Impact of Anesthesia Type on Outcomes of Transcatheter Aortic Valve Implantation (from the Multicenter ADVANCE Study)

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Transcatheter aortic valve implantation (TAVI) has become the standard of care for many patients with symptomatic severe aortic stenosis who are at increased risk of morbidity and mortality during surgical aortic valve replacement. However, there is still no general consensus regarding the use of general anesthesia (GA) versus local anesthesia with sedation (non-GA) during the TAVI procedure. Using propensity score−matching analysis, we analyzed the characteristics and outcomes of patients who underwent TAVI with either GA (n = 245) or non-GA (n = 245) in the fully monitored, international, CoreValve ADVANCE Study. No statistically significant differences existed between the non-GA and GA groups in all-cause mortality (25.4% vs 23.9%, p = 0.78), cardiovascular mortality (16.4% vs 16.6%, p = 0.92), or stroke (5.2% vs 6.9%, p = 0.57) through 2-year follow-up. Major vascular complications were more common in the non-GA group. Total hospital stay was similar between the 2 groups. Conversion from non-GA to GA occurred in 13 patients (5.3%) because of procedural complications in 9 patients and discomfort or restlessness in 4 patients. Most procedural complications were related to valve positioning or vascular issues. Two of the 13 converted patients died during the procedure. Both GA and non-GA are widely used in real-world TAVI practice, and the decision appears to be guided by only a few patient-related factors and dominated by local and national practice. The outcomes of both anesthesia modes are equally good. When conversion from non-GA did occur, the complication requiring GA affected outcomes. **© 2016 Elsevier Inc. All rights reserved.** **(Am J Cardiol 2016;117:1332−1338)**

Transcatheter aortic valve implantation (TAVI) has become standard of care for patients with symptomatic severe aortic stenosis at extreme or high risk for surgery.[1] In practice, even low-risk patients are already being treated, whereas at least 3 TAVI clinical trials are assessing the role of the therapy in patients considered at only intermediate risk from surgical aortic valve replacement (AVR). It is, therefore, likely the number of patients treated with TAVI will increase, requiring additional numbers of operators and hospitals. Concurrently, the procedure is becoming less complex. Smaller sheath sizes, a reduced need for rapid pacing and balloon valvuloplasty, availability of repositionable and recapturable valves, and decreased reliance on intraprocedural transesophageal echocardiography will herald a new era of TAVI. A significant proportion of procedures are already being performed using local anesthesia with sedation. Others have reported potential benefits of using local anesthesia, including shorter intensive care unit and overall hospital stays, less hemodynamic instability, and less need for vasopressors.[2−5] It is likely that the proportion of patients treated in this manner will increase. In the ADVANCE study,[6] patients were treated according to best local practice in experienced centers, and a significant proportion was treated with local rather than general anesthesia (GA). Local anesthesia was used in approximately 50% of patients in this study, reflecting the real-world practice at the time, and we compared patient characteristics and procedural outcomes in patients administered local anesthesia versus GA for TAVI.

Methods

For this report, we analyzed the characteristics and outcomes of patients who underwent TAVI with either GA or local anesthesia with sedation (non-GA) in the Medtronic CoreValve ADVANCE study. Patients treated through the direct aortic approach were excluded from this analysis. The design, methods, and primary results of the ADVANCE study have been previously described.[6] Briefly, the ADVANCE study is a

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prospective, fully monitored, nonrandomized, international, multicenter study evaluating the acute and long-term results of implantation of the Medtronic CoreValve System (Medtronic, Minneapolis, Minnesota) in "real-world" patients with severe, symptomatic aortic stenosis who were considered to have an inoperable condition or to be at high risk for conventional AVR. All ADVANCE study centers were required to have performed a minimum of 40 TAVI procedures before joining the study and to use an on-site, multidisciplinary heart team consisting of at least 1 TAVI-experienced interventional cardiologist and 1 cardiovascular surgeon.

The ethics committee at each study center approved the ADVANCE investigational protocol. ADVANCE was conducted in adherence to the Declaration of Helsinki, and all patients provided written informed consent before the CoreValve implantation procedure.

Detailed device description and implant procedures for the CoreValve System have been previously described.[7,8] The procedures were performed according to standard local hospital practices, which included the selection of access location (transfemoral or subclavian), the type of access (surgical cutdown or completely percutaneous), and the type of anesthesia (GA or non-GA). Procedural characteristics analyzed for the comparisons between anesthesia groups included access type and site, procedure duration, fluoroscopy time, quantity of contrast agent used, procedural complications, and length and type of hospital stay.

Safety outcomes were analyzed at 30 days and at 1 and 2 years postprocedure and included all-cause mortality, cardiovascular mortality, myocardial infarction, reintervention, stroke, stroke or transient ischemic attack, bleeding, vascular complications, acute kidney injury (stage III), and pacemaker implantation.

Death, stroke, myocardial infarction, and reintervention were adjudicated by an independent Clinical Events Committee consisting of TAVI-experienced interventional cardiologists and a cardiac surgeon using the initial Valve Academic Research Consortium definitions.[9] An independent neurologist reviewed the neurologic events and provided a summary of each event to the Clinical Events Committee, which used this information along with any other patient source data to adjudicate all neurologic events. A core laboratory (Cardialysis, Rotterdam, The Netherlands) performed a systematic review and assessment of procedural angiograms and electrocardiograms through 1-year follow-up. Data were recorded on a standardized electronic case report form and sent to a central database (Merge, Chicago, Illinois) over the Internet.

Categorical variables are reported as counts and percentages. Continuous variables are reported as mean and SD except for non-normal data, such as logistic EuroSCORE, Society of Thoracic Surgeons predictive risk of mortality score, procedure duration, fluoroscopy time, amount of contrast given, and length of stay, which are summarized using medians and interquartile ranges.

Comparisons between anesthesia types are based on the chi-square or Fisher's exact tests for categorical variables and *t* tests or Wilcoxon tests for continuous variables, as appropriate. Event rates were generated using the Kaplan-Meier method, and log-rank tests were used for group comparisons. For patients without an event, the date of censoring was the latest date of all follow-up visits (including study exit) and events (including death). A p value <0.05 was considered statistically significant.

To identify 2 comparable groups of patients who underwent GA or non-GA, we performed a propensity score–matching analysis. A multivariable logistic regression model with anesthesia type as the outcome was fit, from which predicted probabilities (i.e., propensity scores) were computed for each patient. Unbalanced variables before matching and an additional 10 variables were included in the model to achieve balance in baseline characteristics in the anesthesia groups after matching. The baseline covariates included in the model were women, New York Heart Association class III or IV, diabetes mellitus, previous median sternotomy, previous aortic valve intervention, previous coronary artery bypass grafting, history of aortic aneurysm, creatinine clearance <20 ml/min, baseline left ventricular ejection fraction, moderate-or-severe tricuspid regurgitation, log-transformed age, square root–transformed EuroSCORE, history of myocardial infarction, peripheral vascular disease, baseline pacemaker, cerebrovascular disease, and atrial fibrillation. Characteristics were considered to be in balance if the percent standardized difference was $<10\%$. All statistical analyses were performed using SAS software (version 9.3; SAS Institute, Inc., Cary, North Carolina).

Results

From March 2010 to July 2011, 1,015 patients were enrolled in the ADVANCE study. Of these, 996 patients had undergone an attempted implantation with the CoreValve System. The mode of anesthesia was entirely site selected and guided by best and customary local practice. Considering the whole group of patients, non-GA was used in 551 patients (55.3%) and GA was used in 445 patients (44.7%). Twenty-one patients treated through the direct aortic access were omitted as they are not considered candidates for both anesthesia options, leaving 424 patients in the GA group. Baseline patient characteristics are presented in Table 1. Significant differences existed between the 2 patient groups in diabetes, previous median sternotomy, previous aortic valve intervention, previous coronary artery bypass grafting, and left ventricular ejection fraction. Despite these differences, the median Society of Thoracic Surgeons predictive risk of mortality score and logistic were similar between the 2 groups. There were national differences in the use of non-GA versus GA (Figure 1), demonstrated by large differences in the use of non-GA among the highest recruiting countries (Germany 78.6%, Italy 70.5%, and the United Kingdom 4.6%).

Because several statistically significant differences in baseline patient characteristics existed between the GA and non-GA groups that could have potentially affected the results of the analysis, we performed a propensity score–matched analysis. A standardized difference of 10% was used as the basis for defining successful matching, where a lower standardized difference corresponds to higher degree of achieved balance. Propensity scoring resulted in 245 matched pairs of patients (Table 1). All the following outcomes analyses are based on these 2 propensity-matched anesthesia groups.

Table 1
Baseline patient characteristics before and after propensity score matching

Characteristic	Before Matching				After Matching			
	Non-GA (N = 551)	GA (N = 424)	Std. Diff.* (%)	*P* Value	Non-GA (N = 245)	GA (N = 245)	Std. Diff.* (%)	*P* Value
Age (years)	80.8 ± 6.5	81.3 ± 6.4	7.8	0.23	81.3 ± 6.2 (245)	81.6 ± 6.5 (245)	5.4	0.55
Female	292 (53.0%)	204 (48.1%)	9.8	0.13	126 (51.4%)	130 (53.1%)	3.3	0.72
STS predictive risk of mortality score, %	5.2 (N=550) [3.6, 7.8]	5.2 [3.5, 7.5]	4.8	0.46	5.3 [3.7, 7.0]	5.2 [3.6,7.6]	3.2	0.72
Logistic EuroSCORE, %	16.0 (N=550) [10.7, 25.6]	16.0 [10.1, 24.6]	4.6	0.47	16.1 [10.7, 24.7]	16.3 [10.2, 24.9]	2.6	0.78
New York Heart Association class III or IV	447/546 (81.9%)	317/412 (76.7%)	12.2	0.06	194 (79.2%)	193 (78.8%)	1.0	0.91
Diabetes mellitus	185/544 (34.0%)	116/421 (27.6%)	14.0	0.03	60 (24.5%)	59 (24.1%)	1.0	0.92
Coronary artery disease	305/550 (55.5%)	253/422 (60.0%)	9.1	0.16	129 (52.7%)	136 (55.7%)	6.2	0.49
Previous myocardial infarction	95/540 (17.6%)	60/410 (14.6%)	8.1	0.22	34 (13.9%)	37 (15.1%)	3.5	0.70
Previous percutaneous coronary intervention	170/545 (31.2%)	132/420 (31.4%)	0.5	0.94	73/243 (30.0%)	76 (31.0%)	2.1	0.81
Previous median sternotomy	63 (11.4%)	102/421 (24.2%)	33.9	< 0.001	37 (15.1%)	38 (15.5%)	1.1	0.90
Previous aortic valve intervention	11/550 (2.0%)	29/423 (6.9%)	23.8	<0.001	7 (2.9%)	8 (3.3%)	2.4	0.79
Previous coronary artery bypass grafting	92/548 (16.8%)	111/423 (26.2%)	23.2	<0.001	46 (18.8%)	46 (18.8%)	0.0	>0.99
Cerebrovascular disease	75/544 (13.8%)	53/415 (12.8%)	3.0	0.65	31 (12.7%)	29 (11.8%)	2.5	0.78
Aortic aneurysm	9/548 (1.6%)	13/420 (3.1%)	9.6	0.13	7 (2.9%)	8 (3.3%)	2.4	0.79
Peripheral vascular disease	100/547 (18.3%)	79/420 (18.8%)	1.4	0.83	38 (15.5%)	44 (18.0%)	6.6	0.47
Chronic obstructive pulmonary disease	133/549 (24.2%)	86/422 (20.4%)	9.3	0.16	53/244 (21.7%)	57 (23.3%)	3.7	0.68
Creatinine clearance <20 ml/min	69/542 (12.7%)	64/414 (15.5%)	7.8	0.23	33 (13.5%)	32 (13.1%)	1.2	0.89
Atrial fibrillation	184/545 (33.8%)	139/421 (33.0%)	1.6	0.81	86 (35.1%)	79 (32.2%)	6.0	0.50
Permanent pacemaker	66 (12.0%)	58 (13.7%)	5.1	0.43	28 (11.4%)	31 (12.7%)	3.8	0.68
Pulmonary hypertension	75/532 (14.1%)	45/398 (11.3%)	8.4	0.21	32/241 (13.3%)	34/233 (14.6%)	3.8	0.68
Prior porcelain aorta	23/548 (4.2%)	16/422 (3.8%)	2.1	0.75	11/244 (4.5%)	7 (2.9%)	8.8	0.33
Prior cirrhosis of the liver	6/550 (1.1%)	4/422 (0.9%)	1.4	>0.99	4 (1.6%)	3/244 (1.2%)	3.4	>0.999
Prior right ventricular insufficiency	23/549 (4.2%)	17/414 (4.1%)	0.4	0.95	12/244 (4.9%)	8/243 (3.3%)	8.2	0.37
Effective orifice area (cm^2)	0.7 ± 0.2 (N=441)	0.7 ± 0.4 (N=340)	8.0	0.28	0.7 ± 0.2 (N=213)	0.7 ± 0.3 (N=218)	9.0	0.35
Mean aortic valve gradient (mm Hg)	45.8 ± 15.1 (N=502)	44.9 ± 16.0 (N=363)	6.1	0.37	45.2 ± 14.7 (N=241)	46.9 ± 16.7 (N=231)	10.9	0.24
Left ventricular ejection fraction (%)	54.8 ± 14.1 (N=464)	51.3 ± 13.3 (N=370)	25.9	<0.001	51.6 ± 13.8	52.7 ± 12.6	8.6	0.34
Left ventricular ejection fraction <35%	42/464 (9.1%)	40/370 (10.8%)	5.9	0.40	28 (11.4%)	22 (9.0%)	8.1	0.37
Moderate or severe mitral regurgitation	148/534 (27.7%)	115/408 (28.2%)	1.0	0.87	72/244 (29.5%)	74/244 (30.3%)	1.8	0.84
Moderate or severe tricuspid regurgitation	103/493 (20.9%)	63/384 (16.4%)	11.5	0.09	49 (20.0%)	44 (18.0%)	5.2	0.57

Continuous variables are presented as mean ± SD (N, if data not available for all patients) and evaluated with the t-test, or median (N), [Q1, Q3] and evaluated with the Wilcoxon Rank Sum test. Categorical variables are presented as n/N (%) and evaluated with the Chi-square test or Fisher's exact test, where appropriate.

GA = general anesthesia; non-GA = local anesthesia with sedation; Std. Diff. = standardized difference; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

* A percent standardized difference >10% indicates imbalance between groups.

Procedural characteristics and outcomes are listed in Table 2. The vast majority of cases were performed transfemorally. Patients treated using GA had significantly longer median procedure and fluoroscopy times. More patients implanted through the percutaneous approach were treated with non-GA compared with GA, whereas more patients who had surgical cutdown were treated with GA (Table 2). Thus, the method of access may have affected choice of anesthesia. No statistically significant

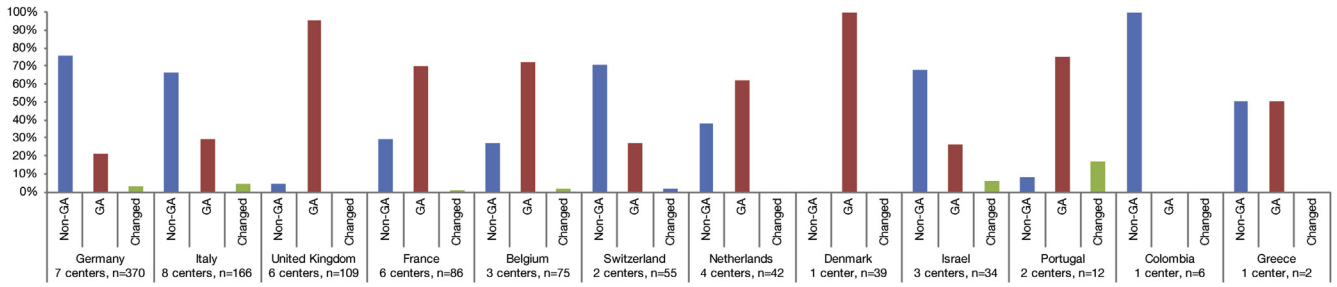

Figure 1. The distribution of the use of GA, local anesthesia (non-GA), and changed (non-GA to GA) by country for all patients. The number of centers per country and the number of patients enrolled are shown.

Table 2
Procedural characteristics by propensity matched anesthesia groups

Characteristic	Non-GA (N = 245)	GA (N = 245)	*P* Value
Access type			
Percutaneous	217 (88.6%)	195 (79.6%)	0.007
Surgical cutdown	28 (11.4%)	55 (20.4%)	0.007
Access site			
Transfemoral	239 (97.6%)	203 (82.9%)	<0.001
Subclavian/axillary	6 (2.4%)	42 (17.1%)	<0.001
Periprocedural outcomes			
Procedure duration (min)	65.0 (N=230) [48.0, 90.0]	83.0 (N=206) [60.0, 108.0]	<0.001
Fluoroscopy time during entire procedure (min)	18.0 (N=229) [13.0, 27.0]	20.0 (N=222) [15.0, 28.0]	0.03
Amount of contrast given (cc)	181.0 (N=243) [140.0, 230.0]	185.0 (N=233) [148.0, 240.0]	0.73
Procedural complications			
Annulus rupture	0 (0.0)	0 (0.0)	—
Valve embolization	0 (0.0)	1 (0.4)	>0.99
Conversion to open aortic valve repair	0 (0.0)	0 (0.0)	—
Coronary compromised	0/221 (0.0%)	1/211 (0.5%)	0.49
Procedural death	2 (0.8%)	3 (1.2%)	>0.99
Total hospital stay (days)	9.0 (N=241) [6.0, 13.0]	9.0 (N=219) [6.0, 12.0]	0.95
Intensive care (days)	2.0 (N=245) [1.0, 4.0]	2.0 (N=241) [1.0, 4.0]	0.41
Non−intensive care (days)	6.0 (N=241) [3.0, 9.0]	6.0 (N=220) [3.0, 9.0]	0.72

Continuous variables are presented as median (N) [Q1, Q3] and evaluated with the Wilcoxon Rank Sum test. Categorical variables are presented as n/N (%) and evaluated with the Chi-square test or Fisher's exact test, where appropriate.

GA = general anesthesia; non-GA = local anesthesia with sedation.

differences were seen in procedural complications. Total hospital stay was similar between the groups.

Conversion from non-GA to GA occurred in 13 patients during their procedure. A total of 20 procedural complications occurred in 9 of the 13 patients. The remaining 4 converted patients did not experience a procedural complication and, thus, were most likely converted to GA because of discomfort or restlessness. Most procedural complications were related to valve positioning or vascular issues. The valve was repositioned with snare or retrieved in 3 patients; failure of the vessel closure device requiring surgery occurred in 3 patients; access vessel occlusion (treated with percutaneous balloon) occurred in 1 patient, access vessel perforation (required transfusion) occurred in 1 patient, and 1 patient experienced hemorrhage requiring transfusion and cardiorespiratory arrest. Two of the 13 converted patients died during the TAVI procedure.

Safety outcomes at 30 days and at 1 and 2 years are presented in Table 3. All-cause mortality (Figure 2), cardiovascular mortality, and stroke were similar between the patients who underwent GA and non-GA through 2 years of follow-up. However, patients who underwent local anesthesia with sedation had significantly higher incidence of major vascular complications at all time points.

Discussion

In the present study, we compared the characteristics and outcome of patients who underwent TAVI with GA versus non-GA. Before discussing the issues identified in this study, it is worth considering the terminology used in previous studies. First, GA is defined by the patient having been placed in a state of "unconsciousness" such that they are unaware of their physical state and are unable to communicate. Typically, this will involve the administration of either inhalational or intravenous anesthetic agents, paralyzing agents, insertion of an endotracheal tube, and artificial ventilation. The terminology of anything that is not general anesthesia (non-GA) is confusing, as evidenced by the wide range of descriptions in the literature. These include "local anesthesia," "regional anesthesia," "conscious sedation," "light sedation," "deep sedation," and "controlled monitored anesthesia." There are 2 components to any non-GA approach. The first component is the relief of pain, and this is administered by true local anesthesia, typically with lidocaine, or with regional or epidural anesthesia. The second component is sedation, and this can range from very mild sedation, where the patient is able to communicate, to deeper sedation, where they cannot. Most anesthesiologists would consider deep sedation a form of GA but without protection of the airway.

Previous studies have suggested potential advantages of a non-GA procedure, including shorter procedure times, shorter intensive care unit and overall hospital stays, lower vasopressor requirements, and equally good outcomes in terms of mortality.[2–5] Others have identified that a non-GA approach may require conversion to GA in up to 5% of

Table 3
Safety outcomes by propensity matched anesthesia groups

Endpoints	30 Days			1 Year			2 Years		
	Non-GA (N = 245)	GA (N = 245)	*P* Value*	Non-GA (N = 245)	GA (N = 245)	*P* Value*	Non-GA (N = 245)	GA (N = 245)	*P* Value*
All-cause mortality	13 (5.3%)	12 (4.9%)	0.84	41 (16.8%)	44 (18.0%)	0.76	61 (25.4%)	58 (23.9%)	0.78
Cardiovascular mortality	11 (4.5%)	9 (3.7%)	0.65	27 (11.4%)	30 (12.5%)	0.70	38 (16.4%)	39 (16.6%)	0.92
Myocardial infarction†	1 (0.4%)	0	0.32	2 (0.9%)	3 (1.4%)	0.65	4 (2.0%)	7 (3.6%)	0.36
Reintervention	2 (0.8%)	3 (1.3%)	0.66	3 (1.3%)	3 (1.3%)	0.99	4 (1.8%)	4 (1.8%)	>0.99
Stroke†	9 (3.7%)	8 (3.3%)	0.80	11 (4.7%)	9 (3.8%)	0.64	12 (5.2%)	15 (6.9%)	0.57
Bleeding	72 (29.5%)	71 (29.1%)	0.94	77 (31.7%)	82 (34.2%)	0.63	82 (34.3%)	85 (35.8%)	0.75
Life-threatening or disabling bleeding	14 (5.8%)	7 (2.9%)	0.12	16 (6.6%)	9 (3.8%)	0.16	18 (7.7%)	10 (4.3%)	0.13
Major bleeding	22 (9.1%)	24 (9.9%)	0.74	24 (10.0%)	32 (13.6%)	0.26	26 (11.0%)	36 (15.6%)	0.17
Minor bleeding	42 (17.2%)	44 (18.0%)	0.84	45 (18.6%)	50 (20.8%)	0.60	47 (19.7%)	51 (21.3%)	0.68
Vascular complications	57 (23.3%)	45 (18.4%)	0.19	57 (23.3%)	50 (20.7%)	0.44	58 (23.9%)	50 (20.7%)	0.38
Major	40 (16.4%)	19 (7.8%)	0.004	40 (16.4%)	23 (9.6%)	0.02	42 (17.4%)	23 (9.6%)	0.01
Minor	19 (7.8%)	26 (10.7%)	0.28	19 (7.8%)	27 (11.1%)	0.22	19 (7.8%)	27 (11.1%)	0.22
Stroke or TIA†	10 (4.1%)	8 (3.3%)	0.63	16 (6.9%)	14 (6.1%)	0.70	18 (7.9%)	20 (9.2%)	0.76
Major stroke†	4 (1.7%)	3 (1.2%)	0.70	5 (2.1%)	4 (1.7%)	0.73	6 (2.7%)	8 (3.8%)	0.60
Minor stroke†	5 (2.1%)	5 (2.1%)	>0.99	6 (2.5%)	5 (2.1%)	0.76	7 (3.0%)	7 (3.2%)	>0.99
TIA†	1 (0.4%)	1 (0.4%)	>0.99	5 (2.3%)	6 (2.8%)	0.76	6 (2.8%)	6 (2.8%)	>0.99
Acute kidney injury, stage III	1 (0.4%)	1 (0.4%)	>0.99	1 (0.4%)	1 (0.4%)	>0.99	1 (0.4%)	1 (0.4%)	>0.99
Pacemaker implantation	69 (28.7%)	51 (21.1%)	0.06	75 (31.4%)	61 (25.8%)	0.13	76 (31.9%)	65 (27.8%)	0.22

Event rates presented as the number of patients with an event (Kaplan-Meier rate as percentages).
GA = general anesthesia; non-GA = local anesthesia with sedation; TIA = transient ischemic attack.
* Log-rank test.
† Valve Academic Research Consortium definition.

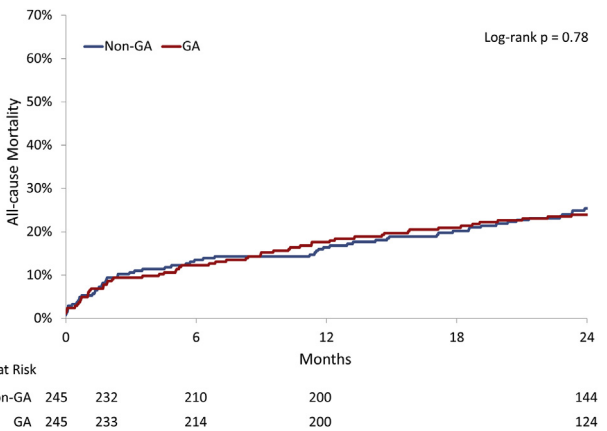

Figure 2. Kaplan-Meier analysis of all-cause mortality through 2 years by propensity-matched anesthesia groups. non-GA = local anesthesia.

cases for cardiac arrest, tamponade, myocardial infarction, or procedural stroke.[10] A higher incidence of paravalvular regurgitation has been recorded in 1 study of patients treated with non-GA, perhaps reflecting a reluctance of operators to prolong the procedure to undertake further post-deployment valvuloplasty or second-valve deployment.[11]

In this study, we did not prospectively define GA or non-GA, nor was the study randomized; instead, it reflected real-world practice. In the ADVANCE study, the choice of anesthetic and mode of local anesthesia was dependent on local practice, and this varied among both hospitals and countries (Figure 1). It, therefore, seems that local trends, both within a hospital and within a country, may define the popularity of using local anesthesia versus GA.[12] There are numerous factors that influence the decision, including patient-related factors, but more often than not it would appear that the factors determining which type of anesthesia is used are operational and logistic as overall risk scores between the 2 groups were no different.

In our study, the baseline patient characteristics between the 2 groups were similar, but some important differences were observed. To account for these differences, we carried out a propensity score−matched analysis. In terms of overall outcomes between the propensity score−matched groups, non-GA procedures were 18 minutes shorter, less than recently reported from a similarly sized cohort.[13] The only other significant difference was a higher preponderance of major vascular complications, and there was a trend toward a higher number of patients receiving pacemakers at 30 days in the non-GA group. This might possibly be explained by a greater enthusiasm for attempted repositioning of a deeply implanted valve in a patient under GA. Apart from these, there were no significant differences in the very low incidence of procedural complications or in intensive care unit stay. Furthermore, outcomes (i.e., mortality and major adverse cardiac and cerebrovascular events) in the non-GA and GA groups were similar at 30 days, 1 year, and 2 years. Major vascular complications occurred more often in the non-GA group, probably reflecting a higher incidence of surgical cutdown as the initial strategy, whereas conversion to cutdown in the non-GA group was considered a major vascular complication.

Although overall outcomes were broadly similar between the 2 groups on an “intention to anesthetize” basis, there was an important subset of patients who converted from non-GA

to GA during the procedure. The rate of conversion in this study was 5.3%, and this is similar to other studies.[4,10,13] The reasons for conversion in this study were predominantly related to valve positioning issues and vascular complications requiring surgery. It is no surprise, therefore, that the need for conversion is actually a surrogate for procedural complications, and the outcomes reflect this. That is not to say that non-GA is not safe—as we have demonstrated, it is. However, it is important to recognize that the need to convert to GA reflects complications that could have occurred in the GA group as well but would not have mandated any change in anesthesia type.

Limitations associated with this study were that we did not prospectively define GA or non-GA, nor did we require sites to supply specific anesthetic details or the specific reason for conversion. The study was nonrandomized, and we relied on the sites to use best and customary local practice to guide the choice of anesthesia mode, but we did not collect the specifics of the rationale. Our propensity score−matched analysis did, however, remove the potential confounding influence of baseline characteristics.

Both GA and non-GA are widely used in real-world TAVI practice, and the decision appears to be guided by only a few patient-related factors and dominated by local and national practice. The outcomes of both modes are equally good, and the need for conversion from non-GA to GA was 5.3% in this study. When conversion did occur, the complication requiring GA affected outcome.

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Disclosures

Dr. Brecker has received consultant fees from Medtronic (Minneapolis, Minnesota) and Boston Scientific (Marlborough, Massachusetts). Dr. Bleiziffer serves as a consultant to Medtronic and as a proctor for Medtronic and JenaValve (Munich, Germany) and has received travel expenses from Edwards Lifesciences (Irving, California), Medtronic, and Johnson & Johnson (New Brunswick, New Jersey). Dr. Bosmans serves as a proctor for Medtronic. Dr. Gerckens has received consultant and lecture fees and study-related travel expenses from Medtronic and Edwards Lifesciences and serves as a proctor for Boston Scientific and Medtronic. Dr. Wenaweser has received consultant fees from Medtronic and Edwards Lifesciences and has received remuneration from Medtronic for study-related travel and for development of education materials. Dr. Linke received speaker honoraria or served as a consultant for the following companies: Medtronic, St. Jude Medical (St. Paul, Minnesota), Claret Medical Inc. (Santa Rosa, California), Boston Scientific, Edwards Lifesciences, Symetis (Ecublens, Switzerland), and Bard (Murray Hill, New Jersey) and holds stock options from Claret Medical Inc. In addition, he received grant support from Medtronic and Claret Medical Inc. Dr. Tamburino has no conflicts of interest. Medtronic (Minneapolis, Minnesota) funded the ADVANCE study.

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