ± 2.8 h in the ES3 group and 11.2 ± 2.9 h in the MER group and did not contribute to a significant cost difference between groups (ES3/MER: 541.9€ ± 135.6 vs. 549.3€ ± 140.8; $p = 0.70$).

Overall ICU stay was not significantly compromised by complication management and did not differ between groups (ES3/MER: 4.1 ± 5.2 days vs. 5.0 ± 5.2 days; $p = 0.21$). Transfusion of packed red blood cell units did not differ significantly between groups. Total ICU/IMC costs contributed 2.522.0€ ± 3.451.0/1.790.0€ ± 1.856.0 in the ES3 and 2.459.0€ ± 3.144.0/2.152.0€ ± 2.155.0 in the MER cohort ($p = 0.89$ and $p = 0.19$, respectively) to the amount of total costs. A major cost driver regarding in-hospital stay was general ward habitation (ES3/MER: 4.040.0€ ± 2.899.0 vs. 4.246.0€ ± 2.584.0; $p = 0.59$) (Fig. 2C).

Taken together, total costs in the ES3 group added up to x + 13.808.0€ ± 5.595.0 with an applicable reimbursement of 1.649.7€ and to x + 10.681.0€ ± 4.518.0 with a refund of 4776.7€ in the MER cohort with no significant difference between groups ($p = 0.6885$) (Fig. 2D). Detailed information regarding periprocedural costs, in-hospital costs, and reimbursement can be obtained in Table 2.

5. Discussion and limitations

Due to demographic changes and superior results TAVI has emerged to be a considerable economic factor in our health care system, which is characterized by limited resources and restricted reimbursement. In regard to the implantation strategy, no precise cost comparison between leading third generation TAVI valves has been performed to date. Our study revealed that 1) a major cost driver is material expenditure with significantly higher valve-kit costs in ES3 group compared to

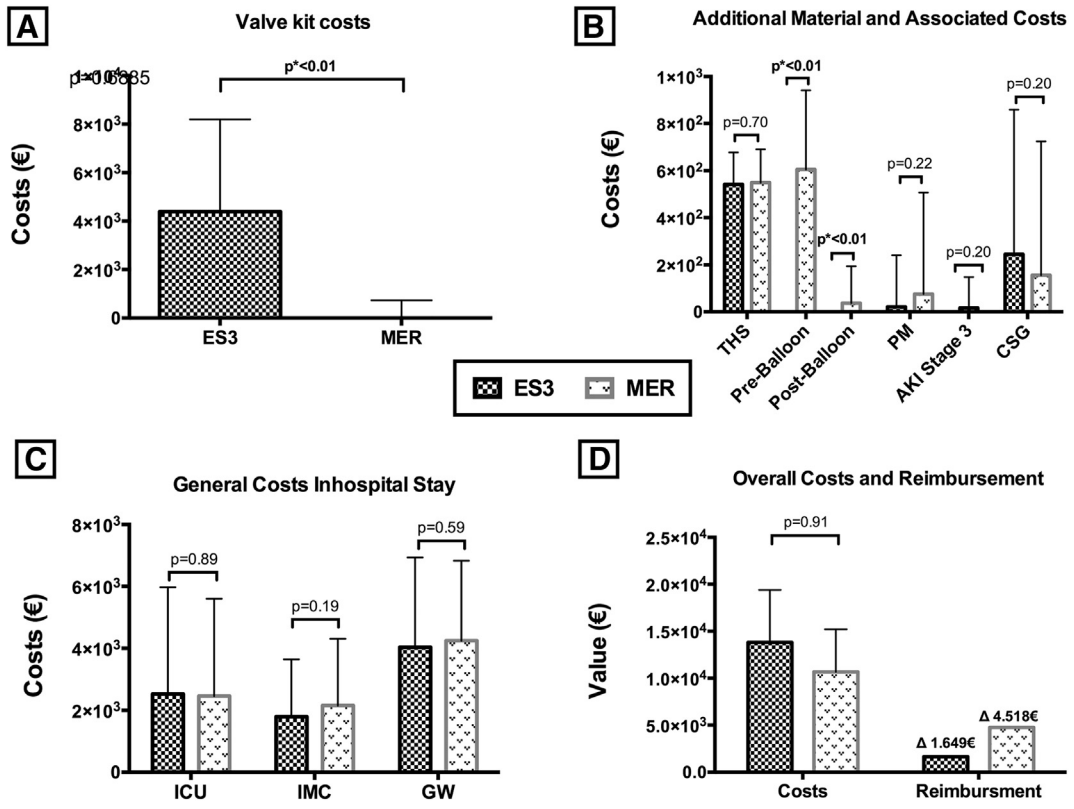

Fig. 2. Overview of selected cost proportions divided by groups. General and detailed additional costs are presented as proportions of total costs (2A–D). The lower valve-kit costs in the MER cohort were set at zero due to internal disclosure agreements and the resulting difference in the ES3 cohort is described as "+" (2A). Total costs (€): Valve kit price difference (x) + additive costs (2D). AKI Stage 3, Acute kidney injury stage 3; CSG, covered stent graft; IMC, intermediate care; PM, pacemaker; GW, general ward; ICU, intensive care unit; THS, total hospital stay.

MER; 2) additional material and associated costs are higher in the MER cohort; and as a result, 3) overall costs do not differ significantly between valve models. Overall reimbursement rate is moderate for this complex procedure and the implementation of potential cost saving strategies will be mandatory in the future.

5.1. Baseline characteristics

Baseline characteristics differed significantly regarding sex, body mass index, aortic valve area, and logistic EuroSCORE I. Even though risk stratification was different between compared subgroups, we did not observe a difference in mortality. This risk stratification tool is independently associated with frequently arising complications after TAVI [6–8]. Likewise, we did not observe a significant difference with an overall low incidence of complications in our study population.

5.2. Material costs

The primary reason for high expenditure was material costs with high valve-kit prices, which are solely determined by the manufacturer and differ worldwide. Whereas the initial monetary investment was significantly higher in the ES3 cohort, additional material costs in the MER group balanced overall costs between groups. Those cost proportions depended on the additional material used as well as the amount of initially provided material in the valve-kit, which did not add extra costs.

5.3. Complication management and associated costs

In general, we did not identify significant additional costs based on complication management as a well-known major cost driver. New generation valve models present the prospect of implantation procedure simplification and reduction of adverse events, which result in cost savings. Even though the clinical benefit of new devices is uncontroversial and discussed elsewhere [3,4], overall complication rates are low but still comparable to older valve models. In comparison to material costs, complication management only contributes a small share of total costs. Hence, expectations within the industry that technical advancement will significantly benefit cost reduction cannot indirectly be ascertained in our real-life cost analysis.

In our study baseline parameters, peri- and postprocedural findings are comparable to large registry findings. Notably, the rate of pacemaker implantation shows a trend in favor of ES3 but not a significant difference between groups. This trend is also reflected in current literature, which compares pacemaker implantation rates in described third generation valve models [9]. Reported rates for ES3 are around 12.6% [10] and 17.5% [2] for MER, respectively. Compared to older generation valve models, overall pacemaker implantation rate is already low in this study.

Acute kidney injury is a frequent complication after TAVI and with aggravating severity, a strong predictor for short-term mortality [11]. Regarding our cost analysis, acute kidney injury stage 3 was more often observed in the ES3 group (ES3/MER: 2.9% vs. 0.0%; $p = 0.08$), the need for dialysis did not differ significantly between groups as well as contrast media exposure, and renal function at was at baseline.

Overt bleeding events in TAVI patients are associated with increased resource use and in-hospital costs [12]. The implantation of peripheral covered stents occurred frequently in our study population and therefore added a greater amount (ES3/MER: 244.7€ ± 614.7 vs. 155.9€ ± 568.1; $p = 0.28$) to overall costs compared to other complications and associated costs.

Table 2
Periprocedural, in-hospital costs, and reimbursement.

	Cohort ES3 (n = 103)	Cohort MER (n = 101)	p-Value
A. Valve-kit costs			
Valve-kit costs (Δ calculation; the lower price is set = 0; + = price difference to MER)	+4.390.0 ± 3.807.0	0.0 ± 734.1	*<0.0001**
B. General in-hospital costs (staff and in-hospital stay)			
Staff and material costs catheter laboratory			
Total working hours (h)	11.0 ± 2.8	11.2 ± 2.9	0.7009
Total working costs (€)	541.9 ± 135.6	549.3 ± 140.8	0.7009
General costs in hospital stay			
ICU costs (€)	2.522.0 ± 3.451.0	2.459.0 ± 3.144.0	0.8910
IMC costs (€)	1.790.0 ± 1.856.0	2.152.0 ± 2.155.0	0.1996
GW costs (€)	4.040.0 ± 2.899.0	4.246.0 ± 2.584.0	0.5929
C. Additional material costs (material and other costs)			
Material costs catheter laboratory			
Pre-balloon (cum), n (%)	63 (61.2)	87 (86.1)	*<0.0001**
Pre-balloon costs (add, €)	0.0 ± 0.0	604.7 ± 336.9	*<0.0001**
Post-balloon (cum), n (%)	3 (2.9)	12 (11.9)	*0.0140**
Post-balloon costs (add, €)	0.0 ± 0.0	37.3 ± 156.9	*0.0166**
Snare (add), n (%)	0 (0.0)	3 (2.9)	0.0787
Snare (add, €)	0.0 ± 0.0	11.1 ± 66.5	0.0910
2nd valve (add), n (%)	0 (0.0)	2 (2.0)	0.1527
2nd valve (add, €)	0.0 ± 0.0	0.0 ± 0.0	1.0000
CSG (add), n (%)	16 (15.5)	10 (9.9)	0.2857
CSG (add, €)	244.7 ± 614.7	155.9 ± 568.1	0.2857
Pacemaker costs catheter laboratory			
SC PM (add), n (%)	1 (1.0)	3 (2.9)	0.3055
SC PM (add, €)	21.6 ± 218.9	73.9 ± 431.6	0.2750
DC PM (add), n (%)	4 (3.9)	8 (7.9)	0.2225
DC PM (add, €)	93.4 ± 558.1	213.0 ± 761.5	0.2016
Other costs			
AKI stage 3 (add), n (%)	3 (2.9)	0 (0.0)	0.0848
GFR < 30 ml/min, n (%)	2 (1.9)	1 (1.0)	0.5746
AKI stage 3 (add, €)	16.6 ± 131.6	0.0 ± 0.0	0.2057
pRBC (add, U)	0.66 ± 1.9	0.56 ± 1.5	0.6586
pRBC (add, €)	70.8 ± 233.3	46.9 ± 124.0	0.3632
Other costs (add, €)	77.4 ± 239.0	132.2 ± 708.7	0.4580
D. Overall costs and reimbursement			
Total costs (€): Valve kit price difference (x) + additive costs	x + 13.808.0 ± 5.595.0	x + 10.681.0 ± 4.518.0	0.6885
Total delta proceeds (€)	⬆ + 1.649.7	⬆ + 4.776.7	

Values are mean ± SD or n (%).
Add; additive; *AF*, Atrial fibrillation; *AKI*, acute kidney injury; *CSG*, covered stent graft; *ICU*, intensive care unit; cum, cumulative; *DC*, double chamber; *IHS*, in-hospital stay; *IMC*, intermediate care unit; *GFR*, glomerular filtration rate; *GW*, general ward; *PM*, pacemaker; *pRBC*, packed blood cell units; *SC*, single chamber.
The lower valve-kit costs in the MER cohort were set at zero due to internal disclosure agreements and the resulting difference in the ES3 cohort is described as "+".
* Significant statistical differences.

Second valve costs did not play a role in this real-life analysis because additional valves are provided for free by the manufacturer. Other major cost drivers regarding TAVI are the applied anesthesia method and chosen access site route [13,14]. These factors can be excluded in this analysis because all procedures were performed under local anesthesia and a femoral access route was chosen in all patients.

5.4. Costs of inpatient stay

As a less invasive procedure, TAVI promises a faster recovery and decreased intensive care unit and total hospital stay [15]. Lately the attempt of fast track discharge concepts proved to be effective and safe [16–18]. In daily clinical practice fast track concepts were not applied to this study population because TAVI was only conducted in old patients with severe morbidities and a high perioperative risk or other contraindications for SAVR. Nevertheless, we see a high potential in the aforementioned concept to significantly decrease costs because general ward costs have been proved to be the major cost driver-regarding general in hospital costs (ES3/MER: 4.040.0€ ± 2.899.0 vs. 4.246.0€ ± 2.584.0; p = 0.59) in our study population.

To our knowledge this is the first study, which directly compares associated costs of TAVI with leading third generation valve models. Major cost drivers were initial valve-kit costs with a significantly higher amount in the ES3 group (ES3/MER: +4.390.0€ ± 3.807.0 vs. 0.0€ ± 734.1; p < 0.01). Higher initial material expenses were balanced by increased additional material investment and associated costs in the MER cohort. Overall cost comparison between third generation valve models did not show a significant difference.

5.5. Limitations

This study is a single center, retrospective analysis. Currently we lack controlled trials in this research area. Moreover, a longer study duration is needed to exactly determine cost effectiveness and assess economic value for our health care system.

6. Conclusion

Valve-kit costs were significantly higher in the ES3 group but balanced by incremented additional material and associated costs in the MER cohort. Peri- and postprocedural complications, outcome, and overall costs did not significantly differ between third generation balloon-expandable and self-expandable valves in a real-world setting. Overall reimbursement is moderate for this complex procedure in Germany. Therefore, the implementation of potential cost saving methods is mandatory in the future.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.12.007.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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