



BMJ Open Institutional infrastructural preconditions and current perioperative anaesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centres

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ABSTRACT

Objectives Transfemoral transcatheter aortic valve implantation (TF-TAVI) is an established therapy for patients with symptomatic aortic stenosis, which requires periprocedural anaesthesia care. In 2015, the German Federal Joint Committee released a directive on minimally invasive heart valve interventions which defines institutional infrastructural requirements in German heart centres. But still generally accepted expert consensus recommendations or national or international guidelines regarding periprocedural anaesthesia management for TF-TAVI are lacking. This nationwide cross-sectional study had two major objectives: first to assess the concordance with existing national regulations regarding infrastructural requirements and second to evaluate the status quo of periprocedural anaesthesia management for patients undergoing TF-TAVI in German heart centres.

Design Multicentre cross-sectional online study to evaluate the periprocedural anaesthesia management.

Setting In this nationwide cross-sectional study, electronic questionnaires were sent out to anaesthesia departments at TF-TAVI-performing centres in Germany in March 2019.

Participants 78 anaesthesia departments of German heart centres.

Results 54 (69.2%) centres returned the questionnaire of which 94.4% stated to hold regular Heart Team meetings, 75.9% to have ready-to-use heart-lung machines available on-site, 77.8% to have cardiac surgeons and 66.7% to have perfusionists routinely attending throughout TF-TAVI procedures. Regarding periprocedural anaesthesia management, 41 (75.9%) of the participating centres reported to predominantly use 'monitored anaesthesia care' and 13 (24.1%) to favour general anaesthesia. 49 (90.7%) centres stated to use institutional standard operating procedures for anaesthesia. Five-lead ECG, central venous lines, capnometry and intraprocedural echocardiography were reported to be routine measures in 85.2%, 83.3%, 77.8% and 51.9% of the surveyed heart centres.

Strengths and limitations of this study

- This is the first cross-sectional study which gives specific insights in anaesthesia practices and periprocedural measures during transfemoral transcatheter aortic valve implantation (TF-TAVI) in Germany.
- Our data demonstrate substantial variability among anaesthesia in-house standards for TF-TAVI in German heart centres.
- This study intended to enhance the awareness and to promote the debate about a standardised anaesthesia management for TF-TAVI, but more clinical studies are required to finally answer open questions.
- Our survey revealed potential infrastructural strengths and weaknesses in the participating centres, which could be addressed by an officially designated international guideline committee or a multidisciplinary clinical-scientific expert panel.
- Expert consensus recommendations and/or guidelines for anaesthesia and periprocedural management for TF-TAVI might be helpful to push forward innovative concepts such as Enhanced Recovery After Surgery for TF-TAVI.

Conclusions The concordance with national regulations, anaesthesia management and in-house standards for TF-TAVI vary broadly among German heart centres. According to the opinion of the authors, international expert consensus recommendations and/or guidelines would be helpful to standardise peri interventional anaesthesia care.

INTRODUCTION

Aortic valve stenosis (AS) is one of the most frequent valve diseases with an increasing prevalence in the ageing population in industrialised countries.^{1 2} With an incidence of

4%–5% in patients over 65 years, AS is the most common reason for valvular surgery and catheter intervention for structural heart disease.^{1–3}

Transfemoral transcatheter aortic valve implantation (TF-TAVI) is an established standard therapy for patients with symptomatic AS, especially in the elderly with high or intermediate surgical risk.³ Nowadays, case numbers for TAVI extend far beyond those of surgical aortic valve replacements (AVR) in Germany.⁴ The Institute for Quality Assurance and Transparency in Health Care analysed data (20 974 TAVI procedures, 8420 AVRs) of 2018 and revealed an in-hospital mortality of 3.1% for AVR and 2.7% for TAVI.⁴

In 2015, the German Federal Joint Committee (G-BA) released a directive for minimum quality standards for the implementation of minimally invasive heart valve interventions.⁵ This directive defined structural and process quality requirements as well as staff, institutional and logistic resources for German heart centres that provide TF-TAVI. As international studies suggested possible associations between TAVI case numbers and outcome,^{6–8} G-BA launched a consultation procedure in June 2020 to consider mandatory minimum thresholds for both: centres and individual operators.

TF-TAVI is performed either in general anaesthesia (GA) or with monitored anaesthesia care (MAC).^{9–13} European guidelines recommend that TAVI should only be performed in heart valve centres with implemented Heart Teams.³ As mandatory members of the Heart Team, anaesthetists are involved in individual risk evaluation, multidisciplinary decision making, choice between TAVI and AVR and perioperative care of these patients.^{3,14}

Although the G-BA directive predefines that a specialist for anaesthesia with expertise in cardiac anaesthesia should be involved in TF-TAVI procedures in German heart centres,⁵ only few specific recommendations on the targeted use of perioperative equipment such as 5-lead ECG or defibrillators, and the availability of transesophageal echocardiography (TOE) on-site for patients undergoing cardiac surgery or interventional cardiology exist.¹⁵

Generally accepted national/international guidelines or expert consensus recommendations on periprocedural anaesthesia management for TF-TAVI are still lacking, and the specific preassessment, anaesthesia techniques, vascular access, choice of drugs and perioperative care for these patients are unknown.

Thus, this nationwide cross-sectional study comprises two major objectives. First, this study aimed to assess the concordance with existing national regulations regarding infrastructural requirements for TF-TAVI in the German healthcare system. Second, this study aimed to evaluate the status quo of periprocedural anaesthesia management for TF-TAVI in German heart centres.

METHODS

TF-TAVI-performing centres were identified using the webpage of the German Cardiac Society. We used an

internet-based questionnaire, hosted by *SurveyMonkey* (SurveyMonkey Europe UC, Dublin, Ireland; www.surveymonkey.de). Invitations were sent to the departments of anaesthesiology of all eligible centres in March 2019 via email and a reminder email or call was initiated within 2 weeks after the start of the survey.

Survey instrument

An electronic questionnaire was created to outline anaesthesia and perioperative management of patients undergoing TF-TAVI and to obtain specific insights in the infrastructure and processes of each participating centre. The electronic questionnaire included 25 questions that focused on:

1. anaesthesia preassessment, preparation and premedication (eg, preprocedural diagnostics and drugs for premedication);
2. standard monitoring (eg, pulse oximetry, non-invasive blood pressure, ECG, capnometry, diuresis (urinary catheter));
3. advanced haemodynamic monitoring and neuro-monitoring (eg, cardiac output, bispectral index (BIS), near-infrared spectroscopy (NIRS));
4. periprocedural measures (eg, echocardiography, defibrillator electrodes);
5. vascular access and devices (eg, arterial, central venous and peripheral lines, pacemaker);
6. standard approach/type of anaesthesia (MAC (local anaesthesia, procedural sedation), GA);
7. drugs (eg, hypnotics, sedatives, opioids, catecholamines, vasoactive drugs);
8. level of postprocedural care (eg, intensive care unit (ICU), intermediate care unit (IMC), normal ward, time of extubation);
9. centre characteristics (eg, approximated case numbers for TF-TAVI, changeover times);
10. infrastructural prerequisites (eg, Heart Team meetings, anaesthesia standard operating procedures (SOPs), ready-to-use heart-lung machines (HLM) available, attending staff during TF-TAVI).

Statistical analysis

SPSS V.26 (SPSS, Chicago, Illinois, USA) was used for statistical analysis. This study has an explorative character. Sample size was predetermined by the number of available participating centres. We used a complete case analysis. Absolute and relative (%) frequencies were used to describe categorical variables.

Binary logistic regression analysis

Regression analysis was applied to evaluate the effects of characteristics and practices of the surveyed centres regarding periprocedural management of TF-TAVI. To identify factors characterising the considered outcomes ‘high-volume centre (HVC)’ (vs ‘low-volume centre’) and ‘MAC’ (vs ‘GA’), we fitted a regression model for each of them.

Outcome measure (dependent variable)

- ▶ HVC for TAVI (yes/no): defined as centre that reports >300 TAVI cases per year. The annual number of TAVI cases was dichotomised.
- ▶ MAC (yes/no): defined as either procedural sedation or local anaesthesia with anaesthesia stand-by as opposed to GA.

Covariates (independent variables)

We chose a two-step approach for variable selection. Data were clustered based on clinical consideration and descriptive analysis to give potentially eligible covariates. Candidate variables were preselected based on literature search, clinical considerations and a simple regression approach considering single predictors. Redundant covariates (which do not contribute to explain the outcome and inherit the risk of multicollinearity) were excluded to avoid imprecise estimations of effect sizes of single predictors in the multiple regression approach. Eight categorised covariates that rely on the reports of the participating centres were included in the multivariable regression models.

The results of multiple regression are reported as adjusted odds ratios (ORs) with their respective p values and the 95% confidence intervals (CIs). A p value <0.05 was considered to be statistically significant.

Patient and public involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Seventy-eight departments of anaesthesiology of German heart centres were contacted; 54 centres returned the questionnaire (response rate 69.2%). The electronic questionnaires were either completed by the head of the department, attending or senior anaesthesiologist.

Centre characteristics

Self-reported characteristics of the surveyed centres are given in [table 1](#).

Based on these self-assessments, centres were clustered into 'low-volume centres' (55.6% (30/54); ≤300 TAVIs per year) and HVCs (44.4% (24/54); >300 TAVIs per year), centres that predominantly performed MAC (75.9% (41/54)) and those that preferred GA (24.1% (13/54)). Of note, most centres provided both: MAC and GA; only three centres stated to exclusively perform MAC and three centres to exclusively perform GA.

Preassessment

Preprocedural standard diagnostics prior to TF-TAVI are shown in [table 1](#); 94.4% (51/54) of the responders reported that coronary angiography was routinely performed, 77.8% (42/54) reported that a chest X-ray was part of standard preparation for TF-TAVI and 42.6%

Table 1 Infrastructural prerequisites and anaesthesia standards for TF-TAVI in the participating heart centres in Germany as reported by the survey respondents

Characteristics of the participating centres	%	n
TAVI procedures per year		
Low-volume centre (≤300)		
<50	5.6	3/54
50–300	50.0	27/54
High-volume centre (>300)		
301–500	27.8	15/54
>500	16.7	9/54
Predominantly used anaesthesia methods		
MAC favoured	75.9	41/54
Local anaesthesia	9.3	5/54
Procedural sedation	66.7	36/54
GA favoured	24.1	13/54
Approximate changeover time		
<45 min	38.9	21/54
45–60 min	40.7	22/54
>60 min	20.4	11/54
Preprocedural standard diagnostics		
TTE	81.5	44/54
TOE	72.2	39/54
Chest X-ray	77.8	42/54
CT or MRI	88.9	48/54
Coronary angiography	94.4	51/54
Spirometry	42.6	23/54
Routine intraprocedural monitoring and instrumentation		
Capnometry	77.8	42/54
5-lead ECG	85.2	46/54
Central venous line (either CVC or introducer sheath)	83.3	45/54
Urinary catheter*	64.8	35/54
Invasive blood pressure monitoring	98.1	53/54
Non-invasive continuous blood pressure monitoring	0	0/54
Cardiac output monitoring (eg, thermodilution technique)	0	0/54
Bispectral index monitoring	13.0	7/54
Near-infrared spectroscopy	7.4	4/54
Pacemaker insertion	94.4	51/54
by anaesthetists	43.1	22/51
by cardiologists	56.9	29/51
Intraprocedural echocardiography	51.9	28/54
Attached defibrillator electrodes	90.7	49/54
Infrastructure and human resources		
Anaesthesia SOP available for TF-TAVI	90.7	49/54
Regular Heart Team meetings	94.4	51/54
Routine staff in attendance during the TF-TAVI procedure		
Anaesthetist	100	54/54
Cardiac surgeon	77.8	42/54
Perfusionist	66.7	36/54

Continued

Table 1 Continued

Characteristics of the participating centres	%	n
Ready-to-use heart-lung machine available on-site	75.9	41/54
Preferred anaesthesia drugs		
Premedication with benzodiazepines	16.7	9/54
Procedural sedation		
Remifentanyl	56.9	29/51
No opioid	5.9	3/51
Propofol	51.0	26/51
No hypnotic	25.5	13/51
General anaesthesia		
Remifentanyl	68.6	35/51
Other opioid	27.5	14/51
No opioid	3.9	2/51
Propofol	68.6	35/51
Inhalational anaesthetic	31.4	16/51
Catecholamines/Vasopressors†		
Epinephrine	29.6	16/54
Norepinephrine	81.5	44/54
Dobutamine or dopamine	13.0	7/54
Cafedrine/Theodrenaline	9.3	5/54
Typical postprocedural care		
Postprocedural care after GA		
Extubation after transmission on ICU	5.9	3/51
Extubation on-site and subsequent		
Transmission to ICU	60.4	29/48
Transmission to IMC	35.4	17/48
Transmission to normal ward (after postanaesthetic recovery room stay)	4.2	2/48
Postprocedural care after MAC‡		
ICU	52.9	27/51
IMC	41.2	21/51
Normal ward (after postanaesthetic recovery room stay)	3.9	2/51

*One centre stated to apply urinary catheters only in women but not in men.

†Catecholamines were used as bolus application and/or continuously.

‡One centre stated that patients are transferred to ICU or IMC dependent on bed availability.

CVC, central venous catheter; GA, general anaesthesia; ICU, intensive care unit; IMC, intermediate care unit; MAC, monitored anaesthesia care; SOP, standard operating procedure; TF-TAVI, transfemoral transcatheter aortic valve implantation; TOE, transesophageal echocardiography; TTE, transthoracic echocardiography.

(23/54) that spirometry was a routine preprocedural measure.

Monitoring and instrumentation

Apart from periprocedural standard monitoring (pulse oximetry, 3-lead or 5-lead ECG and blood pressure measurement (any method)) that was performed in all centres, reported routine monitoring differed between centres (table 1). Centres stated that the following measures were periprocedural standard of care: 5-lead ECG in 85.2% (46/54), capnometry in 77.8% (42/54) and urinary catheters in 64.8% (35/54) of centres,

respectively. Only one centre reported to not use invasive blood pressure measurement routinely. Neither non-invasive continuous blood pressure measurement nor cardiac output monitoring was routinely used for TF-TAVI in any centre. Moreover, cerebral monitoring such as BIS or NIRS was rarely used; 90.7% (49/54) of centres reported to routinely attach defibrillator electrodes to the patient prior to TF-TAVI.

Infrastructure and staff resources

It was found that 90.7% (49/54) of centres reported to have implemented an anaesthesia SOP for TF-TAVI, 94.4% (51/54) of centres stated to hold regular Heart Team meetings. All participating centres reported that anaesthetists were always in attendance and further stated that cardiac surgeons and perfusionists were also routinely in attendance throughout TF-TAVI procedures in 77.8% (42/54) and 66.7% (36/54), respectively; 75.9% (13/54) of heart centres reported to have routinely available ready-to-use HLMs on-site during TF-TAVI (table 1).

Anaesthesia drugs

- MAC: most centres reported to favour combinations of opioids and hypnotics for procedural sedation, with remifentanyl and propofol being the first choice (56.9% (29/51) and 51% (26/51), respectively). Opioid mono-sedation was reported as standard for procedural sedation in 23.5% (12/51) of centres; 13.7% (7/51) of centres reported to prefer dexmedetomidine for procedural sedation.
- GA: remifentanyl was the first-choice opioid (68.6% (35/51)) most frequently reported and propofol the first-choice hypnotic drug (68.6% (35/51)). Most centres reported to favour combinations of opioids and hypnotics (96.1% (49/51)).

Catecholamines

Centres stated to prefer norepinephrine (81.5% (44/54)) or epinephrine (29.6% (16/54)), if catecholamines were required. Few centres reported to favour cafedrine/theodrenaline (five centres), dobutamine (six centres) or dopamine (one centre) during TF-TAVI.

Vascular access

It was noted that 83.3% (45/54) of centres acknowledged to routinely insert central venous lines (either central venous catheters (CVCs) or introducer sheaths) during TF-TAVI (table 2).

In patients undergoing GA, participating centres further reported to routinely insert introducer sheaths (35.3% (18/51) via the jugular vein and 13.7% (7/51) via the femoral vein), CVCs (60.8% (31/51)) and/or large bore peripheral venous catheters (31.4% (16/51)). The reported strategy during procedural sedation was similar (table 2).

Pacemakers were reported to be routinely inserted prior to the TF-TAVI procedure in 94.4% (51/54) of centres (preferentially by anaesthetists in 43.1% (22/51), by cardiologists in 56.9% (29/51)) (table 1).

Table 2 Routinely used venous accesses in patients undergoing general anaesthesia and procedural sedation for TF-TAVI

Routinely used venous access	General anaesthesia		Procedural sedation	
	%	n	%	n
Central venous catheter	60.8	31/51	64.7	33/51
Introducer sheath via				
Jugular vein	35.3	18/51	43.1	22/51
Femoral vein	13.7	7/51	23.5	12/51
Large bore peripheral access (16–14 gauge)	31.4	16/51	37.3	19/51

TF-TAVI, transfemoral transcatheter aortic valve implantation.

Intraprocedural echocardiography

It was reported that 51.9% (28/54) of centres routinely used intraprocedural echocardiography (table 1). They further reported that TOE was more frequently used during GA as opposed to MAC. TOE was often performed by anaesthetists (table 3).

In contrast, transthoracic echocardiography was more frequently used during MAC and in this instance more frequently performed by cardiologists.

Postprocedural care

Most participants reported that patients undergoing GA were routinely extubated after TF-TAVI in the operating room and transferred to either an IMC or ICU thereafter (96.1% (49/51)). Three centres (5.9% (3/51)) stated that patients were not extubated prior to ICU transfer; 94.2% (49/52) of centres reported that patients were admitted to an IMC or ICU after MAC. Only two centres reported that patients were transferred to a postanesthetic recovery room after GA or MAC and to a normal ward thereafter.

Table 3 Intraprocedural echocardiography in relation to the applied technique (TTE or TOE) and investigator (anaesthetist or cardiologist) as reported by the survey participants

Echocardiography during TF-TAVI	TOE		TTE	
	%	n	%	n
During general anaesthesia				
Performed by anaesthetists	47.1	24/51	2.0	1/51
Performed by cardiologists	7.8	4/51	9.8	5/51
Performed by either anaesthetists or cardiologists	17.6	9/51	2.0	1/51
During procedural sedation				
Performed by anaesthetists	7.8	4/51	9.8	5/51
Performed by cardiologists	5.9	3/51	31.4	16/51
Performed by either anaesthetists or cardiologists	2.0	1/51	7.8	4/51

TF-TAVI, transfemoral transcatheter aortic valve implantation; TOE, transesophageal echocardiography; TTE, transthoracic echocardiography.

Binary logistic regression analysis

Multiple regression analysis revealed a significantly lower odds of using echocardiography in centres that prefer MAC compared with those that predominantly use GA (adjusted OR 0.13 (95% CI 0.02 to 0.83); $p=0.031$, table 4). The second multiple regression analysis explains HVCs by faster changeover times ($p=0.036$) and indicates more frequent reports of 'ready-to-use HLM available on-site' (adjusted OR 5.09 (95% CI 0.80 to 32.53); $p=0.086$) and 'SOP implemented and regular Heart Team meetings' (adjusted OR 11.16 (95% CI 0.76 to 163.31); $p=0.078$) in HVCs while none of the other considered factors predicts an HVC.

Potential infrastructural weaknesses and open questions

Table 5 gives an overview of identified potential infrastructural weaknesses and open questions regarding anaesthesia management during TF-TAVI which could be addressed by an expert panel or guideline committee.

DISCUSSION

TAVI is an emerging innovation that developed rapidly, redefined treatment strategies for AS and has become clinical routine in the last two decades. Still, expert consensus recommendations or guidelines regarding anaesthesia management are lacking.

The intention of this survey was to gather a cross-sectional overview of the daily anaesthesia practice for TF-TAVI in Germany, to expose open questions regarding periprocedural management and to reveal infrastructural strengths and weaknesses in the participating centres (table 5).

This survey revealed that the majority of German heart centres have anaesthesia SOPs for TF-TAVI, hold regular Heart Team meetings and have ready-to-use HLMs available on-site. All participating centres stated that anaesthetists were always present (100%) during TF-TAVI procedures as it has been recommended by national directives and international guidelines.^{5 14} Even though the required provision of staff resources is very costly and time consuming,¹⁶ many centres reported that Heart Team members, such as cardiac surgeons, anaesthetists and perfusionists were routinely attending throughout TF-TAVI procedures.

We found a broad variability regarding in-house standards for anaesthesia management among German heart centres: chest X-ray and spirometry were not regarded as preprocedural standard measures in many centres prior to TF-TAVI. Whereas capnometry, 5-lead ECG and attached defibrillator electrodes were reported to be applied in the majority of the centres, CVCs, introducer sheaths, large bore peripheral accesses and echocardiography are not routinely used during TF-TAVI procedures in many centres. Even though transcatheter pulmonary thermodilution and calibrated arterial pulse contour analysis reliably measure cardiac output in patients with severe AS undergoing TAVI,^{17–19} our data demonstrate that advanced

Table 4 Binary logistic regression analysis

Covariates	Simple approaches		Multiple regression analyses	
	OR (95% CI)	P value	Adjusted OR (95% CI)	P value
MAC (y/n) as opposed to GA	NA	NA	NA	NA
	3.50 (0.84 to 14.60)	0.086	2.13 (0.31 to 14.79)	0.443
High-volume centre for TAVI (y/n)	0.29 (0.07 to 1.19)	0.086	0.46 (0.07 to 2.98)	0.415
	NA	NA	NA	NA
Echocardiography during TAVI (y/n)	0.13 (0.03 to 0.66)	0.014	0.13 (0.02 to 0.83)	0.031
	0.65 (0.22 to 1.91)	0.492	2.02 (0.44 to 9.41)	0.369
Changeover time (<45, 45–60, >60 min)		0.033		0.345
		0.008		0.036
45–60 min vs >60 min	4.08 (0.87 to 19.23)	0.075	2.72 (0.38 to 19.11)	0.315
	2.10 (0.36 to 12.40)	0.413	1.44 (0.18 to 11.81)	0.736
<45 min vs >60 min	11.40 (1.74 to 74.65)	0.011	5.01 (0.55 to 45.33)	0.152
	11.25 (1.86 to 68.13)	0.008	8.85 (0.92 to 85.47)	0.060
Ready-to-use HLM available on-site (y/n)	2.58 (0.66 to 10.03)	0.172	1.25 (0.17 to 9.15)	0.830
	3.50 (0.84 to 14.60)	0.086	5.09 (0.80 to 32.53)	0.086
SOP implemented and regular Heart Team meetings (y/n)	2.78 (0.53 to 14.47)	0.226	1.80 (0.20 to 16.33)	0.600
	5.75 (0.64 to 51.53)	0.118	11.16 (0.76 to 163.31)	0.078
Norepinephrine as one of the preferred catecholamines (y/n)	0.30 (0.03 to 2.60)	0.272	0.73 (0.06 to 9.04)	0.808
	0.46 (0.11 to 1.87)	0.279	0.71 (0.12 to 4.09)	0.698
CVC routinely used (y/n)	0.34 (0.04 to 3.05)	0.337	0.46 (0.03 to 7.45)	0.581
	0.59 (0.14 to 2.47)	0.466	1.48 (0.26 to 8.26)	0.658
Complete team* attending throughout the TAVI procedure (y/n)	1.49 (0.42 to 5.25)	0.539	1.73 (0.31 to 9.53)	0.530
	1.11 (0.37 to 3.35)	0.851	0.50 (0.17 to 2.19)	0.360

Binary logistic regression analysis: two multiple regression models were fitted (right side of the table), each with a different dependent variable; in the first model (white background) 'MAC' (as compared with 'GA') was used as dependent variable, while in the second model (shaded in grey lines) 'high-volume centres' (y/n) defined as >300 and ≤300 cases per year was used as dependent variable. Each regression model includes eight categorised covariates that rely on the reports of the participating centres, with the latter category denoting the reference. Bold values denote significant values ($p < 0.05$).

*Complete team was defined as: cardiologist, cardiac surgeons, anaesthetist and perfusionists, MAC was defined as either local anaesthesia or procedural sedation.

CI, confidence interval; CVC, central venous catheter; GA, general anaesthesia; HLM, heart-lung machine; MAC, monitored anaesthesia care; NA, not available; OR, odds ratio; SOP, standard operating procedure; TAVI, transcatheter aortic valve implantation; y/n, yes/no.

haemodynamic monitoring is not routinely implemented during TF-TAVI. Although cerebral oxygen saturation (rScO₂) reflects cerebral and systemic oxygen balance during TAVI,²⁰ NIRS is rarely used during TF-TAVI.

There is growing evidence that MAC is feasible and potentially beneficial in many patients undergoing TF-TAVI.^{9–13 21} This goes in-line with our finding that the majority of German heart centres favour MAC over GA for TF-TAVI. The role of periprocedural echocardiography remains unclear, although TOE guidance might help to reduce the incidence of postprocedural aortic regurgitation²² and overall/late mortality,²³ only half of the surveyed centres reported to routinely perform intraprocedural echocardiography.

After almost two decades of TF-TAVI, international guidelines or widely accepted evidence-based recommendations for the periprocedural and anaesthesia

management are lacking. However, these are essential prerequisites to advance the idea of Enhanced Recovery After Surgery (ERAS) protocols for TF-TAVI that aim to optimise perioperative outcome.²⁴ ERAS protocols for cardiac surgery favour early extubation and mobilisation as prolonged mechanical ventilation is associated with an increased risk of ventilator-associated pneumonia, dysphagia, longer hospitalisation, higher morbidity, mortality and higher costs.²⁵ Studies to demonstrate or disprove these effects in TAVI patients are needed as the development of specific ERAS protocols could potentially improve patients' care.

Limitations

Since experience, standards and infrastructural prerequisites differ among countries, our findings cannot be generalised or extrapolated to other healthcare systems

Table 5 Potential infrastructural weaknesses and open questions regarding anaesthesia management during TF-TAVI

Potential infrastructural weaknesses of German heart centres	%	n
Cardiac surgeon not routinely in attendance throughout the TF-TAVI procedure	22.2	12/54
Perfusionist not routinely in attendance throughout the TF-TAVI procedure	33.3	18/54
No regular Heart Team meetings held	5.6	3/54
No standard operating procedure for anaesthesia care implemented	9.3	5/54
Postoperative care on normal ward	3.7	2/54
Open questions regarding anaesthesia management of patients undergoing TF-TAVI that could be addressed by an expert panel or guideline committee		
► Is chest X-ray routinely required in all patients or should it only be performed on demand? Background: chest X-ray was not routinely used in 22.2% of centres.		
► Which patients should receive preoperative spirometry? Background: spirometry was routinely used in 42.6% of centres, but selection criteria are unclear.		
► Should a 5-lead ECG be periprocedural standard? Background: 5-lead ECG was not routinely used in 14.8% of centres.		
► Should capnometry be used in all patients undergoing MAC? Background: capnometry was not routinely used in 22.2% of centres.		
► Do we need central venous lines perioperatively? Background: one out of six centres (16.7%) did not routinely use central venous lines.		
► Are urinary catheters required routinely? Background: one out of three centres (35.2%) did not routinely use urinary catheters.		
► Could cerebral monitoring be beneficial? Background: only very few centres used bispectral index (BIS) monitoring or near-infrared spectrometry (NIRS).		
► Which patients should receive periprocedural echocardiography? Background: half of centres did, and half of centres did not routinely use echocardiography. Centres that preferred MAC less frequently used intraprocedural echocardiography.		
► Should TF-TAVI preferably be performed in high-volume centres? Background: high-volume centres reported shorter changeover times. Moreover, we noticed a trend towards more implemented SOPs, routine Heart Team meetings and ready-to-use HLM availability on-site in high-volume centres. Of note, G-BA has launched an advisory procedure to address the issue of a minimum quantity of cases per centre and year.		
► Can we define clear indication criteria for MAC or GA? Background: 75.9% of all centres favoured MAC over GA (24.1%).		
► Should defibrillator electrodes be attached to the patient prior to the procedure? Background: 1 out of 10 centres (9.3%) did not attach them prior to the procedure.		
► Is there a rationale to recommend a first-choice catecholamine? Background: most centres stated to prefer norepinephrine (81.5%) or epinephrine (29.6%), if catecholamines were required. Few centres reported to favour cafedrine/theodrenaline, dobutamine or dopamine.		
► Should patients be extubated directly after TF-TAVI in the operating room? Background: some centres (5.9%) reported to routinely transfer intubated patients to the ICU. Guidelines encourage extubating patients early after the procedure. ²⁶		

GA, general anaesthesia; G-BA, German Federal Joint Committee; ICU, intensive care unit; MAC, monitored anaesthesia care; SOP, standard operating procedure; TF-TAVI, transfemoral transcatheter aortic valve implantation.

without critical appraisal. Survey questions were not developed in a Delphi procedure. Since survey participants are influenced by their personal opinions and experiences, a recall bias must be considered. As the survey was anonymised, a non-responder analysis is unfeasible. As cross-sectional studies do not provide data on patients' outcome, superiority of any specific medical regimen

cannot be derived from our data. Our data do not include conversion rates from MAC to GA.

CONCLUSION

In conclusion, we found that the concordance with national regulations, periprocedural anaesthesia

management and anaesthesia in-house standards for TF-TAVI vary broadly among German heart centres. Still, expert consensus recommendations or guidelines for anaesthesia and periprocedural management for TF-TAVI are lacking. In our opinion, the findings might be useful to push forward the idea of standardisation, international expert consensus recommendations or guidelines regarding periprocedural anaesthesia management for TF-TAVI and enhanced recovery after TF-TAVI. Further studies investigating the possible impact on patients' outcome are needed.

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REFERENCES

- lung B, Baron G, Butchart EG, *et al.* A prospective survey of patients with valvular heart disease in Europe: the Euro heart survey on valvular heart disease. *Eur Heart J* 2003;24:1231–43.
- Nkomo VT, Gardin JM, Skelton TN, *et al.* Burden of valvular heart diseases: a population-based study. *Lancet* 2006;368:1005–11.
- Baumgartner H, Falk V, Bax JJ, *et al.* 2017 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J* 2017;38:2739–91.
- IIQTIG - Institute for quality assurance and transparency in health care. Quality report 2019: isolated coronary bypass surgery; isolated aortic valve surgery; combined coronary bypass and aortic valve surgery, 2019. Available: https://iqtig.org/downloads/berichte/2018/IQTIG-Qualitaetsreport-2019_2019-09-25.pdf
- Directive of the German Federal Joint Committee (G-BA) regarding measures for quality assurance for the implementation of minimally invasive heart valve interventions 2015.
- Kim LK, Minutello RM, Feldman DN, *et al.* Association between transcatheter aortic valve implantation volume and outcomes in the United States. *Am J Cardiol* 2015;116:1910–5.
- Kaier K, Oettinger V, Reinecke H, *et al.* Volume-outcome relationship in transcatheter aortic valve implantations in Germany 2008–2014: a secondary data analysis of electronic health records. *BMJ Open* 2018;8:e020204.
- Bestehorn K, Eggebrecht H, Fleck E, *et al.* Volume-outcome relationship with transfemoral transcatheter aortic valve implantation (TAVI): insights from the compulsory German quality assurance registry on aortic valve replacement (AQUA). *EuroIntervention* 2017;13:914–20.
- Fröhlich GM, Lansky AJ, Webb J, *et al.* Local versus general anesthesia for transcatheter aortic valve implantation (TAVR)--systematic review and meta-analysis. *BMC Med* 2014;12:41.
- Husser O, Fujita B, Hengstenberg C, *et al.* Conscious sedation versus general anesthesia in transcatheter aortic valve replacement: the German aortic valve registry. *JACC Cardiovasc Interv* 2018;11:567–78.
- Villablanca PA, Mohanane D, Nikolic K, *et al.* Comparison of local versus general anesthesia in patients undergoing transcatheter aortic valve replacement: a meta-analysis. *Catheter Cardiovasc Interv* 2018;91:330–42.
- Thiele H, Kurz T, Feistritzer H-J, *et al.* General versus local anesthesia with conscious sedation in transcatheter aortic valve implantation: the randomized SOLVE-TAVI trial. *Circulation* 2020;142:1437–47.
- Ehret C, Rossaint R, Foldenauer AC, *et al.* Is local anaesthesia a favourable approach for transcatheter aortic valve implantation? A systematic review and meta-analysis comparing local and general anaesthesia. *BMJ Open* 2017;7:e016321.
- Nishimura RA, Otto CM, Bonow RO, *et al.* 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American heart association Task force on clinical practice guidelines. *Circulation* 2017;135:e1159–95.
- Van Aken H, Biermann E, Dinkel M. Revised recommendations of the German Society of anesthesiology and intensive care medicine: personnel, spatial, technical, and organizational preconditions and requirements for anesthesia services in patients undergoing cardiac surgery or interventional cardiology. *Anästh Intensivmed* 2016;57:92–5.
- Motloch LJ, Rottlaender D, Reda S, *et al.* Local versus general anesthesia for transfemoral aortic valve implantation. *Clin Res Cardiol* 2012;101:45–53.
- Petzoldt M, Riedel C, Braeunig J, *et al.* Stroke volume determination using transcardiopulmonary thermodilution and arterial pulse contour analysis in severe aortic valve disease. *Intensive Care Med* 2013;39:601–11.
- Petzoldt M, Riedel C, Braeunig J, *et al.* Dynamic device properties of pulse contour cardiac output during transcatheter aortic valve implantation. *J Clin Monit Comput* 2015;29:323–31.
- Petzoldt M, Trepte CJ, Ridder J, *et al.* Reliability of transcardiopulmonary thermodilution cardiac output measurement in experimental aortic valve insufficiency. *PLoS One* 2017;12:e0186481.
- Paarmann H, Heringlake M, Heinze H, *et al.* Non-invasive cerebral oxygenation reflects mixed venous oxygen saturation during the varying haemodynamic conditions in patients undergoing transapical transcatheter aortic valve implantation. *Interact Cardiovasc Thorac Surg* 2012;14:268–72.
- Sato K, Jones PM. Sedation versus general anesthesia for transcatheter aortic valve replacement. *J Thorac Dis* 2018;10:S3588–94.
- Oguri A, Yamamoto M, Mouillet G, *et al.* Clinical outcomes and safety of transfemoral aortic valve implantation under general versus local anesthesia: subanalysis of the French Aortic National CoreValve and Edwards 2 registry. *Circ Cardiovasc Interv* 2014;7:602–10.
- de Brito FS, Carvalho LA, Sarmiento-Leite R, *et al.* Outcomes and predictors of mortality after transcatheter aortic valve implantation: results of the Brazilian registry. *Catheter Cardiovasc Interv* 2015;85:E153–62.

- 24 Sola M, Ramm CJ, Kolarczyk LM, *et al.* Application of a multidisciplinary enhanced recovery after surgery pathway to improve patient outcomes after transcatheter aortic valve implantation. *Am J Cardiol* 2016;118:418–23.
- 25 Engelman DT, Ben Ali W, Williams JB, *et al.* Guidelines for perioperative care in cardiac surgery: enhanced recovery after surgery Society recommendations. *JAMA Surg* 2019;154:755–66.
- 26 Otto CM, Kumbhani DJ, Alexander KP, *et al.* 2017 ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis: a report of the American college of cardiology task force on clinical expert consensus documents. *J Am Coll Cardiol* 2017;69:1313–46.