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Anesthesia in patients undergoing transfemoral transcatheter aortic valve implantation (TF-TAVI) – A survey to assess the status quo in Germany Where do we stand and which conclusions should be drawn?

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Anesthesia in patients undergoing transfemoral transcatheter aortic valve implantation (TF-TAVI) – A survey to assess the status quo in Germany

Where do we stand and which conclusions should be drawn?

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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 anesthesia care. Currently, consented expert recommendations or accepted international guidelines regarding the periprocedural anesthesia management are lacking. The main objective of this study was to evaluate the status quo of anesthesia management and concordance with regulations for transfemoral transcatheter aortic valve implantation (TF-TAVI).

Design Multicentric cross-sectional online study to evaluate the periprocedural anesthesia management.

Setting In this nationwide survey, electronic questionnaires were sent out to anesthesia departments at TF-TAVI performing centers in Germany in March 2019.

Participants 78 anesthesia departments of German heart centers.

Results 54 (69.2%) centers returned the questionnaire of which 41 (75.9%) reported to predominantly use “monitored anesthesia care” and 13 (24.1%) to favor general anesthesia. 51 (94.4%) centers stated to use standard operating procedures for anesthesia. 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 centers. Participating centers stated to hold regular Heart Team meetings in 94.4%, to have ready-to-use heart-lung-machines available on site in 75.9% and that cardiac surgeons (77.8%) and perfusionists (66.7%) routinely attend throughout TF-TAVI procedures.

Conclusions Anesthesia management and in-house standards for TF-TAVI vary broadly among German heart centers. An international expert consensus and/or guideline would be helpful to standardize periinterventional anesthesia care.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first cross-sectional study which gives specific insights in anesthesia practices and periprocedural measures during TF-TAVI in Germany.
- Our data demonstrate substantial variability among anesthesia in-house standards for TF-TAVI in German heart centers.
- This study provides some evidence to enhance the awareness and to promote the debate about a standardized anesthesia management for TF-TAVI, but more clinical studies are required to finally answer open questions.
- Our survey reveals potential infrastructural strengths and weaknesses in the participating centers which could be addressed by an officially designated international guideline committee or a multidisciplinary clinical-scientific expert panel.
- A consented unified international standard of care for anesthesia and periprocedural management for TF-TAVI might be helpful to push forward innovative concepts such as Enhanced Recovery After Surgery for TF-TAVI.

INTRODUCTION

Aortic valve stenosis (AS) is one of the most frequent valve diseases with an increasing prevalence in the aging population in industrialized 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 analyzed data (20,974 TAVI procedures, 8,420 AVRs) in 2018 and revealed an in-hospital mortality of 3.1% for AVR and 2.7% for TAVI [4].

European guidelines recommend that TAVI should only be performed in heart valve centers with implemented Heart Teams [3]. As mandatory members of the Heart Team, anesthetists are involved in individual risk evaluation, multidisciplinary decision making, choice between TAVI and AVR, and perioperative care of these patients [3, 5]. TF-TAVI is performed either in general anesthesia (GA) or with monitored anesthesia care (MAC) [6–10].

Only very few recommendations exist which suggest to use perioperative equipment such as a five-lead ECG, defibrillator, and to have transesophageal echocardiography available on site for patients undergoing cardiac surgery or interventional cardiology [11]. Nevertheless, consented recommendations or widely accepted national or international guidelines regarding further important aspects for the periprocedural anesthesia management for TF-TAVI such as preassessment, anesthesia techniques, vascular access, choice of drugs and perioperative care are still lacking.

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 [12]. This directive defined structural and process quality requirements as well as staff, institutional and logistic resources for German heart centers that provide TF-TAVI. As international studies suggested possible associations between TAVI case numbers and outcome [13–15], G-BA launched a consultation procedure in June 2020 to consider mandatory minimum thresholds for both, centers and individual operators.

This nationwide survey aimed to analyze the infrastructural preconditions and the status quo of anesthesia management for TF-TAVI in the German health care system and to assess the concordance with existing regulations.

METHODS

This nationwide survey was approved by the Ethics Committee of the Medical Board of the University of Rostock (A 2019-0009, January 16th, 2019, chairperson Professor A. Büttner).

TF-TAVI-performing centers 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.survymonkey.de)*. Invitations were sent to the departments of anesthesiology of all eligible centers in March 2019 via email. Centers that did not respond within 2 weeks received a reminder via e-mail and/or were contacted via telephone.

Survey instrument

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

I: anesthesia preassessment, preparation and premedication (e.g. preprocedural diagnostics and drugs for premedication)

II: standard monitoring (e.g. pulse oximetry, non-invasive blood pressure, electrocardiography (ECG), capnometry, diuresis [urinary catheter])

III: advanced hemodynamic monitoring and neuromonitoring (e.g. cardiac output, bispectral index [BIS], near-infrared spectroscopy [NIRS])

IV: periprocedural measures (e.g. echocardiography, defibrillator electrodes)

V: vascular access and devices (e.g. arterial, central venous and peripheral lines, pacemaker)

VI: type of anesthesia (MAC [local anesthesia, procedural sedation], GA)

VII: drugs (e.g. hypnotics, sedatives, opioids, catecholamines, vasoactive drugs)

VIII: level of postprocedural care (e.g. intensive care unit [ICU], intermediate care unit [IMC], normal ward, time of extubation)

IX: center characteristics (e.g. approximated case numbers for TF-TAVI, changeover times)

X: infrastructural prerequisites (e.g. Heart Team meetings, anesthesia SOPs, ready-to-use heart-lung-machines [HLM] available, attending staff during TF-TAVI)

Statistical analysis

SPSS 26 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. This study has an explorative character. Sample size was predetermined by the number of available participating centers. 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 centers regarding periprocedural management of TF-TAVI. To identify factors characterizing the considered outcomes "high volume center [HVC]" (vs. "low volume center") and "MAC" (vs. "GA"), we fitted a regression model for each of them:

Outcome measure (dependent variable)

- HVC for TAVI [y/n]: defined as center that reports more than 300 TAVI-cases per year. The annual number of TAVI cases was dichotomized.

- MAC [y/n]: defined as either procedural sedation or local anesthesia with anesthesia 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 categorized covariates that rely on the reports of the participating centers were included in the multivariable regression models.

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

RESULTS

78 departments of anesthesiology of German heart centers were contacted; 54 centers returned the questionnaire (response-rate 69.2%). The electronic questionnaires were either completed by the head of the department, attending or senior anesthesiologist.

Center characteristics

Self-reported characteristics of the surveyed centers are given in table 1.

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

Characteristics of the participating centers	[%]	[n]
TAVI procedures per year		
low-volume center (≤300)		
<50	5.6	3/54
50-300	50.0	27/54
high-volume center (>300)		
301-500	27.8	15/54
>500	16.7	9/54
Predominantly used anesthesia methods		
Monitored anesthesia care (MAC) favored	75.9	41/54
Local anesthesia	9.3	5/54
Procedural sedation	66.7	36/54
General anesthesia (GA) favored	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
TEE	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 sheaeth)	83.3	45/54
Urinary catheter[#]	64.8	35/54
Invasive blood pressure management	98.1	53/54
Non-invasive continuous blood pressure monitoring	0	0/54
Cardiac output monitoring (e.g. 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 the anesthetist	43.1	22/51
by the cardiologists	56.9	29/51
Intraprocedural echocardiography	51.9	28/54
Attached defibrillator electrodes	90.7	49/54

Infrastructure and human resources		
Anesthesia 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		
Anesthetist	100	54/54
Cardiac surgeon	77.8	42/54
Perfusionist	66.7	36/54
Ready-to-use heart-lung-machine available on-site	75.9	41/54
Preferred anesthesia drugs		
Premedication with benzodiazepines	16.7	9/54
Procedural sedation		
Remifentanil	56.9	29/51
No opioid	5.9	3/51
Propofol	51.0	26/51
No hypnotic	25.5	13/51
General anesthesia		
Remifentanil	68.6	35/51
Other opioid	27.5	14/51
No opioid	3.9	2/51
Propofol	68.6	35/51
Inhalational anesthetic	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 post-anesthetic recovery room stay)	4.2	2/48
Postprocedural care after MAC°		
ICU	52.9	27/51
IMC	41.2	21/51
Normal ward (after post-anesthetic recovery room stay)	3.9	2/51

*Catecholamines were used as bolus application and/ or continuously; #One center stated to apply urinary catheters only in women but not in men; °One center stated that patients are transferred to ICU or IMC dependent on bed availability; SOP: standard operating procedure; TTE: transthoracic echocardiography; TEE: transesophageal echocardiography; CT: computed tomography; MRI: magnetic resonance imaging; ICU: intensive care unit; IMC: intermediate care unit; MAC: monitored anesthesia care; GA: general anesthesia

Based on these self-assessments, centers were clustered into "low-volume centers" (55.6% [30/54]; ≤300 TAVIs per year) and HVC (44.4% [24/54]; >300 TAVIs per year), centers that predominantly performed MAC (75.9% [41/54]) and those that preferred GA (24.1% [13/54]). Of note, most centers provided both, MAC and GA; only 3 centers stated to exclusively perform MAC and three centers 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] that a chest x-ray was part of standard preparation for TF-TAVI and 42.6% [23/54] that spirometry was a routine preprocedural measure.

Monitoring and instrumentation

Apart from periprocedural standard monitoring (pulse oximetry, 3- or 5-lead ECG and blood pressure measurement [any method]) that was performed in all centers, reported routine monitoring differed between centers (Table 1). Centers stated that the following measures were periprocedural standard of care: five-lead-ECG in 85.2% [46/54], capnometry in 77.8% [42/54] and urinary catheters in 64.8% [35/54] of centers, respectively. Only one center 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 center. Moreover, monitoring of cerebral activity such as bispectral index monitoring or near-infrared spectrometry was rarely used. 90.7% [49/54] of centers reported to routinely attach defibrillator electrodes to the patient prior to TF-TAVI.

Infrastructure and staff resources

90.7% [49/54] of centers reported to have implemented an anesthesia SOP for TF-TAVI, 94.4% [51/54] of centers stated to hold regular Heart Team meetings. All participating centers reported that anesthetists 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 centers indicated to have routinely ready-to-use HLMs available on site during TF-TAVI (Table 1).

Anesthesia drugs

- MAC: most centers reported to favor combinations of opioids and hypnotics for procedural sedation with remifentanil and propofol being 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 centers. 13.7% of centers reported to prefer dexmedetomidine for procedural sedation.

- GA: remifentanil was the first-choice opioid (68.6% [35/51]) most frequently reported and propofol the first-choice hypnotic drug (68.6% [35/51]). Most centers reported to favor combinations of opioids and hypnotics (96.1% [49/51]).

Catecholamines

Centers stated to prefer norepinephrine (81.5% [44/54]) or epinephrine (29.6% [16/54]), if catecholamines were required. Few centers reported to favor cafedrine/theodrenaline (5 centers), dobutamine (6 centers) or dopamine (1 center) during TF-TAVI.

Vascular access

83.3% [45/54] of centers acknowledged to routinely insert central venous lines (either CVCs or introducer sheaths) during TF-TAVI (Table 2).

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

	General anesthesia		Procedural sedation	
Routinely used venous access	[%]	[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

In patients undergoing GA participating centers 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 preprocedurally in 94.4% [51/54] of centers (preferentially by anesthetists in 43.1% [22/51], by cardiologists in 56.9% [29/51]) (Table 1).

Intraprocedural echocardiography

51.9% [28/54] of centers reported to routinely use intraprocedural echocardiography (Table 1). They further reported that transesophageal echocardiography (TEE) was more frequently used during GA as opposed to MAC. TEE was often performed by anesthetists (Table 3).

Table 3 Intraprocedural echocardiography in relation to the applied technique (TTE or TEE) and investigator (anesthetist or cardiologist) as reported by the survey participators

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

TTE: transthoracic echocardiography; TEE: transesophageal echocardiography

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 centers (5.9% [3/51]) stated that patients were not extubated prior to ICU transfer. 94.2% [49/52] of centers reported that patients were admitted to an IMC or ICU after MAC. Only two centers reported that patients were transferred to a post-anesthetic recovery room after GA or MAC and to a normal ward thereafter.

Binary logistic regression analysis

Multiple regression analysis revealed a significantly lower odds of using echocardiography in centers that prefer MAC compared to those that predominantly use GA (adjusted OR 0.13 [0.02-0.83]; p=0.031, Table 4).

Table 4 Binary logistic regression analysis

Covariates	Simple approaches OR [95% CI]	Simple approaches p-value	Multiple regression analyses adj. OR [95% CI]	Multiple regression analyses p-value
MAC [y/n] as opposed to GA	NA	NA	NA	NA
	3.50 [0.84-14.60]	0.086	2.13 [0.31-14.79]	0.443
High volume center for TAVI [y/n]	0.29 [0.07-1.19]	0.086	0.46 [0.07-2.98]	0.415
	NA	NA	NA	NA
Echocardiography during TAVI [y/n]	0.13 [0.03-0.66]	0.014	**0.13 [0.02-0.83]**	**0.031**
	0.65 [0.22-1.91]	0.492	2.02 [0.44-9.41]	0.369
Changeover time [<45, 45-60, >60 min]		0.033		0.345
		0.008		**0.036**
45-60 min versus >60 min	4.08 [0.87-19.23]	0.075	2.72 [0.38-19.11]	0.315
	2.10 [0.36-12.40]	0.413	1.44 [0.18-11.81]	0.736
<45 min versus >60 min	11.40 [1.74-74.65]	0.011	5.01 [0.55-45.33]	0.152
	11.25 [1.86-68.13]	0.008	8.85 [0.92-85.47]	0.060
Ready-to-use HLM available on site [y/n]	2.58 [0.66-10.03]	0.172	1.25 [0.17-9.15]	0.830
	3.50 [0.84-14.60]	0.086	5.09 [0.80-32.53]	0.086
SOP implemented and regular Heart Team meetings [y/n]	2.78 [0.53-14.47]	0.226	1.80 [0.20-16.33]	0.600
	5.75 [0.64-51.53]	0.118	11.16 [0.76-163.31]	0.078
Norepinephrine as one of the preferred catecholamines [y/n]	0.30 [0.03-2.60]	0.272	0.73 [0.06-9.04]	0.808
	0.46 [0.11-1.87]	0.279	0.71 [0.12-4.09]	0.698
CVC routinely used [y/n]	0.34 [0.04-3.05]	0.337	0.46 [0.03-7.45]	0.581
	0.59 [0.14-2.47]	0.466	1.48 [0.26-8.26]	0.658
Complete team* attending throughout the TAVI procedure [y/n]	1.49 [0.42-5.25]	0.539	1.73 [0.31-9.53]	0.530
	1.11 [0.37-3.35]	0.851	0.50 [0.17-2.19]	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) “monitored anesthesia care” (as compared with “general anesthesia”) was used as dependent variable, while in the second model (shaded in grey lines) “high volume centers” [y/n] defined as >300 and ≤300 cases per year was used as dependent variable. Each regression model includes eight categorized covariates that rely on the reports of the participating centers, with the latter category denoting the reference; *complete team was defined as: cardiologist, cardiac surgeons, anesthetist and perfusionists, MAC: monitored anesthesia care was defined as either local anesthesia or procedural sedation; GA: general anesthesia; HLM: heart lung machine; CVC: central venous catheter; OR: odds ratio, adj. OR: adjusted OR; CI: confidence interval; NA: not applicable

The second multiple regression analysis explains HVCs by faster changeover times ($p=0.031$) and indicates in HVCs more frequent reports of "ready-to-use HLM available on site" (adjusted OR 5.09 [0.80-32.53]; $p=0.086$) and "SOP implemented and regular Heart Team meetings" (adjusted OR 11.16 [0.76-163.31]; $p=0.078$) while none of the other considered factors predicts a HVC.

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, consented recommendations or accepted guidelines regarding anesthesia management are lacking.

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

Table 5 Potential infrastructural weaknesses and remaining controversies regarding anesthesia management during TF-TAVI

Potential infrastructural weaknesses in the survey of German heart centers	[%]	[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 anesthesia care implemented	9.3	5/54
Postoperative care on normal ward	3.7	2/54

Remaining controversies regarding anesthesia 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 only be performed on demand?
  Background: chest x-ray was not routinely used in 22.2% of centers
- Which patients should receive preoperative spirometry?
  Background: spirometry was routinely used in 42.6% of centers, 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 centers.
- Should capnometry be used in all patients undergoing MAC?
  Background: capnometry was not routinely used in 22.2% of centers.
- Do we need central venous lines perioperatively?
  Background: one out of 6 centers (16.7%) did not routinely use central venous lines.
- Are urinary catheters required routinely?
  Background: one out of 3 centers (35.2%) did not routinely use urinary catheters.
- Could monitoring of cerebral activity be beneficial?
  Background: only very few centers used bispectral index monitoring or near-infrared spectrometry.

- Which patients should receive periprocedural echocardiography?
  Background: half of centers did, and half of centers did not routinely use echocardiography. Centers that preferred MAC less frequently used intraprocedural echocardiography.
- Should TF-TAVI preferably be performed in high-volume centers?
  Background: high-volume centers 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 centers. Of note, G-BA has launched an advisory procedure to address the issue of a minimum quantity of cases per center and year.
- Can we define clear indication criteria for MAC or GA?
  Background: 75.9% of all centers favored MAC over GA (23.1%).
- Should defibrillator electrodes be attached to the patient prior to the procedure?
  Background: one out of 10 centers (9.3%) did not attach them prior to the procedure.
- Is there a rational to recommend a first-choice catecholamine?
  Background: most centers stated to prefer norepinephrine (81.5%) or epinephrine (29.6%), if catecholamines were required, few centers reported to favor cafedrine/ theodrenaline, dobutamine or dopamine.
- Should patients be extubated directly after TF-TAVI in the operating room?
  Background: some centers (5.9%) reported to routinely transfer intubated patients to the ICU. Guidelines encourage extubating patients early after the procedure[16].

ECG: electrocardiogram; MAC: monitored anesthesia care; OR: operating room; ICU: intensive care unit

First of all, this survey revealed that the majority of German heart centers have anesthesia SOPs for TF-TAVI, hold regular heart team meetings and have ready-to-use HLMs available on site. All participating centers stated that anesthetists were always present (100%) during TF-TAVI procedures as it has been recommended by national directives and international guidelines [5, 12]. Even though the required provision of staff resources is very costly and time consuming [17], many centers reported that heart team members, such as cardiac surgeons, anesthetists and perfusionists were routinely attending throughout TF-TAVI procedures.

We found a broad variability regarding in-house standards for anesthesia management among German heart centers: Our data indicate that it is up to debate, if chest x-ray or spirometry should routinely be obtained prior to TF-TAVI and if capnometry, five-lead ECG, central venous catheters, introducer sheaths, large bore peripheral accesses, echocardiography and attached defibrillator electrodes should be standard of care during TF-TAVI procedures. Even though transcardiopulmonary thermodilution and calibrated arterial pulse contour analysis reliably measure cardiac output in patients with severe AS undergoing TAVI [18–20], our data demonstrate that advanced hemodynamic monitoring is not routinely implemented during TF-

TAVI. Although cerebral oxygen saturation ($rScO_2$) not only reflects cerebral but also systemic oxygen balance during TAVI [21], near-infrared spectroscopy (NIRS) is rarely used during TF-TAVI.

There is growing evidence, that MAC is feasible and potentially beneficial in many patients undergoing TF-TAVI [6–10, 22]. This goes in-line with our finding that the majority of German heart centers favor MAC over GA for TF-TAVI. The role of periprocedural echocardiography remains unclear: although TEE guidance might help to reduce the incidence of postprocedural aortic regurgitation [23] and overall/late mortality [24], only half of the surveyed centers 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 anesthesia 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 optimize perioperative outcome [25]. ERAS protocols for cardiac surgery favor early extubation and mobilization as prolonged mechanical ventilation is associated with an increased risk of ventilator associated pneumonia, dysphagia, longer hospitalization, higher morbidity, mortality, and higher costs [26]. Studies to demonstrate or deny 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 generalized or extrapolated to other health care systems without critical appraisal. As there was a substantial number of non-responders a possible bias must be considered. A non-responder analysis was not feasible. Since survey participants are influenced by their personal opinions and experiences a reporting bias must be assumed.

In conclusion, we found substantial variability among anesthesia in-house standards for TF-TAVI in German heart centers. Our data indicate that a consented standard of care for anesthesia and periprocedural management for TF-TAVI would be advantageous. This could best be realized by an officially designated international guideline or clinical-scientific expert committee. Further studies are needed to push forward the idea to enhance recovery after TF-TAVI.

Author contributions

BL: This author conceived and designed the study, was responsible for data analysis and interpretation, and drafted the manuscript.

AH: This author conceived and designed the study and drafted the manuscript.

AZ: This author was responsible for data analysis and interpretation, and drafted the manuscript.

AD: This author was responsible for data interpretation and drafted the manuscript.

ST: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

DAR: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

SAH: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

ÄG: This author was responsible for data analysis and interpretation and drafted the manuscript.

MP: This author was responsible for data analysis and interpretation, drafted the manuscript, and supervised the study.

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Competing interests

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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.

Patient consent for publication

Not required.

Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information.

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Institutional infrastructural preconditions and current perioperative anesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centers

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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 anesthesia 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 centers. But still generally accepted expert consensus recommendations or national or international guidelines regarding periprocedural anesthesia 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 secondly to evaluate the status quo of periprocedural anesthesia management for patients undergoing TF-TAVI in German heart centers.

Design Multicenter cross-sectional online study to evaluate the periprocedural anesthesia management.

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

Participants 78 anesthesia departments of German heart centers.

Results 54 (69.2%) centers 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 anesthesia management 41 (75.9%) of the participating centers reported to predominantly use “monitored anesthesia care” and 13 (24.1%) to favor general anesthesia. 51 (94.4%) centers stated to use institutional standard operating procedures for anesthesia. 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 centers.

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

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first cross-sectional study which gives specific insights in anesthesia practices and periprocedural measures during TF-TAVI in Germany.
- Our data demonstrate substantial variability among anesthesia in-house standards for TF-TAVI in German heart centers.
- This study intended to enhance the awareness and to promote the debate about a standardized anesthesia 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 centers 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 anesthesia and periprocedural management for TF-TAVI might be helpful to push forward innovative concepts such as Enhanced Recovery After Surgery for TF-TAVI.

INTRODUCTION

Aortic valve stenosis (AS) is one of the most frequent valve diseases with an increasing prevalence in the aging population in industrialized 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 analyzed data (20,974 TAVI procedures, 8,420 AVRs) in 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 centers 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: centers and individual operators.

TF-TAVI is performed either in general anesthesia (GA) or with monitored anesthesia care (MAC) [9–13]. European guidelines recommend that TAVI should only be performed in heart valve centers with implemented Heart Teams [3]. As mandatory members of the Heart Team, anesthetists 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 anesthesia with expertise in cardiac anesthesia should be involved in TF-TAVI procedures in German Heart Centers [5], only few specific recommendations on the targeted use of perioperative equipment such as five-lead ECG or defibrillators, and the availability of transesophageal echocardiography on site for patients undergoing cardiac surgery or interventional cardiology exist [15].

Generally accepted national/international guidelines or expert consensus recommendations on periprocedural anesthesia management for TF-TAVI are still lacking, and the specific preassessment, anesthesia 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 health care system. Secondly, this study aimed to evaluate the status quo of periprocedural anesthesia management for TF-TAVI in German heart centers.

METHODS

This anonymized nationwide survey was approved by the Ethics Committee of the Medical Board of the University of Rostock (A 2019-0009, January 16th, 2019, chairperson Professor A. Büttner).

TF-TAVI-performing centers 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 anesthesiology of all eligible centers 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 anesthesia and perioperative management of patients undergoing TF-TAVI and to obtain specific insights in the infrastructure and processes of each participating center. The electronic questionnaire included 25 questions that focused on:

I: anesthesia preassessment, preparation and premedication (e.g. preprocedural diagnostics and drugs for premedication)

II: standard monitoring (e.g. pulse oximetry, non-invasive blood pressure, electrocardiography (ECG), capnometry, diuresis [urinary catheter])

III: advanced hemodynamic monitoring and neuromonitoring (e.g. cardiac output, bispectral index [BIS], near-infrared spectroscopy [NIRS])

IV: periprocedural measures (e.g. echocardiography, defibrillator electrodes)

V: vascular access and devices (e.g. arterial, central venous and peripheral lines, pacemaker)

VI: standard approach/type of anesthesia (MAC [local anesthesia, procedural sedation], GA)

VII: drugs (e.g. hypnotics, sedatives, opioids, catecholamines, vasoactive drugs)

VIII: level of postprocedural care (e.g. intensive care unit [ICU], intermediate care unit [IMC], normal ward, time of extubation)

IX: center characteristics (e.g. approximated case numbers for TF-TAVI, changeover times)

X: infrastructural prerequisites (e.g. Heart Team meetings, anesthesia SOPs, ready-to-use heart-lung-machines [HLM] available, attending staff during TF-TAVI)

Statistical analysis

SPSS 26 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. This study has an explorative character. Sample size was predetermined by the number of available participating centers. 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 centers regarding periprocedural management of TF-TAVI. To identify factors characterizing the considered outcomes "high volume center [HVC]" (vs. "low volume center") and "MAC" (vs. "GA"), we fitted a regression model for each of them:

Outcome measure (dependent variable)

- HVC for TAVI [y/n]: defined as center that reports more than 300 TAVI-cases per year. The annual number of TAVI cases was dichotomized.

- MAC [y/n]: defined as either procedural sedation or local anesthesia with anesthesia 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 categorized covariates that rely on the reports of the participating centers were included in the multivariable regression models.

The results of multiple regression are reported as adjusted odds ratios with their respecting p-values and the 95% confidence intervals (95% CIs). A $p<0.05$ was considered 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

78 departments of anesthesiology of German heart centers were contacted; 54 centers returned the questionnaire (response-rate 69.2%). The electronic questionnaires were either completed by the head of the department, attending or senior anesthesiologist.

Center characteristics

Self-reported characteristics of the surveyed centers are given in table 1.

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

Characteristics of the participating centers	[%]	[n]
TAVI procedures per year		
low-volume center (≤300)		
<50	5.6	3/54
50-300	50.0	27/54
high-volume center (>300)		
301-500	27.8	15/54
>500	16.7	9/54
Predominantly used anesthesia methods		
Monitored anesthesia care (MAC) favored	75.9	41/54
Local anesthesia	9.3	5/54
Procedural sedation	66.7	36/54
General anesthesia (GA) favored	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
TEE	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 (e.g. 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 anesthetists	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		
Anesthesia 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		
Anesthetist	100	54/54
Cardiac surgeon	77.8	42/54
Perfusionist	66.7	36/54
Ready-to-use heart-lung-machine available on-site	75.9	41/54
Preferred anesthesia drugs		
Premedication with benzodiazepines	16.7	9/54
Procedural sedation		
Remifentanil	56.9	29/51
No opioid	5.9	3/51
Propofol	51.0	26/51
No hypnotic	25.5	13/51
General anesthesia		
Remifentanil	68.6	35/51
Other opioid	27.5	14/51
No opioid	3.9	2/51
Propofol	68.6	35/51
Inhalational anesthetic	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 post-anesthetic recovery room stay)	4.2	2/48
Postprocedural care after MAC°		
ICU	52.9	27/51
IMC	41.2	21/51
Normal ward (after post-anesthetic recovery room stay)	3.9	2/51

*Catecholamines were used as bolus application and/or continuously; #One center stated to apply urinary catheters only in women but not in men; °One center stated that patients are transferred to ICU or IMC dependent on bed availability; SOP: standard operating procedure; TTE: transthoracic echocardiography; TEE: transesophageal echocardiography; CT: computed tomography; MRI: magnetic resonance imaging; ICU: intensive care unit; IMC: intermediate care unit; MAC: monitored anesthesia care; GA: general anesthesia

Based on these self-assessments, centers were clustered into "low-volume centers" (55.6% [30/54]; ≤300 TAVIs per year) and HVC (44.4% [24/54]; >300 TAVIs per year), centers that predominantly performed MAC (75.9% [41/54]) and those that preferred GA (24.1% [13/54]). Of note, most centers provided both: MAC and GA; only 3 centers stated to exclusively perform MAC and three centers 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] that a chest x-ray was part of standard preparation for TF-TAVI and 42.6% [23/54] that spirometry was a routine preprocedural measure.

Monitoring and instrumentation

Apart from periprocedural standard monitoring (pulse oximetry, 3- or 5-lead ECG and blood pressure measurement [any method]) that was performed in all centers, reported routine monitoring differed between centers (Table 1). Centers stated that the following measures were periprocedural standard of care: five-lead-ECG in 85.2% [46/54], capnometry in 77.8% [42/54] and urinary catheters in 64.8% [35/54] of centers, respectively. Only one center 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 center. Moreover, monitoring of cerebral activity such as bispectral index monitoring or near-infrared spectrometry was rarely used. 90.7% [49/54] of centers reported to routinely attach defibrillator electrodes to the patient prior to TF-TAVI.

Infrastructure and staff resources

90.7% [49/54] of centers reported to have implemented an anesthesia SOP for TF-TAVI, 94.4% [51/54] of centers stated to hold regular Heart Team meetings. All participating centers reported that anesthetists 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 centers reported to have routinely ready-to-use HLMs available on site during TF-TAVI (Table 1).

Anesthesia drugs

- MAC: most centers reported to favor combinations of opioids and hypnotics for procedural sedation with remifentanil and propofol being 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 centers. 13.7% of centers reported to prefer dexmedetomidine for procedural sedation.

- GA: remifentanil was the first-choice opioid (68.6% [35/51]) most frequently reported and propofol the first-choice hypnotic drug (68.6% [35/51]). Most centers reported to favor combinations of opioids and hypnotics (96.1% [49/51]).

Catecholamines

Centers stated to prefer norepinephrine (81.5% [44/54]) or epinephrine (29.6% [16/54]), if catecholamines were required. Few centers reported to favor cafedrine/theodrenaline (5 centers), dobutamine (6 centers) or dopamine (1 center) during TF-TAVI.

Vascular access

83.3% [45/54] of centers acknowledged to routinely insert central venous lines (either CVCs or introducer sheaths) during TF-TAVI (Table 2).

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

Routinely used venous access	General anesthesia [%]	[n]	Procedural sedation [%]	[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

In patients undergoing GA participating centers 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 centers (preferentially by anesthetists in 43.1% [22/51], by cardiologists in 56.9% [29/51]) (Table 1).

Intraprocedural echocardiography

51.9% [28/54] of centers reported to routinely use intraprocedural echocardiography (Table 1). They further reported that transesophageal echocardiography (TEE) was more frequently used during GA as opposed to MAC. TEE was often performed by anesthetists (Table 3).

Table 3 Intraprocedural echocardiography in relation to the applied technique (TTE or TEE) and investigator (anesthetist or cardiologist) as reported by the survey participators

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

TTE: transthoracic echocardiography; TEE: transesophageal echocardiography

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 centers (5.9% [3/51]) stated that patients were not extubated prior to ICU transfer. 94.2% [49/52] of centers reported that patients were admitted to an IMC or ICU after MAC. Only two centers reported that patients were transferred to a post-anesthetic recovery room after GA or MAC and to a normal ward thereafter.

Binary logistic regression analysis

Multiple regression analysis revealed a significantly lower odds of using echocardiography in centers that prefer MAC compared to those that predominantly use GA (adjusted OR 0.13 [0.02-

0.83]; p=0.031, Table 4). The second multiple regression analysis explains HVCs by faster changeover times (p=0.036) and indicates in HVCs more frequent reports of "ready-to-use HLM available on site" (adjusted OR 5.09 [0.80-32.53]; p=0.086) and "SOP implemented and regular Heart Team meetings" (adjusted OR 11.16 [0.76-163.31]; p=0.078) while none of the other considered factors predicts a HVC.

Table 4 Binary logistic regression analysis

Covariates	Simple approaches		Multiple regression analyses	
	OR [95% CI]	p-value	adj. OR [95% CI]	p-value
MAC [y/n] as opposed to GA	NA	NA	NA	NA
	3.50 [0.84-14.60]	0.086	2.13 [0.31-14.79]	0.443
High volume center for TAVI [y/n]	0.29 [0.07-1.19]	0.086	0.46 [0.07-2.98]	0.415
	NA	NA	NA	NA
Echocardiography during TAVI [y/n]	0.13 [0.03-0.66]	0.014	**0.13 [0.02-0.83]**	**0.031**
	0.65 [0.22-1.91]	0.492	2.02 [0.44-9.41]	0.369
Changeover time [<45, 45-60, >60 min]		0.033		0.345
		0.008		**0.036**
45-60 min versus >60 min	4.08 [0.87-19.23]	0.075	2.72 [0.38-19.11]	0.315
	2.10 [0.36-12.40]	0.413	1.44 [0.18-11.81]	0.736
<45 min versus >60 min	11.40 [1.74-74.65]	0.011	5.01 [0.55-45.33]	0.152
	11.25 [1.86-68.13]	0.008	8.85 [0.92-85.47]	0.060
Ready-to-use HLM available on site [y/n]	2.58 [0.66-10.03]	0.172	1.25 [0.17-9.15]	0.830
	3.50 [0.84-14.60]	0.086	5.09 [0.80-32.53]	0.086
SOP implemented and regular Heart Team meetings [y/n]	2.78 [0.53-14.47]	0.226	1.80 [0.20-16.33]	0.600
	5.75 [0.64-51.53]	0.118	11.16 [0.76-163.31]	0.078
Norepinephrine as one of the preferred catecholamines [y/n]	0.30 [0.03-2.60]	0.272	0.73 [0.06-9.04]	0.808
	0.46 [0.11-1.87]	0.279	0.71 [0.12-4.09]	0.698
CVC routinely used [y/n]	0.34 [0.04-3.05]	0.337	0.46 [0.03-7.45]	0.581
	0.59 [0.14-2.47]	0.466	1.48 [0.26-8.26]	0.658
Complete team* attending throughout the TAVI procedure [y/n]	1.49 [0.42-5.25]	0.539	1.73 [0.31-9.53]	0.530
	1.11 [0.37-3.35]	0.851	0.50 [0.17-2.19]	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) "monitored anesthesia care" (as compared with "general anesthesia") was used as dependent variable, while in the second model (shaded in grey lines) "high volume centers" [y/n] defined as >300 and ≤300 cases per year was used as dependent variable. Each regression model includes eight categorized covariates that rely on the reports of the participating centers, with the latter category denoting the reference; *complete team was defined as: cardiologist, cardiac surgeons, anesthetist and perfusionists, MAC: monitored anesthesia care was defined as either local anesthesia or procedural sedation; GA: general anesthesia; HLM: heart lung machine; CVC: central venous catheter; OR: odds ratio, adj. OR: adjusted OR; CI: confidence interval; NA: not applicable

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 anesthesia management are lacking.

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

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

Potential infrastructural weaknesses in the survey of German heart centers	[%]	[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 anesthesia care implemented	9.3	5/54
Postoperative care on normal ward	3.7	2/54

Open questions regarding anesthesia 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 only be performed on demand?
  Background: chest x-ray was not routinely used in 22.2% of centers
- Which patients should receive preoperative spirometry?
  Background: spirometry was routinely used in 42.6% of centers, 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 centers.
- Should capnometry be used in all patients undergoing MAC?
  Background: capnometry was not routinely used in 22.2% of centers.
- Do we need central venous lines perioperatively?
  Background: one out of 6 centers (16.7%) did not routinely use central venous lines.
- Are urinary catheters required routinely?
  Background: one out of 3 centers (35.2%) did not routinely use urinary catheters.
- Could monitoring of cerebral activity be beneficial?
  Background: only very few centers used bispectral index monitoring or near-infrared spectrometry.
- Which patients should receive periprocedural echocardiography?
  Background: half of centers did, and half of centers did not routinely use echocardiography. Centers that preferred MAC less frequently used intraprocedural echocardiography.
- Should TF-TAVI preferably be performed in high-volume centers?
  Background: high-volume centers 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 centers. Of note, G-BA has launched an advisory procedure to address the issue of a minimum quantity of cases per center and year.
- Can we define clear indication criteria for MAC or GA?
  Background: 75.9% of all centers favored MAC over GA (23.1%).
- Should defibrillator electrodes be attached to the patient prior to the procedure?
  Background: one out of 10 centers (9.3%) did not attach them prior to the procedure.

- Is there a rationale to recommend a first-choice catecholamine?
  Background: most centers stated to prefer norepinephrine (81.5%) or epinephrine (29.6%), if catecholamines were required, few centers reported to favor cafedrine/theodrenaline, dobutamine or dopamine.
- Should patients be extubated directly after TF-TAVI in the operating room?
  Background: some centers (5.9%) reported to routinely transfer intubated patients to the ICU. Guidelines encourage extubating patients early after the procedure[16].

ECG: electrocardiogram; MAC: monitored anesthesia care; OR: operating room; ICU: intensive care unit

First of all, this survey revealed that the majority of German heart centers have anesthesia SOPs for TF-TAVI, hold regular heart team meetings and have ready-to-use HLMs available on site. All participating centers stated that anesthetists 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 [17], many centers reported that heart team members, such as cardiac surgeons, anesthetists and perfusionists were routinely attending throughout TF-TAVI procedures.

We found a broad variability regarding in-house standards for anesthesia management among German heart centers: chest x-ray and spirometry were not regarded as preprocedural standard measures in many centers prior to TF-TAVI. Although, capnometry, five-lead ECG, and attached defibrillator electrodes were reported to be applied in the majority of the centers, central venous catheters, introducer sheaths, large bore peripheral accesses, and echocardiography are not routinely used during TF-TAVI procedures in many centers. Even though transcardiopulmonary thermodilution and calibrated arterial pulse contour analysis reliably measure cardiac output in patients with severe AS undergoing TAVI [18–20], our data demonstrate that advanced hemodynamic monitoring is not routinely implemented during TF-TAVI. Although cerebral oxygen saturation ($rScO_2$) not only reflects cerebral but also systemic oxygen balance during TAVI [21], near-infrared spectroscopy (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, 22]. This goes in-line with our finding that the majority of German heart centers favor MAC over GA for TF-TAVI. The role of periprocedural echocardiography remains unclear: although TEE guidance might help to reduce the incidence of postprocedural aortic regurgitation [23] and overall/late mortality [24], only half of the surveyed centers 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 anesthesia 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 optimize perioperative outcome [25]. ERAS protocols for cardiac surgery favor early extubation and mobilization as prolonged mechanical ventilation is associated with an increased risk of ventilator associated pneumonia, dysphagia, longer hospitalization, higher morbidity, mortality, and higher costs [26]. Studies to demonstrate or deny 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 generalized or extrapolated to other health care systems 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 anonymized 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.

In conclusion we found that the concordance with national regulations, periprocedural anesthesia management and anesthesia in-house standards for TF-TAVI vary broadly among German heart centers. Still, expert consensus recommendations or guidelines for anesthesia and periprocedural management for TF-TAVI are lacking. In our opinion, the findings might be useful to push forward the idea of standardization, international expert consensus recommendations or guidelines regarding periprocedural anesthesia management for TF-TAVI and enhanced recovery after TF-TAVI. Further studies investigating the possible impact on patients' outcome are needed.

Author contributions

BL: This author conceived and designed the study, was responsible for data analysis and interpretation, and drafted the manuscript.

AH: This author conceived and designed the study and drafted the manuscript.

AZ: This author was responsible for data analysis and interpretation, and drafted the manuscript.

AD: This author was responsible for data interpretation and drafted the manuscript.

ST: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

DAR: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

SAH: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

ÄG: This author was responsible for data analysis and interpretation and drafted the manuscript.

MP: This author was responsible for data analysis and interpretation, drafted the manuscript, and supervised the study.

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Patient consent for publication

Not required.

Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information.

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Institutional infrastructural preconditions and current perioperative anesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centers

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-9
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9-10
		(*b*) Describe any methods used to examine subgroups and interactions	9-10
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	11-12

Outcome data	15*	Report numbers of outcome events or summary measures	14-17
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 4
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14-17
Discussion			
Key results	18	Summarise key results with reference to study objectives	20-21
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-20
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23

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Institutional infrastructural preconditions and current perioperative anesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centers

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Institutional infrastructural preconditions and current perioperative anesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centers

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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 anesthesia 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 centers. But still generally accepted expert consensus recommendations or national or international guidelines regarding periprocedural anesthesia 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 secondly to evaluate the status quo of periprocedural anesthesia management for patients undergoing TF-TAVI in German heart centers.

Design Multicenter cross-sectional online study to evaluate the periprocedural anesthesia management.

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

Participants 78 anesthesia departments of German heart centers.

Results 54 (69.2%) centers 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 anesthesia management 41 (75.9%) of the participating centers reported to predominantly use “monitored anesthesia care” and 13 (24.1%) to favor general anesthesia. 51 (94.4%) centers stated to use institutional standard operating procedures for anesthesia. 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 centers.

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

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first cross-sectional study which gives specific insights in anesthesia practices and periprocedural measures during TF-TAVI in Germany.
- Our data demonstrate substantial variability among anesthesia in-house standards for TF-TAVI in German heart centers.
- This study intended to enhance the awareness and to promote the debate about a standardized anesthesia 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 centers 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 anesthesia and periprocedural management for TF-TAVI might be helpful to push forward innovative concepts such as Enhanced Recovery After Surgery for TF-TAVI.

INTRODUCTION

Aortic valve stenosis (AS) is one of the most frequent valve diseases with an increasing prevalence in the aging population in industrialized 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 analyzed data (20,974 TAVI procedures, 8,420 AVRs) in 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 centers 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: centers and individual operators.

TF-TAVI is performed either in general anesthesia (GA) or with monitored anesthesia care (MAC) [9–13]. European guidelines recommend that TAVI should only be performed in heart valve centers with implemented Heart Teams [3]. As mandatory members of the Heart Team, anesthetists 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 anesthesia with expertise in cardiac anesthesia should be involved in TF-TAVI procedures in German Heart Centers [5], only few specific recommendations on the targeted use of perioperative equipment such as five-lead ECG or defibrillators, and the availability of transesophageal echocardiography on site for patients undergoing cardiac surgery or interventional cardiology exist [15].

Generally accepted national/international guidelines or expert consensus recommendations on periprocedural anesthesia management for TF-TAVI are still lacking, and the specific preassessment, anesthesia 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 health care system. Secondly, this study aimed to evaluate the status quo of periprocedural anesthesia management for TF-TAVI in German heart centers.

METHODS

This anonymized nationwide survey was approved by the Ethics Committee of the Medical Board of the University of Rostock (A 2019-0009, January 16th, 2019, chairperson Professor A. Büttner).

TF-TAVI-performing centers 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 anesthesiology of all eligible centers 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 anesthesia and perioperative management of patients undergoing TF-TAVI and to obtain specific insights in the infrastructure and processes of each participating center. The electronic questionnaire included 25 questions that focused on:

I: anesthesia preassessment, preparation and premedication (e.g. preprocedural diagnostics and drugs for premedication)

II: standard monitoring (e.g. pulse oximetry, non-invasive blood pressure, electrocardiography (ECG), capnometry, diuresis [urinary catheter])

III: advanced hemodynamic monitoring and neuromonitoring (e.g. cardiac output, bispectral index [BIS], near-infrared spectroscopy [NIRS])

IV: periprocedural measures (e.g. echocardiography, defibrillator electrodes)

V: vascular access and devices (e.g. arterial, central venous and peripheral lines, pacemaker)

VI: standard approach/type of anesthesia (MAC [local anesthesia, procedural sedation], GA)

VII: drugs (e.g. hypnotics, sedatives, opioids, catecholamines, vasoactive drugs)

VIII: level of postprocedural care (e.g. intensive care unit [ICU], intermediate care unit [IMC], normal ward, time of extubation)

IX: center characteristics (e.g. approximated case numbers for TF-TAVI, changeover times)

X: infrastructural prerequisites (e.g. Heart Team meetings, anesthesia SOPs, ready-to-use heart-lung-machines [HLM] available, attending staff during TF-TAVI)

Statistical analysis

SPSS 26 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. This study has an explorative character. Sample size was predetermined by the number of available participating centers. 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 centers regarding periprocedural management of TF-TAVI. To identify factors characterizing the considered outcomes "high volume center [HVC]" (vs. "low volume center") and "MAC" (vs. "GA"), we fitted a regression model for each of them:

Outcome measure (dependent variable)

- HVC for TAVI [y/n]: defined as center that reports more than 300 TAVI-cases per year. The annual number of TAVI cases was dichotomized.

- MAC [y/n]: defined as either procedural sedation or local anesthesia with anesthesia 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 categorized covariates that rely on the reports of the participating centers were included in the multivariable regression models.

The results of multiple regression are reported as adjusted odds ratios with their respecting p-values and the 95% confidence intervals (95% CIs). A $p<0.05$ was considered 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

78 departments of anesthesiology of German heart centers were contacted; 54 centers returned the questionnaire (response-rate 69.2%). The electronic questionnaires were either completed by the head of the department, attending or senior anesthesiologist.

Center characteristics

Self-reported characteristics of the surveyed centers are given in table 1.

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

Characteristics of the participating centers	[%]	[n]
TAVI procedures per year		
low-volume center (≤300)		
<50	5.6	3/54
50-300	50.0	27/54
high-volume center (>300)		
301-500	27.8	15/54
>500	16.7	9/54
Predominantly used anesthesia methods		
Monitored anesthesia care (MAC) favored	75.9	41/54
Local anesthesia	9.3	5/54
Procedural sedation	66.7	36/54
General anesthesia (GA) favored	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
TEE	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 (e.g. 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 anesthetists	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		
Anesthesia 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		
Anesthetist	100	54/54
Cardiac surgeon	77.8	42/54
Perfusionist	66.7	36/54
Ready-to-use heart-lung-machine available on-site	75.9	41/54
Preferred anesthesia drugs		
Premedication with benzodiazepines	16.7	9/54
Procedural sedation		
Remifentanil	56.9	29/51
No opioid	5.9	3/51
Propofol	51.0	26/51
No hypnotic	25.5	13/51
General anesthesia		
Remifentanil	68.6	35/51
Other opioid	27.5	14/51
No opioid	3.9	2/51
Propofol	68.6	35/51
Inhalational anesthetic	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 post-anesthetic recovery room stay)	4.2	2/48
Postprocedural care after MAC°		
ICU	52.9	27/51
IMC	41.2	21/51
Normal ward (after post-anesthetic recovery room stay)	3.9	2/51

*Catecholamines were used as bolus application and/or continuously; #One center stated to apply urinary catheters only in women but not in men; °One center stated that patients are transferred to ICU or IMC dependent on bed availability; SOP: standard operating procedure; TTE: transthoracic echocardiography; TEE: transesophageal echocardiography; CT: computed tomography; MRI: magnetic resonance imaging; ICU: intensive care unit; IMC: intermediate care unit; MAC: monitored anesthesia care; GA: general anesthesia

Based on these self-assessments, centers were clustered into "low-volume centers" (55.6% [30/54]; ≤300 TAVIs per year) and HVC (44.4% [24/54]; >300 TAVIs per year), centers that predominantly performed MAC (75.9% [41/54]) and those that preferred GA (24.1% [13/54]). Of note, most centers provided both: MAC and GA; only 3 centers stated to exclusively perform MAC and three centers 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] that a chest x-ray was part of standard preparation for TF-TAVI and 42.6% [23/54] that spirometry was a routine preprocedural measure.

Monitoring and instrumentation

Apart from periprocedural standard monitoring (pulse oximetry, 3- or 5-lead ECG and blood pressure measurement [any method]) that was performed in all centers, reported routine monitoring differed between centers (Table 1). Centers stated that the following measures were periprocedural standard of care: five-lead-ECG in 85.2% [46/54], capnometry in 77.8% [42/54] and urinary catheters in 64.8% [35/54] of centers, respectively. Only one center 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 center. Moreover, monitoring of cerebral activity such as bispectral index monitoring or near-infrared spectrometry was rarely used. 90.7% [49/54] of centers reported to routinely attach defibrillator electrodes to the patient prior to TF-TAVI.

Infrastructure and staff resources

90.7% [49/54] of centers reported to have implemented an anesthesia SOP for TF-TAVI, 94.4% [51/54] of centers stated to hold regular Heart Team meetings. All participating centers reported that anesthetists 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 centers reported to have routinely ready-to-use HLMs available on site during TF-TAVI (Table 1).

Anesthesia drugs

- MAC: most centers reported to favor combinations of opioids and hypnotics for procedural sedation with remifentanil and propofol being 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 centers. 13.7% of centers reported to prefer dexmedetomidine for procedural sedation.

- GA: remifentanil was the first-choice opioid (68.6% [35/51]) most frequently reported and propofol the first-choice hypnotic drug (68.6% [35/51]). Most centers reported to favor combinations of opioids and hypnotics (96.1% [49/51]).

Catecholamines

Centers stated to prefer norepinephrine (81.5% [44/54]) or epinephrine (29.6% [16/54]), if catecholamines were required. Few centers reported to favor cafedrine/theodrenaline (5 centers), dobutamine (6 centers) or dopamine (1 center) during TF-TAVI.

Vascular access

83.3% [45/54] of centers acknowledged to routinely insert central venous lines (either CVCs or introducer sheaths) during TF-TAVI (Table 2).

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

	General anesthesia		Procedural sedation	
Routinely used venous access	[%]	[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

In patients undergoing GA participating centers 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 centers (preferentially by anesthetists in 43.1% [22/51], by cardiologists in 56.9% [29/51]) (Table 1).

Intraprocedural echocardiography

51.9% [28/54] of centers reported to routinely use intraprocedural echocardiography (Table 1). They further reported that transesophageal echocardiography (TEE) was more frequently used during GA as opposed to MAC. TEE was often performed by anesthetists (Table 3).

Table 3 Intraprocedural echocardiography in relation to the applied technique (TTE or TEE) and investigator (anesthetist or cardiologist) as reported by the survey participators

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

TTE: transthoracic echocardiography; TEE: transesophageal echocardiography

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 centers (5.9% [3/51]) stated that patients were not extubated prior to ICU transfer. 94.2% [49/52] of centers reported that patients were admitted to an IMC or ICU after MAC. Only two centers reported that patients were transferred to a post-anesthetic recovery room after GA or MAC and to a normal ward thereafter.

Binary logistic regression analysis

Multiple regression analysis revealed a significantly lower odds of using echocardiography in centers that prefer MAC compared to those that predominantly use GA (adjusted OR 0.13 [0.02-

0.83]; p=0.031, Table 4). The second multiple regression analysis explains HVCs by faster changeover times (p=0.036) and indicates in HVCs more frequent reports of "ready-to-use HLM available on site" (adjusted OR 5.09 [0.80-32.53]; p=0.086) and "SOP implemented and regular Heart Team meetings" (adjusted OR 11.16 [0.76-163.31]; p=0.078) while none of the other considered factors predicts a HVC.

Table 4 Binary logistic regression analysis

	Simple approaches		Multiple regression analyses	
Covariates	OR [95% CI]	p-value	adj. OR [95% CI]	p-value
MAC [y/n] as opposed to GA	NA	NA	NA	NA
	3.50 [0.84-14.60]	0.086	2.13 [0.31-14.79]	0.443
High volume center for TAVI [y/n]	0.29 [0.07-1.19]	0.086	0.46 [0.07-2.98]	0.415
	NA	NA	NA	NA
Echocardiography during TAVI [y/n]	0.13 [0.03-0.66]	0.014	**0.13 [0.02-0.83]**	**0.031**
	0.65 [0.22-1.91]	0.492	2.02 [0.44-9.41]	0.369
Changeover time [<45, 45-60, >60 min]		0.033		0.345
		0.008		**0.036**
45-60 min versus >60 min	4.08 [0.87-19.23]	0.075	2.72 [0.38-19.11]	0.315
	2.10 [0.36-12.40]	0.413	1.44 [0.18-11.81]	0.736
<45 min versus >60 min	11.40 [1.74-74.65]	0.011	5.01 [0.55-45.33]	0.152
	11.25 [1.86-68.13]	0.008	8.85 [0.92-85.47]	0.060
Ready-to-use HLM available on site [y/n]	2.58 [0.66-10.03]	0.172	1.25 [0.17-9.15]	0.830
	3.50 [0.84-14.60]	0.086	5.09 [0.80-32.53]	0.086
SOP implemented and regular Heart Team meetings [y/n]	2.78 [0.53-14.47]	0.226	1.80 [0.20-16.33]	0.600
	5.75 [0.64-51.53]	0.118	11.16 [0.76-163.31]	0.078
Norepinephrine as one of the preferred catecholamines [y/n]	0.30 [0.03-2.60]	0.272	0.73 [0.06-9.04]	0.808
	0.46 [0.11-1.87]	0.279	0.71 [0.12-4.09]	0.698
CVC routinely used [y/n]	0.34 [0.04-3.05]	0.337	0.46 [0.03-7.45]	0.581
	0.59 [0.14-2.47]	0.466	1.48 [0.26-8.26]	0.658
Complete team* attending throughout the TAVI procedure [y/n]	1.49 [0.42-5.25]	0.539	1.73 [0.31-9.53]	0.530
	1.11 [0.37-3.35]	0.851	0.50 [0.17-2.19]	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) "monitored anesthesia care" (as compared with "general anesthesia") was used as dependent variable, while in the second model (shaded in grey lines) "high volume centers" [y/n] defined as >300 and ≤300 cases per year was used as dependent variable. Each regression model includes eight categorized covariates that rely on the reports of the participating centers, with the latter category denoting the reference; *complete team was defined as: cardiologist, cardiac surgeons, anesthetist and perfusionists, MAC: monitored anesthesia care was defined as either local anesthesia or procedural sedation; GA: general anesthesia; HLM: heart lung machine; CVC: central venous catheter; OR: odds ratio, adj. OR: adjusted OR; CI: confidence interval; NA: not applicable

Potential infrastructural weaknesses and open questions

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

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

Potential infrastructural weaknesses in the survey of German heart centers	[%]	[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 anesthesia care implemented	9.3	5/54
Postoperative care on normal ward	3.7	2/54

Open questions regarding anesthesia 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 only be performed on demand?
  Background: chest x-ray was not routinely used in 22.2% of centers
- Which patients should receive preoperative spirometry?
  Background: spirometry was routinely used in 42.6% of centers, 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 centers.
- Should capnometry be used in all patients undergoing MAC?
  Background: capnometry was not routinely used in 22.2% of centers.
- Do we need central venous lines perioperatively?
  Background: one out of 6 centers (16.7%) did not routinely use central venous lines.
- Are urinary catheters required routinely?
  Background: one out of 3 centers (35.2%) did not routinely use urinary catheters.
- Could monitoring of cerebral activity be beneficial?
  Background: only very few centers used bispectral index monitoring or near-infrared spectrometry.
- Which patients should receive periprocedural echocardiography?
  Background: half of centers did, and half of centers did not routinely use echocardiography. Centers that preferred MAC less frequently used intraprocedural echocardiography.
- Should TF-TAVI preferably be performed in high-volume centers?
  Background: high-volume centers 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 centers. Of note, G-BA has launched an advisory procedure to address the issue of a minimum quantity of cases per center and year.
- Can we define clear indication criteria for MAC or GA?
  Background: 75.9% of all centers favored MAC over GA (23.1%).
- Should defibrillator electrodes be attached to the patient prior to the procedure?
  Background: one out of 10 centers (9.3%) did not attach them prior to the procedure.
- Is there a rationale to recommend a first-choice catecholamine?
  Background: most centers stated to prefer norepinephrine (81.5%) or epinephrine (29.6%), if catecholamines were required, few centers reported to favor cafedrine/theodrenaline, dobutamine or dopamine.
- Should patients be extubated directly after TF-TAVI in the operating room?
  Background: some centers (5.9%) reported to routinely transfer intubated patients to the ICU. Guidelines encourage extubating patients early after the procedure [16].

ECG: electrocardiogram; MAC: monitored anesthesia care; OR: operating room; ICU: intensive care unit

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 anesthesia management are lacking.

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

First of all, this survey revealed that the majority of German heart centers have anesthesia SOPs for TF-TAVI, hold regular heart team meetings and have ready-to-use HLMs available on site. All participating centers stated that anesthetists 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 [17], many centers reported that heart team members, such as cardiac surgeons, anesthetists and perfusionists were routinely attending throughout TF-TAVI procedures.

We found a broad variability regarding in-house standards for anesthesia management among German heart centers: chest x-ray and spirometry were not regarded as preprocedural standard measures in many centers prior to TF-TAVI. Although, capnometry, five-lead ECG, and attached defibrillator electrodes were reported to be applied in the majority of the centers, central venous catheters, introducer sheaths, large bore peripheral accesses, and echocardiography are not routinely used during TF-TAVI procedures in many centers. Even though transcardiopulmonary thermodilution and calibrated arterial pulse contour analysis reliably measure cardiac output in patients with severe AS undergoing TAVI [18–20], our data demonstrate that advanced hemodynamic monitoring is not routinely implemented during TF-TAVI. Although cerebral oxygen saturation ($rScO_2$) not only reflects cerebral but also systemic oxygen balance during TAVI [21], near-infrared spectroscopy (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, 22]. This goes in-line with our finding that the majority of German heart centers favor MAC over GA for TF-TAVI. The role of periprocedural echocardiography remains unclear: although TEE guidance might help to reduce the incidence of postprocedural aortic regurgitation [23] and overall/late mortality [24], only half of the surveyed centers 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 anesthesia 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 optimize perioperative outcome [25]. ERAS protocols for cardiac surgery favor early extubation and mobilization as prolonged mechanical ventilation is associated with an increased risk of ventilator associated pneumonia, dysphagia, longer hospitalization, higher morbidity, mortality, and higher costs [26]. Studies to demonstrate or deny 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 generalized or extrapolated to other health care systems 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 anonymized 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.

In conclusion we found that the concordance with national regulations, periprocedural anesthesia management and anesthesia in-house standards for TF-TAVI vary broadly among German heart centers. Still, expert consensus recommendations or guidelines for anesthesia and periprocedural management for TF-TAVI are lacking. In our opinion, the findings might be useful to push forward the idea of standardization, international expert consensus recommendations or guidelines regarding periprocedural anesthesia management for TF-TAVI and enhanced recovery after TF-TAVI. Further studies investigating the possible impact on patients' outcome are needed.

Author contributions

BL: This author conceived and designed the study, was responsible for data analysis and interpretation, and drafted the manuscript.

AH: This author conceived and designed the study and drafted the manuscript.

AZ: This author was responsible for data analysis and interpretation, and drafted the manuscript.

AD: This author was responsible for data interpretation and drafted the manuscript.

ST: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

DAR: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

SAH: This author was responsible for data interpretation and critically revised the manuscript for important intellectual content.

ÄG: This author was responsible for data analysis and interpretation and drafted the manuscript.

MP: This author was responsible for data analysis and interpretation, drafted the manuscript, and supervised the study.

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Competing interests

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Patient consent for publication

Not required.

Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information.

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None.

Ethics statement

Not applicable; no animal subjects included; no human participants included;

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Institutional infrastructural preconditions and current perioperative anesthesia practice in patients undergoing transfemoral transcatheter aortic valve implantation: a cross-sectional study in German heart centers

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-9
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9-10
		(*b*) Describe any methods used to examine subgroups and interactions	9-10
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	11-12

Outcome data	15*	Report numbers of outcome events or summary measures	14-18
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 4
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14-18
Discussion			
Key results	18	Summarise key results with reference to study objectives	20-21
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20-21
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-20
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23