

# Comparison of Local Versus General Anesthesia Following Transfemoral Transcatheter Self-Expanding Aortic Valve Implantation (from the Transcatheter Valve Therapeutics Registry)



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**Transfemoral transcatheter aortic valve replacement (TF-TAVR) is mostly performed under general anesthesia (GA) in most US centers. We examined in-hospital and 30-day outcomes in patients who underwent TF-TAVR with a self-expanding bioprosthesis using local anesthesia (LA) or GA. Patients from the Transcatheter Valve Therapeutics Registry who underwent TF-TAVR from January 2014 to June 2016 with LA or GA were evaluated. Propensity matching was performed and procedural and clinical outcomes compared up to 30 days. A total of 11,006 patients were included (GA: 8,239 [74.9%] and LA: 2,767 [25.1%]). After propensity matching (n = 1,988 matched sets), device success was similar (94.5% vs 94.6%, p = 0.905). No differences in in-hospital stroke (2.7% vs 2.3%, p = 0.413) or paravalvular regurgitation grade (p = 0.113) were noted. Fewer LA patients were converted to open heart surgery (0.2% vs 0.6%, p = 0.076) or experienced an in-hospital major vascular complication (0.7% vs 1.4%, p = 0.026). Intensive care unit time (40.1 ± 58.4 vs 50.9 ± 72.1 hours, p < 0.001) and postprocedure length of stay (4.1 ± 3.6 vs 5.0 ± 4.5 days, p < 0.001) were significantly shorter with LA. In-hospital and 30-day all-cause mortality were lower in the LA cohort compared to the GA cohort ([1.1% vs 2.7%, p < 0.001] and [2.1% vs 3.9%, p = 0.001]). In conclusion, in the largest series of self-expanding bioprostheses for TF-TAVR, these propensity-matched cohorts demonstrate that LA is an acceptable alternative to GA with comparable success, lower safety outcomes, complications rates, and in-hospital and 30-day all-cause mortality. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:419–425)**

Although the majority of transcatheter aortic valve replacement (TAVR) procedures are performed under general anesthesia (GA) with transesophageal echocardiography (TEE) guidance in hybrid operating rooms (i.e., conventional approach),<sup>1,2</sup> lately there has been a progressive increase in the utilization of a less invasive strategy

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See page 424 for disclosure information.

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performed under local anesthesia (LA) and conscious sedation, mostly without TEE guidance either in hybrid rooms or in a regular catheterization laboratory (i.e., minimalist approach).<sup>3–5</sup> Although, relatively small studies have suggested that the minimalist approach is safe and associated with lower resource utilization, reduced procedural costs and length of hospital stay, there remains a lack of robust data evaluating clinical outcomes associated with these 2 strategies.<sup>6–8</sup> Thus, we elected to compare whether the utilization of GA or LA (primary determinants of the conventional and minimalist approaches, respectively) overtime in the multicenter Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry (TVT Registry) impacts clinical outcomes associated with transfemoral TAVR (TF-TAVR) with self-expanding bioprostheses using these 2 approaches.

## Methods

Patients with documented percutaneous TF-TAVR with the self-expanding CoreValve System or the Evolut R transcatheter aortic bioprosthesis (Medtronic, Minneapolis, Minnesota) in the TVT Registry were included and dichotomized to LA and GA groups. The LA for TF-TAVR group included patients treated with the use of LA with conscious sedation. The following patients were excluded from the

analysis: patients with failed transcatheter or surgical bioprosthetic valves and patients treated with a combination of anesthesia (e.g., epidural or combination).

Device success was defined as a single valve in the proper anatomical position per the Valve Academic Research Consortium-2.<sup>9</sup> Patient data were submitted by each participating institution and undergo regular quality checks including random site audit checks.

Baseline characteristics, preprocedural and postprocedural echocardiographic measurements, and clinical outcomes through 30 days were extracted from the TVT Registry database. End points were defined per Valve Academic Research Consortium-2.<sup>9</sup> Hospital length of stay was calculated from the procedure date to the discharge date of the index hospitalization. Survival and discharge disposition data were collected when available.

This manuscript was reviewed by the TVT Registry publications committee. The institutional review board at Duke University School of Medicine (Durham, North Carolina) approved the TVT Registry and granted an informed consent waiver for this registry.

The analysis cohort comprised patients with procedures January 2014 to June 2016. A total of 1,988 patients who underwent implant with LA were propensity matched with 1,988 patients treated with the GA. The propensity score was estimated using multivariable logistic regression model, with treatment LA and GA as the dependent variable and all selected matching variables as covariates. Matching was performed with the use of a 1:1 matching approach without replacement (Greedy-matching algorithm with 5->1 digit of the propensity score) between patients treated with LA and GA. Matching variables were selected based on previous reports and clinical judgment (eTable 1 in the Supplement).<sup>10</sup>

Categorical variables were compared using chi-square or Fisher's exact test. Continuous variables were presented as means ( $\pm$  standard deviation) and compared using the Student's *t* test. All testing used a 2-sided alpha of 0.05. In-hospital events were reported as the proportion of patients with an event and compared using Chi-square test. Clinical outcomes at 30 days are reported as Kaplan-Meier estimates and were compared with the log-rank test. All statistical

Table 1  
Patient baseline demographics and clinical characteristics for all patients and for the propensity matched groups

Demographics	All GA (n = 8,239)	All LA (n = 2,767)	Matched GA (n = 1,988)	Matched LA (n = 1,988)	p Value*	p Value <sup>†</sup>
Age (years)	81.0 $\pm$ 8.3	81.9 $\pm$ 7.7	81.7 $\pm$ 7.7	81.9 $\pm$ 7.6	<0.001	0.48
Body surface area (m <sup>2</sup> )	1.9 $\pm$ 0.3	1.8 $\pm$ 0.3	1.8 $\pm$ 0.3	1.8 $\pm$ 0.2	<0.001	0.83
Men	4153 (50.4%)	1356 (49.0%)	997 (50.2%)	988 (49.7%)	0.20	0.78
Non-Hispanic/Latino	7737 (95.4%)	2648 (96.8%)	1847 (94.7%)	1903 (96.9%)	0.003	<0.001
White	7722 (93.7%)	2537 (91.7%)	1831 (92.1%)	1843 (92.7%)	<0.001	0.47
New York Heart Association class					<0.001	0.55
I	176 (2.2%)	52 (1.9%)	38 (1.9%)	40 (2.0%)		
II	1140 (14.0%)	507 (18.5%)	379 (19.1%)	368 (18.5%)		
III	5282 (64.8%)	1815 (66.2%)	1315 (66.1%)	1310 (65.9%)		
IV	1559 (19.1%)	366 (13.4%)	256 (12.9%)	270 (13.6%)		
Society of thoracic surgeons predicted risk of mortality (%)	8.0 $\pm$ 5.2	7.9 $\pm$ 4.7	7.7 $\pm$ 4.9	7.8 $\pm$ 4.6	0.66	0.40
<4%	1427 (17.8%)	433 (16.0%)	359 (18.1%)	328 (16.5%)		
4 to 8%	3464 (43.2%)	1187 (44.0%)	914 (46.0%)	893 (44.9%)		
>8%	3134 (39.1%)	1079 (40.0%)	715 (36.0%)	767 (38.6%)		
Diabetes mellitus	3041 (37.0%)	976 (35.4%)	710 (35.7%)	691 (34.8%)	0.13	0.53
Creatinine >2 mg/dl	694 (8.5%)	233 (8.5%)	148 (7.4%)	153 (7.7%)	>0.99	0.76
Chronic renal replacement therapy	328 (4.0%)	115 (4.2%)	63 (3.2%)	68 (3.4%)	0.68	0.66
Hypertension history	7376 (89.7%)	2502 (90.7%)	1820 (91.5%)	1810 (91.0%)	0.12	0.57
Peripheral vascular disease	2242 (27.2%)	673 (24.4%)	511 (25.7%)	509 (25.6%)	0.003	0.94
Prior stroke	1020 (12.4%)	325 (11.8%)	246 (12.4%)	237 (11.9%)	0.39	0.66
Prior transient ischemic attack	818 (10.0%)	235 (8.5%)	177 (8.9%)	190 (9.6%)	0.03	0.48
Chronic lung disease/obstructive pulmonary disease	3719 (45.5%)	1179 (43.0%)	875 (44.0%)	860 (43.3%)	0.02	0.63
Current/recent smoker (<1 year)	365 (4.4%)	139 (5.0%)	111 (5.6%)	104 (5.2%)	0.19	0.62
Cardiac surgery (open heart)	2248 (27.7%)	671 (24.6%)	506 (25.5%)	511 (25.7%)	0.002	0.86
1	1966 (24.2%)	587 (21.5%)	459 (23.1%)	450 (22.6%)	0.005	0.73
$\geq$ 2	282 (3.5%)	84 (3.1%)	47 (2.4%)	61 (3.1%)	0.33	0.17
Prior aortic valve surgery	787 (9.6%)	299 (10.8%)	219 (11.0%)	212 (10.7%)	0.05	0.72
Prior nonaortic valve surgery	239 (2.9%)	75 (2.7%)	52 (2.6%)	53 (2.7%)	0.61	0.93
Coronary bypass	2171 (26.4%)	629 (22.8%)	483 (24.3%)	480 (24.2%)	<0.001	0.89
Percutaneous coronary intervention	2947 (35.9%)	948 (34.4%)	668 (33.7%)	662 (33.4%)	0.16	0.80
Pre-existing implantable pulse generator or cardioverter defibrillator	1779 (21.6%)	559 (20.3%)	425 (21.4%)	410 (20.6%)	0.13	0.56
Conduction defect	3067 (37.5%)	960 (35.0%)	766 (38.7%)	739 (37.4%)	0.02	0.39
Congestive heart failure (w/in 2 weeks)	6839 (83.2%)	2216 (80.5%)	1673 (84.2%)	1595 (80.5%)	0.001	0.002
Atrial fibrillation/atrial flutter	3383 (41.2%)	1117 (40.6%)	783 (39.4%)	802 (40.3%)	0.58	0.54
Coronary artery disease	5498 (66.7%)	1807 (65.3%)	1291 (64.9%)	1300 (65.4%)	0.17	0.76

\* p value comparing the unmatched general anesthesia (GA) and local anesthesia (LA) groups.

<sup>†</sup> p value for the comparisons between the matched groups. Data presented as mean  $\pm$  or no. (percentage) accounting for missing values.

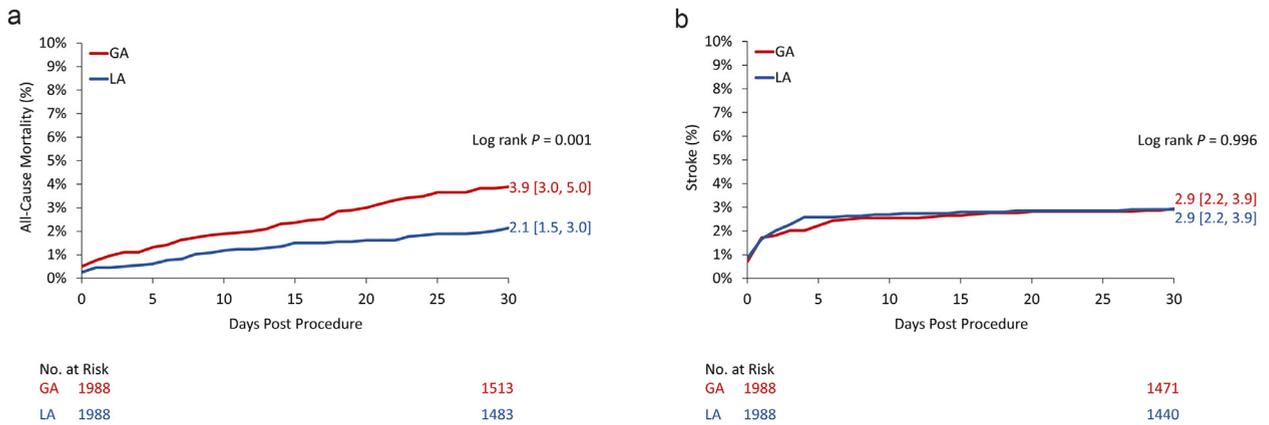


Figure 1. All-cause mortality and stroke at 30 days

Kaplan-Meier display of all-cause mortality (A) and any stroke (not including TIA) (B) to 30 days post-transcatheter aortic valve replacement for patients in the LA and GA cohorts. Kaplan-Meier rates as percentages (95% confidence intervals). GA = general anesthesia; LA = local anesthesia.

analyses were performed using statistical software version 9.4 (SAS Institute, Inc., Cary, North Carolina).

**Results**

A total of 11,006 patients from the TVT Registry were analyzed; 8,239 (74.9%) underwent implantation with the

use of GA and 2,767 (25.1%) underwent LA. Baseline characteristics are shown in Table 1.

Propensity matching was performed and resulted in 1,988 matched sets. Baseline characteristics for the matched patients are also shown in Table 1. The use of LA and GA per year in the entire cohort and the propensity matched population is described with bar graphs (Figure 1).

Table 2  
In-hospital events for propensity matched groups

Events	Matched GA (n = 1,988)	Matched LA (n = 1,988)	p Value
All-cause mortality	53 (2.7%)	21 (1.1%)	< 0.001
Lab or operating room death	5 (0.3%)	7 (0.4%)	0.56
Neurological events	52 (2.6%)	55 (2.8%)	0.77
Transient ischemic attack	7 (0.4%)	3 (0.2%)	0.34
Any stroke	45 (2.3%)	53 (2.7%)	0.41
Myocardial infarction	8 (0.4%)	3 (0.2%)	0.23
Any bleeding event	112 (5.6%)	116 (5.8%)	0.79
Vascular complication	107 (5.4%)	76 (3.8%)	0.02
Major	27 (1.4%)	13 (0.7%)	0.03
Conduction disturbance requiring implantation of a permanent pacemaker or implantable cardioverter defibrillator	376 (18.9%)	338 (17.0%)	0.12
Coronary compression or obstruction	6 (0.3%)	2 (0.1%)	0.29
Cardiac arrest	63 (3.2%)	30 (1.5%)	< 0.001
Atrial fibrillation	52 (2.6%)	52 (2.6%)	> 0.99
Annular dissection	1 (0.1%)	1 (0.1%)	> 0.99
Aortic dissection	3 (0.2%)	2 (0.1%)	> 0.99
Perforation with or without tamponade	18 (0.9%)	15 (0.8%)	0.60
Device migration	15 (0.8%)	6 (0.3%)	0.05
Device embolization left ventricle	0 (0.0%)	1 (0.1%)	> 0.99
Device embolization aorta	17 (0.9%)	4 (0.2%)	0.007
Aortic valve reintervention	13 (0.7%)	6 (0.3%)	0.11
Unplanned other cardiac surgery or intervention	24 (1.2%)	9 (0.5%)	0.009
Unplanned vascular surgery or intervention	85 (4.3%)	72 (3.6%)	0.29
Percutaneous coronary intervention	4 (0.2%)	3 (0.2%)	> 0.99
New requirement for dialysis	22 (1.1%)	11 (0.6%)	0.05
Paravalvular regurgitation, n*	1,597	1,453	
None	960 (60.1%)	835 (57.5%)	0.14
Mild	539 (33.8%)	514 (35.4%)	
Moderate	91 (5.7%)	99 (6.8%)	
Severe	7 (0.4%)	5 (0.3%)	

Data presented as the no. (percentage of patients with an event).

\* Based on postprocedure site-reported echocardiographic assessment

GA = general anesthesia; LA = local anesthesia.

Implant procedure volumes are shown in eTable 2 and eTable 3 in the Supplement.

There were no differences in device success between the LA and GA matched groups or postprocedure AV gradients. Contrast volume, fluoroscopy time, and procedural time were all significantly reduced with LA as compared to GA (eTable 4). There were no differences in the proportion of patients with mild or more paravalvular leak between groups postprocedure (Table 2).

There were differences in procedural events between the matched groups. Fewer LA patients experienced a major vascular complication (0.7% vs 1.4%,  $p=0.02$ ) or cardiac arrest (1.5% vs 3.2% vs  $p < 0.001$ ) (Table 2). Intensive care unit (ICU;  $40.1 \pm 58.4$  vs  $50.9 \pm 72.1$  hours,  $p < 0.001$ ) and hospitalization duration ( $4.1 \pm 3.6$  vs  $5.0 \pm 4.5$  days,  $p < 0.001$ ) were significantly shorter in the LA group. Additionally, LA patients were more often discharged to home compared to the GA cohort (80.9% vs 74.9%,  $p < 0.001$ ). In-hospital all-cause mortality was significantly lower in the LA versus GA cohorts (1.1% vs 2.7%,  $p < 0.001$ ; Table 2).

Outcomes at 30 days are shown in Table 3. There were no differences between the LA and GA cohorts for stroke or valve-related readmission. Importantly, LA patients demonstrated significantly lower 30-day mortality compared with GA patients (2.1% vs 3.9%, respectively,  $p = 0.001$ , Figure 1).

## Discussion

This analysis represents the largest, multicenter, and propensity-matched comparison of LA versus GA for

TF-TAVR using self-expanding bioprostheses. Our major findings were: (1) Procedural and in-hospital outcomes showed similar safety and efficacy profiles between groups, (2) in-hospital and 30-day mortality were lower in the patients treated using LA, (3) ICU and overall hospitalization duration were shorter using LA, and (4) Patients treated with LA were more frequently discharged home (Figure 2).

Since the advent of TF-TAVR, USA, and European experience with LA has grown considerably and continues to demonstrate equivalent outcomes with significant cost reduction.<sup>1–3,5</sup> Despite increasing experience, most US centers are still performing TF-TAVR using GA,<sup>4</sup> likely due to the misconception that GA provides for increased control and improved safety and patient outcomes.

This report demonstrates similar and high procedural success between the 2 approaches with a low risk of complications in patients underwent implantation with self-expanding bioprostheses. Moderate or greater paravalvular leak postimplantation was similar between groups and consistent with recent randomized self-expanding valve trials.<sup>6,8</sup> Many believe that with dual-imaging support (TEE and angiography), the results of implantation can be improved. Our report implies that the use of GA, presumably with TEE, during and after the implantation can be considered optional, rather than mandatory. Yet comparing TEE to angiographic guidance showed no differences in outcomes to 1 year<sup>11</sup> and high doses of sedation during GA may result in an underestimation in the degree of aortic regurgitation.<sup>12</sup>

Table 3  
Clinical outcomes at 30 days for matched patients

Events	Matched GA (n = 1,988)	Matched LA (n = 1,988)	p Value
All-cause mortality	74 (3.9%)	40 (2.1%)	0.001
Neurological events	74 (3.8%)	62 (3.2%)	0.30
Transient ischemic attack	18 (1.0%)	6 (0.3%)	0.01
Any stroke	57 (2.9%)	57 (2.9%)	> 0.99
Myocardial infarction	10 (0.5%)	5 (0.3%)	0.20
Life-threatening /major bleeding*	123 (6.3%)	130 (6.7%)	0.66
Vascular complication	115 (5.8%)	87 (4.4%)	0.04
Major	29 (1.5%)	16 (0.8%)	0.05
Conduction disturbance requiring implantation of a permanent pacemaker or implantable cardioverter defibrillator	394 (20.2%)	363 (18.6%)	0.23
Valve thrombosis	0 (0.0%)	0 (0.0%)	NA
Valve fracture	0 (0.0%)	0 (0.0%)	NA
Aortic valve reintervention	15 (0.8%)	6 (0.3%)	0.05
Unplanned other cardiac surgery or intervention	26 (1.3%)	13 (0.7%)	0.04
Unplanned vascular surgery or intervention	92 (4.7%)	74 (3.7%)	0.15
Percutaneous coronary intervention	5 (0.3%)	5 (0.3%)	> 0.99
Valve related readmission	19 (1.0%)	15 (0.8%)	0.49
Nonvalve related readmission	191 (10.5%)	174 (9.4%)	0.36
New requirement for dialysis	24 (1.3%)	13 (0.7%)	0.07
Paravalvular regurgitation, n <sup>†</sup>	1217	1053	
None	662 (54.4%)	536 (50.9%)	0.10
Mild	453 (37.2%)	416 (39.5%)	
Moderate	99 (8.1%)	94 (8.9%)	
Severe	3 (0.2%)	7 (0.7%)	

Data presented as no. of patient with an event (Kaplan-Meier rates).

\* In-hospital bleeds were not reported as life-threatening or major, therefore rates only include bleeds reported after index hospitalization.

<sup>†</sup> Based on 1-month site-reported echocardiographic assessment.

GA = general anesthesia; LA = local anesthesia. NA = not analyzable.

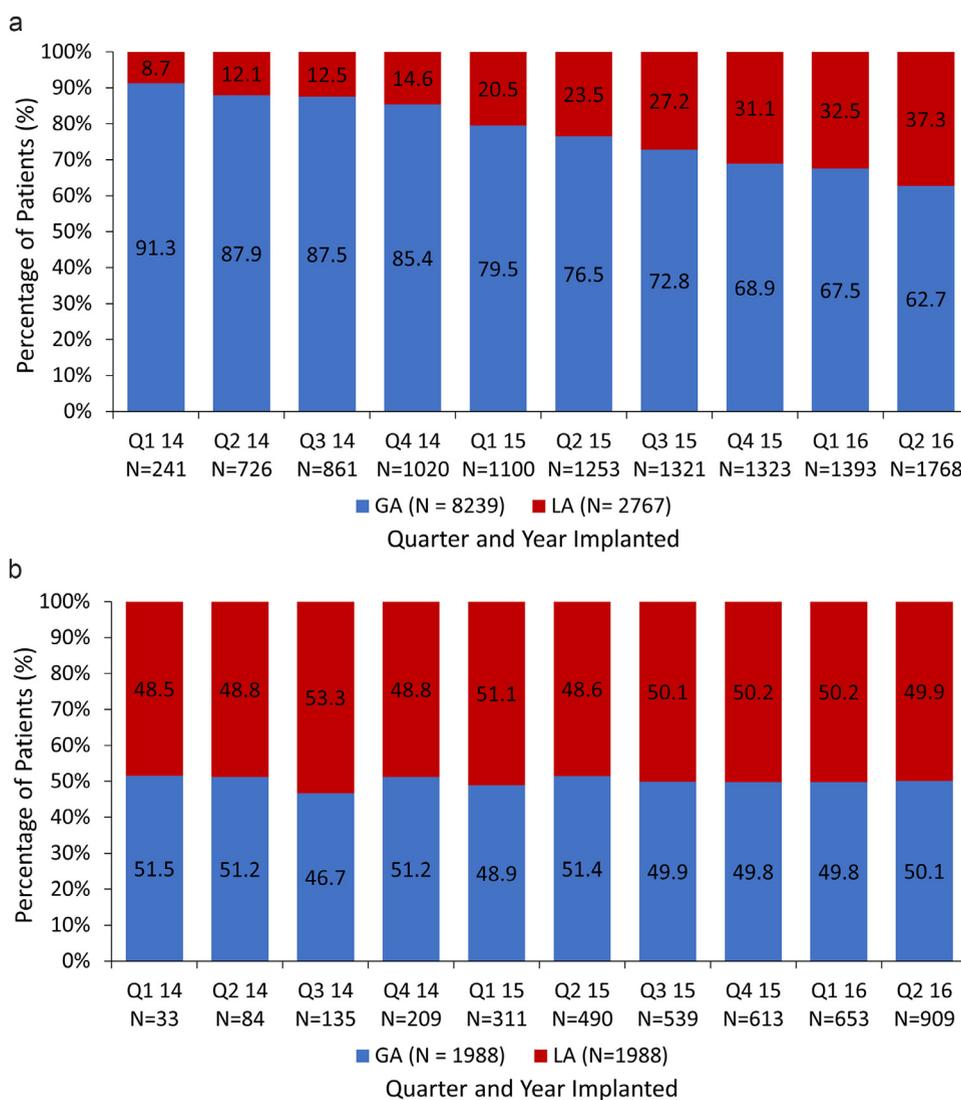


Figure 2. Anesthesia use by quarter  
Anesthesia use by quarter for (A) all patients, and (B) matched cohorts for the studied patients implanted from January 2014 to June 2016.

Most notably, our analysis is the first to demonstrate a reduction in in-hospital and 30-day mortality favoring the use of LA compared with GA for self-expanding prostheses. Previous reports have demonstrated a trend but were limited due to the small numbers of patients, heterogeneous patient selection, and various degrees in the use of self-expanding prosthesis.<sup>4,5,7,13–15</sup>

As TF-TAVR becomes standard of care, there is a need to reduce ICU time and the overall length of hospitalization for the benefits to patient health and care-related costs. Our report demonstrates that LA versus GA led to reduced time in ICU and postprocedure length of stay, consistent with previously reported smaller studies.<sup>1–3,5,7,15–18</sup> In addition, in the current report, LA was also associated with more frequent discharges to home rather than a skilled nursing facility. The use of GA imposes multiple risks upon the already critically ill patients with severe symptomatic aortic stenosis which includes the need for intubation with mechanical ventilation, paralytic agents, length of time to extubation,

hemodynamic fluctuations, risk of pulmonary infection, and the possibility of renal compromise<sup>19,20</sup> all contributing to increasing morbidity and mortality associated with TF-TAVR.

Although no cost analysis was performed, it can be reasonably inferred that with a shorter length of stay in the ICU, shorter overall length of hospitalization, and with more patients being discharged home, the overall health-care cost is reduced utilizing LA compared with GA. Other studies have shown similar trends with cost savings estimating \$2,000 to \$16,000 per case.<sup>7,15</sup> Further, the current report demonstrates fewer valvular and nonvalvular related readmissions at 30 days. Kolte et al performed a study regarding readmissions after TAVR and noted that an index hospitalization length of stay >5 days and discharge to skilled nursing facility were 2 important independent predictors of 30-day rehospitalization,<sup>21</sup> both of which are reduced with the use of LA as compared to GA in the current study.<sup>22</sup>

The results of the current study are quite promising; however, notable limitations exist. The results are based on the use of self-expanding prostheses, such that generalizability is not absolute. Rates and reasons for conversion to GA were not available, thus we were unable to account for these instances; however, we intentionally excluded patients in which combination anesthesia was used. We could not account for the evolution of operator proficiency but did include annual case volumes and trends to help elucidate the former.

This is the largest study of self-expanding aortic valve prosthesis implantation comparing the use of LA versus the GA in a propensity-matched analysis. We demonstrated that using LA does not compromise procedural outcomes, is associated with reduced ICU and index hospitalization duration, increased discharges to home, and importantly, demonstrates a reduced in-hospital and 30-day mortality. These findings support the notion that LA (and the MA) may ultimately become the default strategy for performing percutaneous, TF-TAVR using self-expanding prostheses. Further, large, randomized, and multicenter trials are needed.

## Disclosures

Dr. Attizzani is a consultant and serves as a proctor for Edwards Lifesciences and Medtronic, and is a consultant for St Jude Medical, Inc and Abbott Vascular; Dr. Patel reports no financial conflicts; Dr. Dangas reports no financial conflicts; Dr. Reardon reports consulting fees paid to his institution from Medtronic; Dr. Szeto serves as a speaker, investigator and Steering Committee member of the PARTNER Trial (Edwards Lifesciences) and as a clinical investigator for Medtronic; Dr. Sorajja serves as a consultant to Edwards Lifesciences, Abbott Structural, Boston Scientific, and Integer; Dr. Popma reports grants to his institution from Medtronic and Boston Scientific, consultant fees from Direct Flow, and fees for serving on a medical advisory board from Boston Scientific; Dr. Kodali has received grants and research support from Medtronic, Boston Scientific, Claret Medical, and Edwards Lifesciences; has served on steering committees for Claret Medical, Edwards Lifesciences, and Meril; has held equity in Thubrikar Aortic Valve; and has received honoraria from Claret Medical and St. Jude Medical; Chenoweth is an employee and shareholder of Medtronic, plc; Dr. Costa serves as a consultant to Edwards Lifesciences. The views expressed in this manuscript represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR.

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G.A. and S.P. had full access to all Registry data for this report and takes responsibility for the integrity of the data

and the accuracy of the data analysis. S.C. performed all statistical analyses for this report.

## Supplementary Materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.amjcard.2018.10.041.

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