CLINICAL STUDY

General Anesthesia or Conscious Sedation for Transfemoral Aortic Valve Replacement with the SAPIEN 3 Transcatheter Heart Valve

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Summary

Differences in the benefits of conscious sedation (CS) and general anesthesia (GA) during transfemoral aortic valve implantation (TAVI) are unclear.

We aimed to assess differences in procedural and clinical outcomes based on the type of anesthesia received during TAVI.

We analyzed SOURCE 3 Registry data for patients who received the SAPIEN 3 valve by type of anesthesia used during TAVI.

Of the 1694 TAVI patients, 1027 received CS and 667 received GA. Patients were similar at baseline (81.5 years; Society of Thoracic Surgeons risk score 7.0). Compared with the GA group, the CS group had fewer intra-procedural transesophageal echocardiography (TEE) and post implantation dilatations performed, and less contrast medium was used. The CS group had significantly less kidney injury at 7 days post-procedure than the GA group (0.4% versus 1.5%, \( P = 0.014 \)). Moderate paravalvular leaks (PVL) occurred more frequently in the CS group versus the GA group (2.2% versus 0.8%; \( P = 0.041 \)). No severe PVL were reported. Median total hospital length of stay (LOS) after TAVI was 10 days in the CS group and 11 days in the GS group. At 30 days, all-cause death was 2.1% in CS and 1.7% in GS (\( P = 0.47 \)), and myocardial infarction was 0.2% in CS and 0.1% in GS (\( P = 0.83 \)).

Our analyses found no significant major outcome differences between CS and GA during TAVI.

Key words: Aortic stenosis, Balloon-expandable transcatheter heart valve, SOURCE 3 Registry

Since the introduction of transcatheter aortic valve implantation (TAVI), the majority of cases have been performed with general anesthesia (GA); however, increasing operator experience and technological device innovations have expanded anesthesia choices. Some TAVI centers now use conscious sedation (CS) almost exclusively or a combination of CS and GA. CS appears to offer benefits, such as shorter procedural times and less use of inotropic and vasopressor agents. Additionally, CS may offer faster recovery time than GA, but GA facilitates intra-procedural use of transesophageal echocardiography (TEE) that assists with optimal valve apposition and may be more convenient for operators and more comfortable for patients. Nonetheless, delayed recovery with GA is a growing concern is, which necessitates further examination.

While no randomized studies have compared resource utilization and patient outcomes of TAVI performed under CS and GA, several nonrandomized studies1-11 and meta-analyses12,13 have addressed this issue. A systematic review and meta-analysis by Maas, et al.13 suggested that CS reduced procedural times and hospital length of stay (LOS). However, these positive outcomes were at the expense of a higher rate of new pacemaker insertion and moderate-to-severe paravalvular leaks (PVL).13

The authors found no significant differences in hard endpoints, such as 30-day mortality or incidence of stroke,13 but noted that their results might have been confounded.

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This study was funded by Edwards Lifesciences.

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Received for publication October 23, 2019. Revised and accepted March 16, 2020.

Released in advance online on J-STAGE July 18, 2020.

doi: 10.1536/ihj.19-567

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by selection bias (e.g., CS tends to be used with self-expandable valves), performance bias (operators tend to switch from GA to CS with increasing experience), and publication bias. SOURCE 3 is a large European registry of contemporary TAVI practice in experienced centers using a single transcatheter heart valve (THV), SAPIEN 3 (Edwards Lifesciences, Inc.; Irvine, CA). Thus, the SOURCE 3 Registry provided an opportunity to investigate anesthesia management for TAVI without the potential confounders of differing valve technologies and noncontemporary practice patterns. Therefore, this study investigated the role of these anesthesia techniques during TAVI in SOURCE 3 with respect to key clinical outcomes and resource utilization.

Methods

Patient selection and TAVI procedure: We analyzed patient data from the SOURCE 3 Registry, the largest European, post-market approval registry of TAVI performed with the SAPIEN 3 THV, which enabled us to evaluate a large number of patients who were treated by experienced TAVI operators using a single type of valve, i.e., the balloon expandable SAPIEN 3, as has been previously described in detail. The detailed parameters of the SOURCE 3 trial, such as the protocol, Institutional Review Board processes, TAVI technical aspects, and the components for overall and 30-day outcomes, have also been previously published. The SOURCE 3 Registry was approved by the Institutional Review Board of all participating centers, and all patients gave written informed consent to be included. The indications for TAVI with the SAPIEN 3 THV and the choice of anesthetic technique were made by the local heart teams and were based on individual preference.

The SOURCE 3 Registry includes 1947 patients who underwent TAVI with the SAPIEN 3 valve in 80 centers in 10 European countries. Patients who received transapical and transaortic valve replacements were excluded from this analysis due to the more invasive nature of these access sites, which necessitates the use of GA.

Study protocol and data management: SOURCE 3 patients were assessed at discharge, 30 days, and 1 year and will be followed annually for up to 5 years post TAVI. The major outcome measures were all-cause death, cardiac mortality, major vascular complications, life-threatening bleeding, stroke, acute kidney injury (AKI), permanent pacemaker insertion, procedural complications, LOS, New York Heart Association (NYHA) functional class, and echocardiographic assessment of valve function. All study endpoints were defined by the Valve Academic Research Consortium 2 criteria. The clinical events were reviewed and adjudicated by an independent clinical events committee. All echocardiographic data shown in this manuscript were site reported.

Statistical analysis: The analyzed population was based on the intention-to-treat principle; therefore, patients who converted to GA from CS were analyzed in the CS group.

We reported continuous variables as mean ± standard deviation or median. For baseline and procedural characteristics, categorical variables were compared using Fisher’s exact test and described as frequencies and percentages. For comparisons of country differences between the two groups, we used the Wilcoxon rank-sum test. Hemodynamic parameters were tested using the Fisher’s exact and Wilcoxon rank-sum tests for categorical and continuous variables, respectively. Kaplan-Meier estimates were used to describe 30-day outcomes.

For all statistical analyses, we used SAS version 9.4 (SAS Institute Inc.; Cary, NC).

Results

Baseline patient characteristics: We analyzed 1694 patients from the SOURCE 3 Registry who underwent TAVI: 1,027 patients who were planned to receive CS and 667 patients who received GA. Due to procedural complications, 12 patients (2.9%) who had been planned to receive CS were converted to GA (Table I). All of these complications resolved without sequelae. The treatment groups were similar in mean age (about 81.5 years old) and STS risk scores (about 7.0; Table I). Compared with the GA group, the CS group had a significantly lower prevalence of coronary artery disease (44.5% versus 55.5%; P < 0.001; Table I), congestive heart failure (32.2% versus 38.7%; P = 0.007), carotid disease (11.7% versus 17.2%; P = 0.002), and moderate-to-severe mitral regurgitation (11.5% versus 14.8%; P = 0.043). Conversely, the CS group had significantly more patients aged ≥80 years (70.4% versus 66.0%; P = 0.041) than did the GA group (Table I).

Procedural characteristics and outcomes: Of the valve sizes used in the procedures, the 29-mm valve was implanted significantly more often in the CS group than in the GA group (24.4% versus 18.7%; P = 0.007; Table II). Notably, TEE was used to guide TAVI in significantly fewer CS patients (5%) compared with GA patients (82%; P < 0.001). The valve was placed correctly in 99% of all patients.

The rate of post-dilatation was significantly less in the CS group compared with the GA group (7.1% versus 15.4%; P < 0.001). The rate of surgical closures of the femoral access was also significantly less in the CS group (1.2%) than in the GA group (12.7%; P < 0.001). In terms of resource utilization outcomes, the CS group experienced significantly shorter procedure times (64 minutes versus 79.2 minutes; P < 0.001) and received significantly lower volumes of contrast (121.6 mL versus 132.2 mL; P = 0.040) than the GA group.

Overall, procedural events did not differ significantly between the two study groups (Table II).

Echocardiographic data: At discharge, echocardiographic data were available for 907 patients in the CS group and in 604 patients of the GA group. Echocardiograms at 30 days were available for 512 patients in the CS group and 393 in the GA group. As shown in Table III, effective orifice area and mean transvalvular gradients did not differ between the two subsets at any time point. No statistically significant difference in the overall distribution of PVL grades (P = 0.118) was found between the two groups (Figure). Yet, the proportion of patients with
Table I. Demographics and Baseline Characteristics in Patients with Conscious Sedation or General Anesthesia

| Patient characteristic, Mean ± SD (n) or n (%) | Conscious sedation n = 1027 | General anesthesia n = 667 | P-value* |
|-----------------------------------------------|-----------------------------|---------------------------|---------|
| Age (years)                                   | 81.9 ± 6.72 (1027)          | 81.3 ± 6.60 (667)         | 0.057   |
| Age ≥ 80 years                                 | 723 (70.4)                  | 440 (66.0)                | 0.041   |
| Female                                        | 511 (49.8)                  | 323 (48.4)                | 0.061   |
| Mean Logistic EuroSCORE                       | 17.9 ± 12.96 (960)          | 17.7 ± 12.79 (593)        | 0.947   |
| EuroSCORE < 10                                | 296 (28.8)                  | 179 (26.8)                | 0.821   |
| EuroSCORE > 30                                | 144 (14.0)                  | 81 (12.1)                 | 0.505   |
| STS score                                     | 7.4 ± 8.01 (503)            | 7.0 ± 7.53 (400)          | 0.406   |
| Hypertension                                  | 830 (80.8)                  | 551 (82.6)                | 0.370   |
| Dyslipidemia                                  | 539 (52.5)                  | 367 (55.0)                | 0.319   |
| History of smoking                            | 253 (24.6)                  | 157 (23.5)                | 0.642   |
| Diabetes                                      | 281 (27.4)                  | 206 (30.9)                | 0.124   |
| Insulin-dependent diabetes                    | 96 (9.3)                    | 76 (11.4)                 | 0.188   |
| Coronary artery disease                       | 457 (44.5)                  | 370 (55.5)                | < 0.001 |
| Myocardial infarction                         | 105 (10.2)                  | 75 (11.2)                 | 0.519   |
| Percutaneous coronary intervention            | 312 (30.4)                  | 241 (36.1)                | 0.015   |
| Coronary bypass grafting                      | 84 (8.2)                    | 75 (11.2)                 | 0.041   |
| Congestive heart failure                      | 331 (32.2)                  | 258 (38.7)                | 0.007   |
| Left ventricular ejection fraction < 30%      | 59 (5.7)                    | 32 (4.8)                  | 0.579   |
| New York Heart Association Class IV           | 97 (9.4)                    | 55 (8.2)                  | 0.433   |
| Mitral regurgitation (moderate to severe)     | 118 (11.5)                  | 99 (14.8)                 | 0.043   |
| Tricuspid regurgitation (moderate to severe)  | 91 (8.9)                    | 62 (9.3)                  | 0.480   |
| Atrial fibrillation                           | 232 (22.6)                  | 133 (19.9)                | 0.330   |
| Pacemaker                                     | 117 (11.4)                  | 78 (11.7)                 | 0.876   |
| Chronic obstructive pulmonary disease         | 149 (14.5)                  | 107 (16.0)                | 0.405   |
| Renal insufficiency                           | 260 (25.3)                  | 195 (29.2)                | 0.082   |
| Severe liver disease/cirrhosis                | 18 (1.8)                    | 15 (2.2)                  | 0.477   |
| Porcelain aorta                               | 43 (4.2)                    | 16 (2.4)                  | 0.057   |
| Peripheral vascular disease                   | 129 (12.6)                  | 73 (10.9)                 | 0.357   |
| Peripheral stent (femoral, iliac)             | 20 (1.9)                    | 5 (0.7)                   | 0.062   |
| Stroke                                        | 83 (8.1)                    | 49 (7.3)                  | 0.643   |
| Transient ischemic attack                     | 37 (3.6)                    | 28 (4.2)                  | 0.605   |
| Carotid disease                               | 120 (11.7)                  | 115 (17.2)                | 0.002   |
| Carotid endarterectomy/stent                  | 27 (2.6)                    | 26 (3.9)                  | 0.155   |
| Coagulopathy                                  | 15 (1.5)                    | 5 (0.7)                   | 0.251   |

*P-values compare conscious sedation versus general anesthesia using Fisher’s exact and t tests for categorical and continuous measures, respectively.

Table II. Procedural Characteristics and Outcomes between Patients Receiving TAVI with Conscious Sedation or General Anesthesia

| Characteristic                             | Conscious sedation n = 1027 | General anesthesia n = 667 | P-value* |
|--------------------------------------------|-----------------------------|---------------------------|---------|
| Valve size 23 mm, n (%)                    | 377 (36.7)                  | 256 (38.4)                | 0.504   |
| Valve size 26 mm, n (%)                    | 399 (38.9)                  | 286 (42.9)                | 0.105   |
| Valve size 29 mm, n (%)                    | 250 (24.4)                  | 125 (18.7)                | 0.007   |
| Valve-in-bioprosthesis, n/N (%)            | 15/1024 (1.5)               | 12/645 (1.9)              | 0.554   |
| Transesophageal echocardiography, n/N (%)  | 14/272 (5.1)                | 352/428 (82.2)            | < 0.001 |
| Pre-balloon valvuloplasty, n/N (%)         | 543/1024 (53.0)             | 369/666 (55.4)            | 0.343   |
| Correct site placement, n/N (%)            | 1011/1023 (98.8)            | 659/665 (99.1)            | 0.809   |
| Post-dilation, n/N (%)                     | 73/1023 (7.1)               | 102/664 (15.4)            | < 0.001 |
| Procedure time, minutes, mean ± SD (n)     | 64.5 ± 27.75 (870)          | 79.2 ± 40.53 (513)        | < 0.001 |
| Fluoroscopy time, minutes, mean ± SD (n)   | 14.7 ± 6.75 (872)           | 15.0 ± 7.56 (609)         | 0.855   |
| Contrast volume, mL, mean ± SD (n)         | 121.6 ± 51.49 (982)         | 132.2 ± 69.15 (626)       | 0.040   |
| Surgical closure of access site, n/N (%)   | 12/1014 (1.2)               | 83/854 (12.7)             | < 0.001 |
| Valve-in-valve bailout, n (%)              | 6 (0.6)                     | 5 (0.7)                   | 0.761   |
| Conversion to open heart surgery           | 4 (0.4)                     | 6 (0.9)                   | 0.205   |
| Cardiopulmonary bypass, n (%)              | 1 (0.1)                     | 0 (0.0)                   | > 0.999 |
| Coronary obstruction, n (%)                | 4 (0.4)                     | 3 (0.4)                   | > 0.999 |
| Annular rupture, n (%)                     | 1 (0.1)                     | 2 (0.3)                   | 0.566   |

TAVI indicates transfemoral aortic valve implantation. *P-values compare conscious sedation versus general anesthesia using Fisher’s exact and t tests for categorical measures and continuous measures, respectively. † n = 1026. ‡ n = 666.
and 1.9% of the GA group. Improvement of at least 1 NYHA class. Worsening of symptoms (Table VII), consistent results were obtained (data not shown).

Regardless of anesthesia used, the median ICU LOS was 1 day in most countries, except France (2 days; Table V). Median total LOS also tended to vary by country, with the shortest total LOS (5.0 days) reported in both Denmark and the United Kingdom. Total LOS also did not differ significantly between the two anesthesia regimens (Table V).

At 7 days post-procedure, AKI was significantly less prevalent in the CS group than in the GA group (0.4% versus 1.5%; P = 0.014; Table VI). However, the rate of unplanned hemodialysis after TAVI did not differ significantly between the two anesthesia regimens (Table V).

At 30 days post-procedure, no significant differences were found between treatment groups in all-cause mortality, cardiovascular mortality, major vascular complications, life-threatening bleeding, myocardial infarction, new pacemaker implantation, stroke, and disabling stroke (Table VI). After adjusting for differences in baseline characteristics (Table VII), consistent results were obtained (data not shown).

At the 30-day follow-up, 79.5% of patients in the CS group and 80.0% in the GA group had symptomatic improvement of at least 1 NYHA class. Worsening of symptoms by 1 NYHA class occurred in 2.3% of the CS group and 1.9% of the GA group.

**Discussion**

This analysis of the SOURCE 3 Registry comparing patients who underwent TAVI with CS or GA found little evidence to demonstrate the superiority of either anesthesia technique. Specifically, procedural success and freedom from death or myocardial infarction at 30 days were similar, irrespective of the type of anesthesia used. With either CS or GA, patients derived essentially the same symptomatic benefit, as demonstrated by a decrease in NYHA class at 30 days post-procedure.

**Procedural parameters:** Our study revealed specific differences in TAVI procedural management based on the use of CS or GA. As expected, GA facilitates the more liberal use of TEE for procedure monitoring, which, in turn, may lead to more meticulous optimization of valve deployment, as evidenced in our study by more post-dilatation procedures in the GA than CS group. This ability to optimize valve deployment with GA was associated with a lower rate of moderate PVL in the GA group versus the CS group. Conversely, CS had the advantage of reduction in procedural time by 15 minutes and the amount of contrast media by 10 cc, which correlates with significantly less AKI in the CS group compared with the GA group. This finding is, however, dependent on interventional practice. When angiographic assessment of PVL is replaced by TEE, the combination of GA and TEE may be used to reduce contrast administration and decrease kidney injury.

The conversion rate to GA of 1.3% in our study was substantially lower than the conversion rate of 5%-11% in earlier studies. This may be attributed to increasing operator experience and advanced valve design facilitating deployment.

**Country differences:** The similarity in patient characteristics, overall and between countries, is a potential strength of this study, as it reduces the degree of confounding factors associated with differences in patient profiles. Conversely, the choice of anesthesia technique differed sub-

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**Table III.** Mean Aortic Gradient and Effective Orifice Area

| Visit        | Mean aortic gradient, mmHg | Effective orifice area, cm² |
|--------------|----------------------------|-----------------------------|
|              | GA | CS | GA | CS |
| Baseline     | 44.2 ± 14.9 (601) | 44.2 ± 16.3 (924) | 0.7 ± 0.2 (513) | 0.7 ± 0.2 (805) |
| Discharge    | 11.7 ± 5.1 (604)  | 11.7 ± 4.7 (907)  | 1.7 ± 0.5 (217) | 1.7 ± 0.5 (489) |
| 30 days      | 11.9 ± 5.1 (354)  | 12.2 ± 5.4 (505)  | 1.6 ± 0.5 (171) | 1.6 ± 0.5 (337) |

Mean ± SD (n). CS indicates conscious sedation; and GA, general anesthesia.

**Table IV.** Proportion of Patients Who Underwent TAVI with Conscious Sedation or General Anesthesia between Countries

| Country         | Overall | Conscious sedation, % | General anesthesia, % |
|-----------------|---------|----------------------|----------------------|
| Denmark         | 1027    | 60.6                 | 39.4                 |
| Finland         | 18      | 90.0                 | 10.0                 |
| France          | 429     | 67.9                 | 32.1                 |
| Germany         | 419     | 54.8                 | 45.2                 |
| Italy           | 11      | 47.8                 | 52.2                 |
| The Netherlands | 17      | 89.5                 | 10.5                 |
| Spain           | 1       | 100.0                | 0                    |
| Switzerland     | 56      | 84.9                 | 15.2                 |
| United Kingdom  | 40      | 30.3                 | 69.7                 |

TAVI indicates transcatheter aortic valve implantation.
Table V. Length of Stay by Country

| Country             | Conscion sedation Median (min, max) | General anesthesia Median (min, max) | Tests comparing groups* |
|---------------------|-------------------------------------|-------------------------------------|-------------------------|
|                     | n=1027                              | n=667                               |                         |
| Length of stay      | Total LOS   | ICU LOS    | Total LOS   | ICU LOS    | P-value | P-value |
| All countries       | 10.0 (2.0, 73.0) | 1.0 (0.0, 62.0) | 11.0 (2.0, 116.0) | 1.0 (0.0, 43.0) | 0.060    | 0.702   |
| Denmark             | 5.0 (4.0, 37.0)  | 0.0 (0.0, 1.0)  | 0.0 (0.0, 1.0)  | 0.0 (0.0, 1.0)  | -        | -       |
| Finland             | 7.0 (4.0, 11.0)  | 1.0 (0.0, 5.0)  | 2.0 (0.0, 39.0) | 203         | 9.0 (3.0, 58.0) | 2.0 (0.0, 21.0) | 0.795    | 0.478   |
| France              | 9.0 (2.0, 70.0)  | 2.0 (0.0, 39.0) | 346         | 13.0 (4.0, 75.0) | 1.0 (0.0, 43.0) | 0.247    | 0.001   |
| Germany             | 12.0 (2.0, 73.0) | 1.0 (0.0, 62.0) | 12.0 (7.0, 35.0) | 1.0 (1.0, 13.0) | 0.621    | 0.516   |
| Italy               | 10.0 (5.0, 32.0) | 1.0 (0.0, 17.0) | 17.0         | 7.5 (7.0, 8.0)  | 0.0 (0.0, 0.0)  | 1.000    | 0.864   |
| The Netherlands     | 7.0 (7.0, 14.0)  | 0.0 (0.0, 1.0)  | 1.0 (1.0, 1.0) | 0.0 (0.0, 1.0)  | -        | -       |
| Spain               | 7.0 (7.0, 7.0)   | 1.0 (1.0, 1.0) | 1.0         | 7.5 (7.0, 8.0)  | 0.0 (0.0, 0.0)  | -        | -       |
| Switzerland         | 9.0 (4.0, 47.0)  | 1.0 (0.0, 8.0)  | 10.0         | 8.0 (5.0, 13.0) | 0.0 (0.0, 2.0)  | 0.786    | < 0.001 |
| United Kingdom      | 5.0 (2.0, 65.0)  | 0.0 (0.0, 15.0) | 92.0         | 5.5 (2.0, 116.0) | 0.0 (0.0, 24.0) | 0.536    | 0.036   |

ICU indicates intensive care unit; and LOS, length of stay. *P-values are based on Wilcoxon rank-sum test.

Paravalvular leaks: In the unadjusted analysis of the FRANCE-2 registry on early generation valves reported by Oguri, et al., there was a statistically significant surplus in greater than mild PVL with CS compared with GA. This difference disappeared after adjusting for the use of TEE, which supports our hypothesis that more liberal use of TEE contributes to a lower incidence of PVL with GA. Similar to the FRANCE-2 registry, our SOURCE 3 analysis found a significant difference in moderate-to-severe PVL between groups.

Permanent pacemaker implantation: We did not find significant differences in the need for new pacemaker/defibrillator implantation between CS and GA, which is consistent with a study in patients undergoing elective percutaneous transfemoral TAVI between April 2014 and June 2015, in which post hoc falsification endpoint analyses were performed to evaluate for residual confounding factors. In this study, vascular complications, bleeding, and new pacemaker/defibrillator implantation demonstrated no significant differences between the types of anesthesia management after adjustment, in alignment with our findings.

Length of stay: The LOS post TAVI have been reportedly shorter with CS compared with GA in a study and a meta-analysis. This meta-analysis identified articles...
Table VI. Clinical Outcomes at 30 Days Post Implantation

| Clinical outcomes                        | Conscious sedation (n = 1027) | General anesthesia (n = 667) | P-value* |
|------------------------------------------|-------------------------------|------------------------------|----------|
| All-cause mortality, %                   | 2.1                           | 1.7                          | 0.473    |
| Cardiovascular mortality, %              | 1.5                           | 0.9                          | 0.309    |
| Stroke, %                                | 1.7                           | 0.6                          | 0.055    |
| Disabling stroke, %                      | 0.6                           | 0.3                          | 0.404    |
| Myocardial infarction, %                 | 0.2                           | 0.1                          | 0.830    |
| Major vascular complication, %           | 4.2                           | 4.4                          | 0.872    |
| Life-threatening bleeding, %             | 4.1                           | 4.7                          | 0.582    |
| New permanent pacemaker, %               | 12.1                          | 12.6                         | 0.754    |
| Acute kidney injury (II–III) to 7 days, %| 0.4                           | 1.5                          | 0.014    |
| Unplanned hemodialysis to 7 days, n/N (%)| 2/29 (6.9)                    | 4/25 (16.0)                  | 0.399    |
| New onset atrial fibrillation, %         | 4.7                           | 6.8                          | 0.070    |
| ICU median length of stay, median (IQR)  | 1.0 (0.62)                    | 1.0 (0.43)                   | 0.702    |
| Length of stay, median (IQR)             | 10.0 (2.73)                   | 11.0 (2.116)                 | 0.060    |
| Moderate-to-severe paravalvular leak, n/N (%) | 32/512 (6.3)              | 28/393 (7.1)                 | 0.686    |
| Effective orifice area, cm², mean ± SD   | 1.6 ± 0.46, n = 337           | 1.6 ± 0.45, n = 171          | 0.449    |
| Mean gradient (mmHg), mean ± SD          | 12.2 ± 5.40, n = 505          | 11.9 ± 5.05, n = 354         | 0.727    |

*P-values compare conscious sedation versus general anesthesia using Fisher’s exact and Wilcoxon rank-sum tests for categorical and continuous measures, respectively.

Table VII. Reasons for Conversion

| Patient | Reason for conversion from CS to GA | Outcome of the conversion |
|---------|------------------------------------|---------------------------|
| 1       | Pericardial effusion and need of valve verification by TEE | Resolved without sequelae |
| 2       | Ventricular tachycardia and asystole resolved with shock, cardiac massage, medication, intubation, and pacing. | Resolved without sequelae |
| 3       | Valve was placed too ventricular; therefore, it was decided to implant a second valve. The first valve embolized into the ventricle, and open heart surgery was required to remove it through the apical access. | Resolved without sequelae |
| 4       | Left ventricle perforation requiring re-thoracotomy. | Resolved without sequelae |
| 5       | Low output                         | Resolved without sequelae |
| 6       | Hemodynamic instability and agitation | Resolved without sequelae |
| 7       | Respiratory insufficiency with known paralysis of the recurrent nerve, COPD, and pulmonary emphysema that required ventilation to be prolonged. | Resolved without sequelae |
| 8       | Severe pain during the sheath insertion. Dissection with occlusion of the right external iliac artery in the puncture area occurred. Surgical revision and implantation of a vascular prosthesis (Hemashield 8 mm) was necessary. | Resolved with sequelae |
| 9       | Cardiac arrest because valve was implanted upside down. Valve-in-valve was required. | Resolved without sequelae |
| 10      | After procedure for surgical repair of access site due to failure of Proglide vessel closure | Resolved without sequelae |
| 11      | Intubation and general anesthesia for treating acute tamponade and perforation of the left ventricle | Resolved without sequelae |
| 12      | Patient was restless.              | Resolved without sequelae |
| 13      | Failure of Prostar (closure device) | Resolved without sequelae |

COPD indicates chronic obstructive pulmonary disease; and TEE, transesophageal echocardiography.

published between January 2006 and June 2016 that compared CS with GA in a study population undergoing TAVI. CS presented shorter hospital and ICU stays but did not impact 30-day mortality. In contrast to these studies, we found no differences in total LOS based on anesthesia technique employed. This finding was also consistent for ICU LOS.

Limitations: Our findings may be subject to selection bias and confounders, because of the non-randomized nature of our study population. There were, however, differences in baseline characteristics between the two study groups. Therefore, we cannot exclude unknown confounders that may have affected our study results.

Although our analysis is based on 1694 patients, the number of major events was low. This limits the power of our analysis, particularly with respect to stroke and death rates.
Conclusions

In addition to the large patient population, another strength of this study is that a single THV, SAPIEN 3, was used. Moreover, this research addressed contemporary practice patterns across a European spectrum in a fairly homogeneous cohort of patients irrespective of the chosen anesthesia management. Our study expands the existing evidence that the choice of anesthesia does not affect major outcome measures. The large patient population allowed us to address specific additional issues. Thus, our results suggest that for patients who underwent contemporary TAVI with the optimized, balloon-expandable SAPIEN 3 THV, neither CS nor GA technique appeared to offer any major advantages with respect to LOS measures. Specifically, we found no indication that modern GA regimens delivered by dedicated cardiac anesthesiologists was associated with increased harm to the patient or that GA delayed recovery. However, as shown in our study, TAVI operators should be aware that GA may invite procedural complexity and increased volumes of contrast medium, which may increase risk of kidney injury. On the other hand, the use of TEE under GA facilitates valve deployment and helps optimize apposition.

While CS simplifies the procedure, the potential for a slightly higher risk of residual PVL needs to be considered. However, either technique appears to have little effect on recovery times or clinical outcomes. Our findings show that TAVI outcomes appear to be similar irrespective of anesthesia type; therefore, the choice of anesthesia may be left to the preference of the patient and the heart team.

Acknowledgments

Jason Hokama, Frédérique Maneval, and Tracey Fine of Edwards Lifesciences provided medical writing services.

Disclosure

Conflicts of interest: F.J. Neumann reports grants and fees to the institution from Daiichi Sankyo, Astra Zeneca, Sanofi-Aventis, Bayer, The Medicines Company, Bristol, Novartis, Roche, Boston Scientific, Biotronik, Medtronic, and Edwards Lifesciences, and Ferrer. S. Redwood reports grants and personal fees from Edwards Lifesciences; T. Lefèvre is proctor for Abbott Vascular, Boston Scientific, and Edwards Lifesciences; D. Frank reports grants and personal fees from Edwards Lifesciences; Pieter R. Stella is a member of the Keystone Heart advisory board; T. Ho-vorka is an Edwards Lifesciences employee; G. Tarantini reports personal fees from Edwards Lifesciences; O. Wendler and H. Baumgartner are proctors for Edwards Lifesciences. G. Tarantini reports personal fees from Edwards Lifesciences. Other authors have no conflict of interest to declare.

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