



# Clinical and economical impact of the presence of an extended heart team throughout the balloon-expandable transcatheter aortic valve implantation procedure

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## Abstract

**Background** Transcatheter aortic valve implantation (TAVI) is a standard therapy for aortic valve stenosis in patients at intermediate-to-high surgical risk. Previously, TAVI at our site was performed by a minimalist heart team (MHT), comprised of two interventional cardiologists, echocardiography staff and two cardiac catheterization laboratory nurses. After revision of German Federal Joint Committee (G-BA) guidelines in September 2015, the presence of an extended heart team (EHT; including a full cardiac surgical team) became mandatory throughout the TAVI procedure. We aimed to evaluate the impact of the EHT on clinical and economical outcomes.

**Methods** Data was retrospectively extracted from the medical records of patients receiving an Edwards SAPIEN 3 valve at the University Hospital Tübingen, Germany, between 2014 and 2017 and matched with cost data from the national invoice system of hospitals (InEK). For comparison, patients were grouped according to whether they underwent TAVI with or without the EHT.

**Results** Overall, data for 341 patients (MHT 233; EHT 118) were analysed. Baseline characteristics were largely similar between groups (mean age 81.0 years; 54.5% female), though EHT patients had a lower mean logEuroSCORE (17.5% vs. 19.8%;  $p=0.011$ ) and more prior PCI/stenting (39.0% vs. 26.9%;  $p=0.022$ ). The rate of immediate procedural death (1.7%) was comparable between groups, as was mortality at 30 days (4.2%). Overall, 1.2% of patients required conversion to surgery. The cost of the index hospitalisation (minus the prosthesis) was higher in the EHT condition (difference +€1604), largely driven by expenditure on physicians (difference +€581;  $p<0.001$ ), medical technicians (difference +€372;  $p<0.001$ ) and medical supplies (difference +€244;  $p=0.001$ ).

**Conclusion** At our site, the presence of an EHT throughout the TAVI procedure appears to substantially increase hospital expenditure without significantly improving patient outcomes. We suggest that TAVI by a minimalist HT with a surgical team on call in case of emergency may be sufficient.

**Keywords** Transcatheter aortic valve implantation (TAVI) · Heart team · Conversion to surgery · Mortality · Economical impact

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## Introduction

Transcatheter aortic valve implantation (TAVI) is now recognised by leading cardiology authorities worldwide as the standard approach to the treatment of severe symptomatic aortic stenosis (AS) in patients at intermediate-to-high surgical risk [1–3]. Over recent years, increasing experience has meant that the procedure can now be safely performed under local anaesthesia by a minimalist heart team (MHT) led by interventional cardiologists [4, 5]. However, due to the potential for complications that may require conversion

to open surgery [6, 7], European guidelines recommend that TAVI should only be carried out in centres with on-site cardiac surgery departments [1]. Nevertheless, there is controversy over whether the cardiac surgical team should be present in the operating room throughout the TAVI procedure or whether their being on call in the case of emergency is sufficient [8, 9].

In previous years, TAVI at our site was performed in the latter manner by two interventional cardiologists and their accompanying team. However, a new directive on minimally invasive heart valve interventions introduced by the German Federal Joint Committee (Gemeinsamer Bundesausschuss; G-BA) in September 2015 dictates that a full cardiac surgical team must also be in attendance throughout all TAVI procedures [10]. The logic behind the G-BA's decision is that this allows complications requiring surgical attention to be treated more rapidly, minimising their escalation and increasing the patient's likelihood of survival [11]. Accordingly, all TAVI procedures at our site have been performed in the presence of an extended heart team (EHT) since the aforementioned legislation came into force. However, there is little data available as to the clinical and financial impact of this procedural requirement.

In the present analysis, we aimed to determine the relative clinical value of the EHT by comparing the outcomes of patients that underwent TAVI with an EHT to those of patients that underwent TAVI with a MHT at our site. We also aimed to explore the relative financial impact of the EHT from a hospital perspective, based on the associated costs documented in the German nationwide hospital invoice system (InEK: Institut für das Entgeltsystem im Krankenhaus).

## Methods

The present study is a single-centre, retrospective analysis of transfemoral TAVI procedures performed at the University Hospital of Tübingen, Germany, between February 2014 and May 2017. The study was approved by the site's ethical committee and complied with the Declaration of Helsinki and its amendments. Given the use of anonymised data already collected as part of routine diagnosis and treatment, written informed consent was not required.

### Patient population

To be included, patients must have undergone TAVI with the Edwards SAPIEN 3 transcatheter heart valve at our site within the specified time period. In every case, the decision to perform TAVI was taken by an interdisciplinary Heart Team consisting of interventional cardiologists, cardiac surgeons and anaesthesiologists and based on periprocedural

assessment using the logistic EuroScore and other relevant factors. Patients without complete InEK data available for the index TAVI hospitalisation were excluded.

### Heart Teams and patient stratification

In September 2015, new G-BA guidelines on minimally invasive heart valve interventions came into force [10]. Before this time, TAVI at our site had been performed by two interventional cardiologists, one echocardiographer and two cardiac catheterization laboratory nurses (HT), with a surgical team (cardiac surgeon, anaesthetist, cardiovascular perfusionist, surgical nurse and nurse anaesthetist) on call in case of complications necessitating conversion to open surgery. In case of emergency our ICU "resuscitation team" is available within 1–2 min after alarm in our clinic. While the exact duration until the advent of the surgical team was not assessed, there is a 24 h on call system with short arrival times making the surgical team available within 5 min. ECLS was available on site and could be immediately implanted by interventional cardiologist.

From September 2015 onwards, all TAVI procedures were performed with an EHT present in the procedure room at all times, made up of two interventional cardiologists, an echocardiographer, a cardiac surgeon, an anaesthetist, a cardiovascular perfusionist, two cardiac catheterization laboratory nurses, a surgical nurse and a nurse anaesthetist. While, according to GBA guidelines, a surgeon and anesthesiologist is required during the procedure, clinic cardiovascular perfusionist and also surgical and anesthesiological nurse staff were present during the procedure and we factored them into our analysis. This reflects and implies that the exact team setting can vary in other centers. For the purpose of the present analysis, patients were grouped into those that underwent TAVI in the presence of the MHT and those that underwent TAVI in the presence of the EHT.

### Data, outcomes and definitions

Data regarding patient demographics, baseline comorbidities, prior interventions, pre- and post-TAVI echocardiographic parameters, periprocedural details and complications, and events at 30 days were retrospectively extracted from patient medical records. The primary outcome was the rate of immediate procedural death, defined according to the Valve Academic Research Consortium-2 consensus document (VARC-2) as intraprocedural events resulting in immediate or consequent death within 72 h [12]. Other periprocedural outcomes of interest included the rates of VARC-2-defined device success (absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location and its intended performance), stroke, major vascular complications, and

conversion to open/vascular surgery [12], as well as Bleeding Academic Research Consortium (BARC)-defined type 3b/3c/5 bleeding events [13]. Short- and medium-term outcomes of interest included the rates of mortality, stroke, myocardial infarction (MI) and life-threatening or disabling bleeding events (Bleeding Academic Research Consortium (BARC) type 3b/3c/5 [13]) at 30 days.

The cost of each index TAVI hospitalisation was calculated by matching individual patients with their corresponding InEK data. In addition to total expenditure, a complete breakdown of expenses according to InEK criteria was obtained [14]. This included the cost of the prosthesis, medical personnel (physicians, nursing/care staff and medical technicians), pharmaceuticals, other medical supplies, third-party medical services, and infrastructure. For definitions and examples of InEK criteria, the reader is referred to Supplementary Table 1.

## Statistics

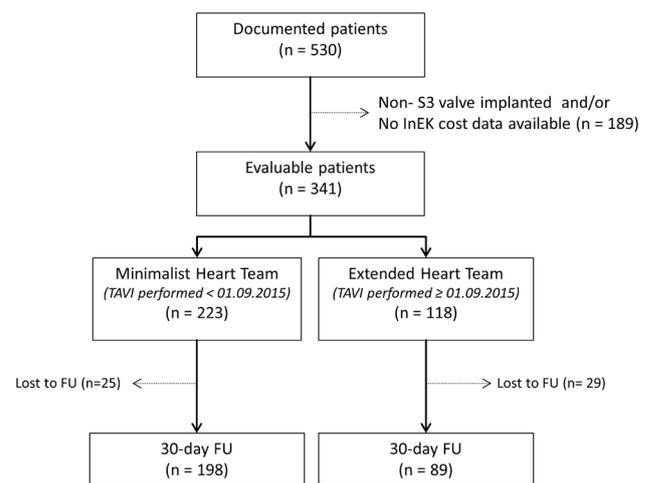
Data were analysed using descriptive statistics, with categorical variables presented as absolute values and frequencies (%) and continuous variables as means with standard deviations (SDs). Comparisons between MHT and EHT groups were carried out using a Student's *t* test or Mann–Whitney *U* test for continuous variables and a Fisher's exact or Chi square test for categorical variables. In all cases, a two-tailed *p* value of  $<0.05$  was considered statistically significant. All statistical tests were performed using IBM SPSS Statistics software version 24.0 (Armonk, NY. IBM Corporation).

## Results

Between February 2014 and May 2017, TAVI with a SAPIEN 3 valve was performed in 341 patients at our hospital (Fig. 1). Of these patients, 223 (65.4%) underwent the procedure with the MHT prior to September 2015 and 118 (34.6%) with the EHT from September 2015 onwards.

### Patient characteristics

At baseline, the EHT group had a lower mean logEuroSCORE than the MHT group ( $17.5 \pm 14.7$  vs.  $19.8 \pm 12.1$ ;  $p=0.011$ ). Mitral and tricuspid insufficiency grade II/III were both significantly more common amongst EHT patients (51.3% vs. 37.8%,  $p=0.017$  and 34.5% vs. 23.0%,  $p=0.024$ , respectively), as was prior PCI/stenting (39.0% vs. 26.9%;  $p=0.022$ ). There was a borderline significant trend towards a higher mean age ( $81.9 \pm 6.4$  vs.  $80.5 \pm 6.8$  years;  $p=0.059$ ) in the EHT group (Table 1). No other differences in baseline characteristics were apparent.



**Fig. 1** Patient flow. S3 Edwards SAPIEN 3, InEK Institute for the Hospital Remuneration System, TAVI transcatheter aortic valve implantation, FU follow-up

### Periprocedural characteristics and outcomes

The rate of immediate periprocedural death was not significantly different between MHT and EHT patients (2.0% [four patients] vs. 1.1% [one patient];  $p=1.000$ ) (Table 2). The four deaths in the MHT group resulted from post-interventional atrioventricular block with cardiopulmonary deterioration leading to death within 4 h (one patient), thoracic aorta perforation leading to thoracic haemorrhage (one patient), pelvic arterial bleeding requiring conversion to vascular surgery (one patient), and haemopericardium with retrosternal bleeding requiring conversion to open surgery (one patient). The one death in the EHT group resulted from MI due to incomplete occlusion of the left coronary artery leading to cardiogenic shock. The need for conversion to surgery was extremely rare (1.2% overall), again being comparable between groups.

The mean fluoroscopy time was significantly longer in the EHT compared to the MHT group ( $13.1 \pm 5.3$  vs.  $10.9 \pm 4.7$  min;  $p<0.001$ ), with a borderline significant trend towards implantation of larger valves ( $p=0.058$ ) and a higher rate of major vascular complications (13.6% vs. 7.2%;  $p=0.054$ ).

### Outcomes at 30 days

There were no significant differences in outcomes between MHT and EHT groups at 30 days (Table 3). By this time point, 12 deaths had occurred (4.2%), all of which were due to procedural-related causes during the index hospital stay. 7 deaths occurred due to non-cardiac causes (4 bleeding events (MHT 3, EHT 1); 1 stroke (MHT), 1 renal failure (MHT) and 1 respiratory failure (MHT)). Five cardiac

**Table 1** Patient characteristics

	Total Mean $\pm$ SD [n] or n/N (%) N = 341	MHT Mean $\pm$ SD [n] or n/N (%) N = 223	EHT Mean $\pm$ SD [n] or n/N (%) N = 118	p value
Age (years)	81.0 $\pm$ 6.7 [341]	80.5 $\pm$ 6.8 [223]	81.9 $\pm$ 6.4 [118]	0.059
Female gender	186/341 (54.5)	124/223 (55.6)	62/118 (52.5)	0.589
BMI (kg/m <sup>2</sup> )	26.9 $\pm$ 4.9 [308]	26.6 $\pm$ 4.6 [198]	27.4 $\pm$ 5.4 [110]	0.399
Diabetes	111/341 (32.6)	76/223 (34.1)	35/118 (29.7)	0.407
Kidney failure (GFR < 60 ml/min)	167/340 (49.1)	108/222 (64.7)	59/118 (50.0)	0.812
Cardiac comorbidity				
AF	161/341 (47.2)	99/223 (44.4)	62/118 (52.5)	0.152
CAD	215/341 (63.0)	140/223 (62.8)	75/118 (63.6)	0.332
Prior MI	41/341 (12.0)	22/223 (9.9)	19/118 (16.1)	0.092
Prior PCI/stent	106/341 (31.1)	60/223 (26.9)	46/118 (39.0)	0.022
Prior CABG	19/341 (5.6)	16/223 (7.2)	3/118 (2.5)	0.076
Prior SAVR	4/341 (1.2)	3/223 (1.3)	1/118 (0.8)	1.000
Prior PM/ICD	39/341 (11.5)	28/223 (12.6)	11/118 (9.3)	0.365
Echocardiographic parameters				
Peak AV gradient (mmHg)	69.5 $\pm$ 24.0 [334]	68.7 $\pm$ 22.2 [222]	71.1 $\pm$ 27.4 [112]	0.382
Mean AV gradient (mmHg)	41.9 $\pm$ 16.2 [332]	41.3 $\pm$ 15.1 [222]	43.1 $\pm$ 18.1 [110]	0.731
AVA (cm <sup>2</sup> )	0.720 $\pm$ 0.212 [324]	0.721 $\pm$ 0.217 [214]	0.717 $\pm$ 0.203 [118]	0.796
Mitral insufficiency grade II/III	144/339 (42.5)	84/222 (37.8)	60/117 (51.3)	0.017
Tricuspid insufficiency grade II/III	91/338 (26.9)	51/222 (23.0)	40/116 (34.5)	0.024
PAsys (mmHg)	36.7 $\pm$ 12.8 [297]	37.0 $\pm$ 12.6 [204]	36.2 $\pm$ 13.3 [93]	0.740
LVEF (%)	55.2 $\pm$ 12.2 [341]	54.7 $\pm$ 12.5 [223]	56.0 $\pm$ 11.6 [118]	0.341
LogEuroSCORE I (%)	19.0 $\pm$ 13.1 [341]	19.8 $\pm$ 12.1 [223]	17.5 $\pm$ 14.7 [118]	0.011

BMI body mass index, GFR glomerular filtration rate, AF atrial fibrillation, CAD coronary artery disease, MI myocardial infarction, PCI percutaneous coronary intervention, CABG coronary artery bypass graft, SAVR surgical aortic valve replacement, PM pacemaker, ICD implantable cardioverter defibrillator, AV aortic valve, AVA aortic valve area, PAsys systolic pulmonary artery pressure, LVEF left ventricular ejection fraction, MHT minimalist heart team, EHT extended heart team, SD standard deviation

deaths were documented (1 ventricle perforation (MHT), 1 AV-Block/asystole (MHT), 2 cases with cardiac failure (EHT both) and 1 MI (EHT)).

## Costs

While the total cost of the index hospitalisation did not differ significantly according to the extent of the Heart Team present during TAVI (€32351  $\pm$  8472 per patient, overall), a nominally higher expenditure in the EHT group was revealed after subtraction of prosthesis expenses (cost difference + €1604;  $p = 0.110$ ) (Table 4). This was largely driven by the higher costs of physicians (cost difference + €581;  $p = 0.005$ ); medical technicians (cost difference: + €372;  $p < 0.001$ ); medical supplies (other than pharmaceuticals, implantables and transplantables; cost difference + €244;  $p = 0.002$ ); and third-party medical services (cost difference + €145.76; not applicable prior to January 2016) in the EHT group.

No significant differences were seen in the presence of an EHT rather than an MHT during TAVI in any subgroup analysis (Table 5).

## Discussion

At our site, periprocedural, short- and medium-term outcomes appeared to be largely similar irrespective of whether TAVI was performed by an MHT with a surgical team on call or in the presence of a full EHT. However, the cost of physicians, medical technicians, medical supplies and third-party medical services was significantly higher in the EHT condition. This suggests that mandating the presence of an EHT may increase hospital expenditure, without significantly improving clinical outcomes.

**Table 2** Periprocedural characteristics and outcomes

	Total Mean ± SD [n] or n/N (%) N = 341	MHT Mean ± SD [n] or n/N (%) N = 223	EHT Mean ± SD [n] or n/N (%) N = 118	p value
General anaesthesia	2/338 (0.6)	2/218 (0.9)	0 (0)	0.544
SAPIEN 3 valve size				0.058
23 mm	98/341 (28.7)	68/223 (30.5)	30/118 (25.4)	
26 mm	154/341 (45.2)	106/223 (47.5)	48/118 (40.7)	
29 mm	89/341 (26.1)	49/223 (22.0)	40/118 (33.9)	
Fluoroscopy time (min)	11.6 ± 5.0 [324]	10.9 ± 4.7 [218]	13.1 ± 5.3 [106]	<0.001
Contrast agent volume (ml)	147.3 ± 63.1 [333]	146.2 ± 57.7 [222]	149.5 ± 73.0 [111]	0.576
Device success <sup>a</sup>	328/341 (96.2)	215/223 (96.4)	113/118 (95.8)	0.766
Periprocedural complications				
Immediate procedural death <sup>b</sup>	5/341 (1.5)	4/223 (1.8)	1/118 (0.8)	0.663
Stroke	6/340 (1.8)	3/223 (1.3)	3/117 (2.6)	0.418
Bleeding <sup>c</sup>	16/341 (4.7)	9/223 (4.0)	7/118 (5.9)	0.431
Major vascular complication	28/341 (8.2)	17/223 (7.6)	11/118 (9.3)	0.587
Conversion to open heart surgery <sup>d</sup>	3/341 (0.9)	1/223 (0.4)	2/118 (1.7)	0.276
Post-procedural echocardiographic parameters				
Peak AV gradient (mmHg)	20.3 ± 8.5 [308]	19.8 ± 8.0 [209]	21.4 ± 9.5 [99]	0.212
Mean AV gradient (mmHg)	10.4 ± 4.6 [305]	10.2 ± 4.4 [206]	11.0 ± 5.0 [99]	0.146
LVEF (%)	57.4 ± 10.6 [306]	57.7 ± 10.4 [214]	56.6 ± 11.2 [92]	0.422

AV aortic valve, AVA aortic valve area, LVEF left ventricular ejection fraction, MHT minimalist heart team, EHT extended heart team, SD standard deviation

<sup>a</sup>Defined as absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location and its intended performance (VARC-2) [12]

<sup>b</sup>Defined as intraprocedural events resulting in immediate or consequent death within 72 h (VARC-2) [12]

<sup>c</sup>Life-threatening or disabling bleeding (Bleeding Academic Research Consortium (BARC) type 3b/3c/5) [13]

<sup>d</sup>No conversion to vascular surgery was documented

**Table 3** Outcomes at 30 days

	Total n/N (%) N = 341	MHT n/N (%) N = 223	EHT n/N (%) N = 118	p value
Outcomes at 30 days				
Death <sup>a</sup>	12/287 (4.2)	8/198 (4.0)	4/89 (4.5)	1.000
Non-cardiac death	7/287 (2.4)	6/198 (3.0)	1/89 (1.1)	0.442
Cardiac death	5/287 (1.7)	2/198 (1.0)	3/89 (3.4)	0.175
Non-fatal stroke	3/283 (1.1)	2/197 (1.0)	1/86 (1.2)	1.000
Non-fatal MI	1/283 (0.4)	0/197	1/86 (1.2)	0.304
Non-fatal bleeding <sup>b</sup>	1/281 (0.4)	1/197 (0.5)	0/84	1.000

MI myocardial infarction

<sup>a</sup>All deaths were procedural-related and occurred during hospital stay

<sup>b</sup>Life-threatening or disabling bleeding (Bleeding Academic Research Consortium (BARC) type 3b/3c/5) [13]

### Influence of an extended Heart Team on mortality

The rates of immediate procedural death and 30-day mortality were low and comparable between MHT and EHT

groups, resembling those previously reported by large-scale TAVI studies with the SAPIEN 3 valve [15–17]. This suggests that the presence of the surgical team in the operating room throughout the TAVI procedure at our highly experienced site offers no immediate benefit in terms of survival metrics. This is particularly striking, given that EHT patients had a significantly lower logEuroSCORE (and therefore risk of mortality) than MHT patients, likely reflecting temporal trends towards the performance of TAVI in lower-risk patients [18]. Nevertheless, logEuroSCORE is not specific to the TAVI procedure [19] and other variables not included in this score may have predisposed EHT patients to complications and/or death. Indeed, prior PCI/stenting, which was more prevalent in the EHT group, has been associated with vascular and bleeding events during TAVI [20, 21], with a higher rate of both these complications observed in the EHT group. As such, heterogeneity between study groups at baseline may have implications for the interpretation of our findings.

Regardless of baseline characteristics, the most likely reason that the immediate presence/absence of the surgical team made little difference to survival in the present

**Table 4** Costs per patient

	Total N= 341 Mean ± SD (€)	MHT N= 223 Mean ± SD (€)	EHT N= 118 Mean ± SD (€)	Cost difference (EHT – MHT) (€)	p value~ (EHT vs. MHT)
Total cost	32,351 ± 8472	32,095 ± 6850	32,835 ± 10,918	740	0.504
Cost of prosthesis <sup>a</sup>	19,941 ± 2475	20,240 ± 1978	19,377 ± 3145	– 863	0.007
Total cost without prosthesis	12,410 ± 7690	11,855 ± 6203	13,459 ± 9858	1604	0.110
In-house medical personnel costs	6494 ± 5916	6168 ± 3730	7109 ± 5800	941	0.112
Physicians	2551 ± 1626	2350 ± 1359	2931 ± 1989	581	0.005
Nursing/care staff	3000 ± 2544	3004 ± 2053	2992 ± 3288	– 12	0.970
Medical technicians	943 ± 550	814 ± 437	1186 ± 653	372	<0.001
Other costs	5916 ± 3203	5687 ± 2568	6350 ± 4126	663	0.114
Unit-priced <sup>a</sup> pharmaceuticals	272 ± 180	271 ± 158	274 ± 216	3	0.893
Directly costed <sup>c</sup> pharmaceuticals	139 ± 390	126 ± 337	165 ± 480	39	0.515
Other unit-priced <sup>b</sup> medical supplies <sup>d</sup>	585 ± 472	569 ± 359	615 ± 634	47	0.460
Other directly costed <sup>c</sup> medical supplies <sup>d</sup>	1312 ± 5999	1227 ± 468	1471 ± 767	244	0.002
Third-party medical services <sup>e</sup>	146 ± 207	–	146 ± 207	146	n.a.
Medical infrastructure	1263 ± 732	1248 ± 636	1292 ± 887	44	0.635
Non-medical infrastructure	2315 ± 1366	2247 ± 1161	2443 ± 1686	196	0.261

n.a. not applicable

<sup>a</sup>Also includes cost of any other implantable/transplantable entities

<sup>b</sup>Based on purchase/average/unit prices

<sup>c</sup>Based on actual consumption rather than unit price

<sup>d</sup>Excluding pharmaceuticals, implantables and transplantables

<sup>e</sup>Not applicable prior to 2016. Student's *t* test

**Table 5** Total costs (without prosthesis) within different patient subsets

	Total Mean ± SD (€)	MHT Mean ± SD (€)	EHT Mean ± SD (€)	Cost difference (EHT – R'MHT) (€)	p value (EHT vs. MHT)
Age > 82 years (median; n = 154)	13,663 ± 8188	13,040 ± 7403	14,614 ± 9242	1574	0.245
Age ≤ 82 years (median; n = 187)	11,378 ± 7113	11,007 ± 5038	12,223 ± 10,417	1216	0.283
Female gender (n = 186)	12,638 ± 6629	12,620 ± 6952	12,675 ± 5984	55	0.958
Male gender (n = 155)	12,136 ± 8812	10,896 ± 4982	14,327 ± 12,866	3431	0.060
GFR < 60 ml/min (n = 167)	13,771 ± 9446	12,979 ± 7181	15,222 ± 12,527	2243	0.209
GFR ≥ 60 ml/min (n = 173)	11,104 ± 5222	10,797 ± 4941	11,696 ± 5724	899	0.285
Concomitant valve disease (n = 172)	11,765 ± 7680	12,263 ± 6668	13,780 ± 8392	1517	0.189
No concomitant valve disease (n = 167)	12,898 ± 7453	11,539 ± 5825	12,380 ± 11344	841	0.531
LogEuroScore I ≤ 15.2 (n = 172)	11,203 ± 5545	10,742 ± 4707	11,844 ± 6515	1102	0.200
LogEuroScore I > 15.2 (n = 169)	13,638 ± 9241	12,759 ± 7084	15,987 ± 13,228	3228	0.122
Non-lethal periprocedural complication (any; n = 179)	13,022 ± 6839	12,653 ± 6356	13,703 ± 7656	1051	0.328
No non-lethal periprocedural complications (n = 162)	11,733 ± 8504	10,990 ± 5941	13,179 ± 11,962	2189	0.205

All monetary values refer to total cost without the cost of the prosthesis. Student's *t* test

SD standard deviation

population was the overall rarity of the need for surgical conversion (1.2%), with open heart surgery required in just 0.3% of patients. This rate is even lower than that recently reported by a similar high-volume centre (2%) [22] and

by the multi-centre European SOURCE 3 registry (0.6%) [17], and demonstrates that the vast majority of patients can safely undergo TAVI at our site with an MHT alone. Adherence to the EHT aspect of the new G-BA guidelines

may thus result in inefficient allocation of the cardiac surgeon's time, as well as that of other specialist surgical personnel.

### Utility of an extended Heart Team where surgical conversion is required

There were two instances in the MHT group (0.9%) where the in-theatre presence of the surgical team may have been beneficial: two out of three patients that required conversion to open surgery experienced immediate periprocedural death, accounting for half of the group's procedural mortality. One of these patients died due to haemopericardium with retrosternal bleeding, which typically results from errors in equipment handling and leads to rapid cardiac tamponade [23, 24], particularly where anticoagulant therapy is in use. In this case, the delay while awaiting the arrival of the surgical team may feasibly have impacted upon survival [25]; however, even with rapid surgical intervention, prognosis is poor [23]. The same is true for the other MHT patient who died from pelvic vascular rupture, a result of mechanical damage from delivery apparatus that necessitated surgical repair. Again, even with immediate surgical attention the likelihood that the patient would have survived such a major complication is low. As such, we may speculate that death in the small subset of MHT patients requiring surgical attention was unlikely to have been greatly influenced by the immediate presence of a surgical team. Indeed, an additional MHT patient that required conversion to vascular surgery survived the operation regardless of the short delay while the surgical team arrived, likely due to the lesser severity of the complication and greater overall degree of salvageability. Only one conversion to surgery (vascular) occurred in the EHT group, likely due to the greater degree of interventional cardiologist experience at the later time point [4, 18, 26]. Consequently, it is difficult to determine the value of the EHT in emergency conversion situations based on the present data. With ever-growing procedural experience, the evolution of technology to permit smaller valve crimping and delivery sheaths, and the trend towards TAVI being performed in lower-risk patients [27], procedural complications are expected to become even scarcer in future, with the need for conversion applying to ever fewer patients. Given that even in the case of conversion the prognosis of patients with major TAVI complications is poor [28], we suggest that an EHT may be considered an unnecessary luxury, and that an MHT with a surgical team on call would suffice. Nevertheless, it is important to note that as TAVI becomes more common in lower-risk patients, the potential for surgical salvage may increase [4]. As

such, the value of an EHT in lower-risk patients should be explored separately.

### Influence of the extended Heart Team on costs

The cost of the index hospital stay was higher in the EHT compared to MHT condition, with the difference being in excess of €1600 per patient after exclusion of prosthesis costs. This was largely a result of higher physician and medical technician outlay (salaries, social security contributions, pension and other expenses), which is calculated proportionally to time–expenditure per patient [14]. While a single surgical team on call can serve multiple procedure rooms simultaneously, with their hourly costs split between patients, a team that must remain with one patient throughout a procedure is limited in this respect. Thus, in the EHT condition, an additional surgical personnel is required to perform the same number of interventions, necessitating not only an increment in the number of in-house medical professionals, but also in the use of external physicians. This results in considerably higher costs per patient. Furthermore, the outlay for directly costed medical supplies was also higher in the EHT condition, likely due to all members present during TAVI wishing to contribute to the procedure in some way and consuming more resources in the process. Indeed, the significantly longer fluoroscopy times in the EHT group may be due to more Heart Team members wishing to contribute their expertise, resulting in a longer procedure and increased personnel costs. Considering the extremely low probability that surgical intervention will be required and the evidence that survival rates are not significantly affected by the presence/absence of the EHT, such additional outlay appears unjustified. We would argue that the performance of TAVI by an MHT with a surgical team on call is a more appropriate use of hospital funds.

### Limitations

Several limitations related to the retrospective, observational, single-centre nature of the study apply. First, data for certain fields may have been missing/inaccurate, though standard protocol at our site means that medical records are kept largely up to date and complete. Second, baseline differences between groups existed, representing a possible source of bias. Some variables are more likely to have been influential than others: while the nominally higher frequency of prior MI in the EHT group may explain the nominally greater rate of this complication at 30 days, differences in mitral and tricuspid insufficiency grade II/III are unlikely to have had a significant impact on outcomes, given that neither appears to be associated with periprocedural complications [29, 30]. Unfortunately, relatively modest patient numbers and low event frequencies limit statistical power

and preclude adjustment for differing characteristics through multivariate analysis. Thus, an independent effect of the EHT on outcomes cannot be unequivocally ruled out.

Several limitations regarding the G-BA legislation change also merit acknowledgement. First, the directive sets novel requirements for the qualifications of medical and nursing staff working with TAVI patients; however, this required very little change at our site, which had already been largely compliant prior to September 2015. Second, the separation of groups prior to and after this cut-off allows the possibility for temporal trends to have influenced outcomes, with increased technical experience and more refined patient selection (i.e., lower surgical risk patients considered) in the EHT group. However, this would mean that MHT patients had comparable outcomes despite being at a temporal disadvantage, strengthening our position. Finally, our findings cannot be extrapolated to lower-volume centres with higher rates of conversion to open surgery.

## Conclusions

At our highly experienced site, the presence of an EHT throughout the TAVI procedure appears to substantially increase hospital expenditure without significantly improving patient outcomes. We suggest that TAVI by an MHT with a surgical team on call in case of emergency may be sufficient. However, our results are largely exploratory and corroboration in larger-scale studies would be of interest.

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## Compliance with ethical standards

**Conflict of interest** MD received travel honoraria by Medtronic; MG has received speaker's fees from Medtronic and AstraZeneca; TG received restricted grants by Edwards and travel honoraria by Medtronic; PB received consultancy honoraria from Edwards Lifesciences for the preparation of the first draft; OB, TK, RK, HL, CS, CG have nothing to disclose.

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