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ORIGINAL RESEARCH

Nurse Led Sedation: The Clinical and Echocardiographic Outcomes of the 5-Year Emory Experience

Patricia Keegan, NP, DNP[a], John C. Lisko, MD, MPH[a], Norihiko Kamioka, MD[a], Samuel Maidman, MD [a], Jose N. Binongo, PhD[b], Jane Wei, MPH[b], Ratna Vadlamudi, MD[c], J. Kirk Edwards, MD[c], Nishant Vatsa, MD, Aneesha Maini[a], Shawn Reginauld[a], Patrick Gleason, MD[a], James Stewart, MD[a], Chandan Devireddy, MD[a], Peter C. Block, MD[a], Adam Greenbaum, MD[a], Robert A. Guyton, MD[d], and Vasilis C. Babaliaros, MD[a]

[a]Division of Cardiology, Emory University School of Medicine, Atlanta, Georgia, USA; [b]Department of Biostatistics, Rollins School of Public Health, Emory University, Atlanta, Georgia, USA; [c]Division of Anesthesiology, Emory University School of Medicine, Atlanta, Georgia, USA; [d]Division of Cardiothoracic Surgery, Emory University School of Medicine, Atlanta, Georgia, USA

ABSTRACT

Background: Our center has developed protocols for nurse-led sedation (NLS) where dedicated cardiac catheterization laboratory nurses directly provide sedation with fentanyl and midazolam. This study compares outcomes of patients undergoing minimalist TAVR with anesthesia led sedation (ALS) using monitored anesthesia (MAC) care delivered by a dedicated anesthesia team vs. sedation delivered by catheterization laboratory nurses (NLS).

Methods: We reviewed each patient's medical record and divided them into two groups: those in whom the multi-disciplinary heart team chose NLS vs. anesthesia led sedation (ALS). Patients were propensity matched in a 2:1 fashion to compare clinical and echocardiographic outcomes.

Results: Using a 2:1 propensity score matching, 407 patients who underwent TAVR under the NLS protocol were matched with 243 patients who underwent TAVR under the monitored anesthesia care pathway with ALS. In the NLS group, 2.2% of patients required conversion to general anesthesia, while 0.8% of patients in the ALS group underwent conversion ($p = 0.22$). Similarly, 1% of patients required conversion to open surgery in the NLS group compared to 0.8% in the ALS group ($p = 0.99$). Both groups had comparable survival to discharge (98.3% NLS vs. 100% ALS, $p = 0.05$). No mortality was directly attributable to anesthesia method. Discharge echocardiographic assessment of procedural success was similar between groups.

Conclusions: NLS appears to have procedural outcomes similar to anesthesia-led moderate sedation. NLS is associated with significantly shorter procedure-room time and contrast volume than anesthesia-led moderate sedation. At 1 year, there was no difference in the combined endpoint of death or readmission between groups.

Abbreviations: ALS: Anesthesia led sedation; ECMO: Extra corporeal membrane oxygenation; LOS: Length of stay; LVEF: Left ventricular ejection fraction; MAC: Monitored anesthesia care; NYHA: New York Heart Association; NLS: Nurse led sedation; PROM: Predicted Risk of Mortality; STS: Society of Thoracic Surgeons; TAVR: Transcatheter aortic valve replacement; VARC: Valve Academic Research Consortium

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Introduction

During initial clinical research trials and commercial adoption in the United States, patients underwent transcatheter aortic valve replacement (TAVR) with endotracheal intubation and sedation provided by a dedicated anesthesia team. Our center has developed protocols for nurse led sedation (NLS) where non-anesthetist Heart Team nurses directly provide sedation with fentanyl and midazolam. Currently, the STS/ACC TVT registry only classifies patients as undergoing general anesthesia (GA) or monitored anesthesia care (MAC); thus there is only classification for anesthesiology-administered sedation and not a specific separate category for NLS.[1] While minimalist TAVR has consistently shown to be similar, or superior, to TAVR using general anesthesia,[2-4] the addition of NLS raises the concern for an additional degree of risk that, to date, has not been well studied in the United States. The aim of this study is to evaluate the clinical and echocardiographic outcomes of patients undergoing minimalist TAVR with anesthesia provided by a dedicated anesthesia team vs. catheterization laboratory nurses.

Materials and methods

We queried the Emory Healthcare database for all patients undergoing TAVR for severe calcific aortic stenosis with a balloon-expandable valve from 2012 to 2017 under

CONTACT Vasilis C. Babaliaros vbabali@emory.edu Structural Heart and Valve Center, Emory University Midtown Hospital, 550 Peachtree St. NE, Davis Fischer Bldg., Ste. 4303, Atlanta, GA 30308, USA.

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a previously described minimalist protocol.[5] The diagnosis of severe aortic stenosis was made using standard transthoracic echocardiographic parameters. All patients were deemed to be TAVR candidates by a Heart Team comprised of interventional cardiologists, cardiothoracic surgeons, and other stakeholders. The multi-disciplinary heart team selected both the method of implantation and the anesthesia plan. Our institution's procedural technique has been previously reported and is standard among operators.[5] Briefly, patients undergo transfemoral TAVR in a cardiac catheterization laboratory under conscious sedation without the routine placement of an arterial blood pressure monitoring line. Transthoracic echocardiography is used to guide valve deployment, to assess for complications, and to evaluate paravalvular leak. Following TAVR, patients are transferred to a telemetry floor with four hours of bedrest. Pending clinical stability and a stable EKG, patients are discharged within 24–48 hours of the procedure.

All patients who did not undergo TAVR utilizing general anesthesia were further divided into two groups: those who underwent minimalist TAVR with NLS and those who underwent minimalist TAVR with anesthesiology-led MAC using our institutional minimalist decision tree (Figure 1). The investigators personally reviewed each patient's chart to determine the sedation provider. All nurses administering sedation were Registered Nurses. Nurses delivering sedation during TAVR are under protocol agreements and practicing within the scope of their practice as dictated by the Georgia State Nursing Board.

Nurse led sedation protocol

All patients deemed to be candidates for minimalist TAVR were also screened for NLS. On initial assessment, all patients were screened using the American Society of Anesthesiologists (ASA) Score and Mallampati score. An ASA score < 4 with a Mallampati score < 2 resulted in further screening to rule out a history of an adverse reaction to anesthesia. Patients with an ASA score > 4 or with a Mallampati score > 2 were referred for general anesthesia evaluation. Only patients meeting all criteria were eligible to undergo NLS. A dedicated nurse provided sedation and patient assessment for each TAVR and was not assigned other responsibilities during the procedure. The sedation nurse determined the initial dose of midazolam, up to 0.5 mg and fentanyl 12.5 mg as needed for sedation and pain control per protocol. Flumazenil and Naloxone were available in all cases (Figure 2). In accordance with Joint Commission requirements, patients were assessed every five minutes for vital signs, level of consciousness, oxygen saturation, and pain score. Level of consciousness was assessed as 0: Unconscious, 1: Sedate but responsive, and 2: Alert. The target level of sedation was 1: Sedate but responsive. Pain was patient reported and scaled from 1–10, with 10 signifying maximum pain. Analgesia was provided based on patient reported pain.

Variables of interest

The following were collected on all patients using the Society of Thoracic Surgeons (STS) adult cardiac surgery database specifications[6] and Valve Academic Research Consortium (VARC)-2 definitions[7]: baseline STS demographic characteristics, procedural characteristics, left-ventricular ejection fraction (LVEF), aortic valve mean gradient, and aortic valve area. Lung disease was dichotomized into >/= moderate and New York Heart Association (NYHA) class was recorded if patients were Class IV. STS Predicted Risk of Mortality (PROM) was calculated for each patient prior to undergoing TAVR. The primary clinical endpoints were conversion of

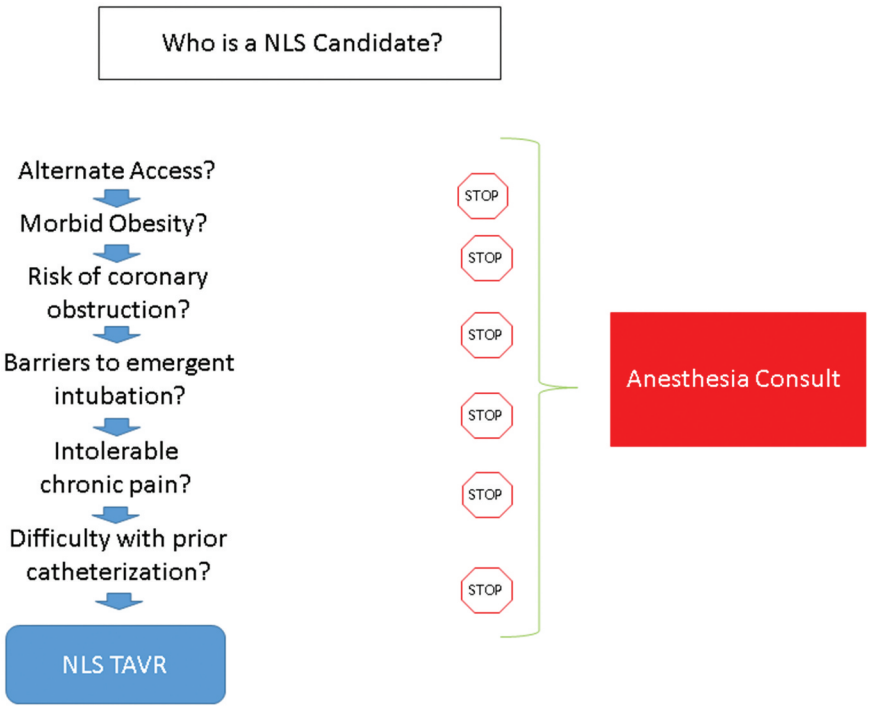

Figure 1. NLS screening. All patients are screened for NLS using the above algorithm during the multidisciplinary heart team meeting.

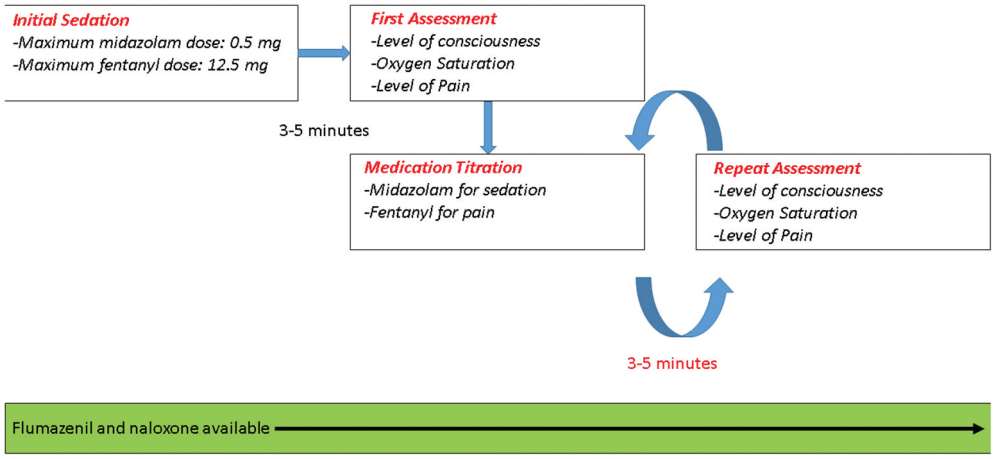

Figure 2. The NLS protocol. A nurse titrates sedation using the above protocol with frequent patient assessment.

anesthesia method, conversion to open surgery, survival to discharge, and the combined endpoint of death or readmission at 1 year. Additional clinical endpoints were total procedural-room time, total fluoroscopy time, vascular complications, bleeding, minor or major stroke, new-onset atrial arrhythmia, need for deployment of a second valve, length of ICU stay, and post-procedural length-of-stay (LOS).

Primary echocardiographic endpoints were valve gradients and valve area at discharge. All endpoints were determined using VARC-2 definitions.[7] The study was approved and performed in accordance with the regulations of the Emory University institutional review board. Informed consent was not required for this retrospective analysis.

Statistical analysis

Prior to assessing differences in postoperative outcomes, it was essential to ensure that the nurse-led sedation group and the anesthesia led sedation group had similar preoperative characteristics. A propensity score for each patient was estimated using a logistic regression model with the following preoperative variables as the predictors: NYHA classification, peripheral vascular disease, atrial fibrillation, aortic valve area, left ventricular ejection fraction (LVEF), lung disease, and immunocompromised status. Then patients in the two groups with similar propensity scores were matched in a 2:1 fashion. The standardized difference was calculated to determine the success of the propensity score matching approach that aimed to reduce preoperative imbalance between the two groups. Guidelines suggest that standardized differences larger than 0.20 indicate that the groups being compared are too different from each other for reliable comparison. Once between-group imbalances were reduced, the two groups were compared using the two-sample t-test (or the Mann-Whitney U test, as appropriate) for continuous outcomes and the chi-square test (or Fisher's exact test, as appropriate) for dichotomous outcomes. Using the unmatched sample, sensitivity analyses were performed using two approaches: regression adjustment by propensity score and traditional regression adjustment using the preoperative variables (Table 4). All tests of hypotheses were two-tailed and conducted at a 0.05 level of significance. SAS Version 9.4 was employed to perform the statistical analyses.

Results

Pre-matched patient characteristics

For this study, 1092 patients met the inclusion criteria (Table 1). Of these, 807 were in the NLS group and 285 were in the anesthesia led sedation (ALS) group. The majority of patients in this study were male (60.8% in NLS group vs. 59.3% in ALS group, $p = 0.65$). There were no significant differences in baseline demographic characteristics except for the following: patients in the NLS group had a greater prevalence of patients that were immunocompromised (11.9% vs. 7.4%, $p = 0.03$), NYHA IV HF (45.7% vs. 24.2%, $p < 0.001$), and higher baseline STS Predicted Risk of Mortality Predicted Risk of Mortality score (5.9% vs. 5.2%, $p = 0.01$). Patients in the ALS group had a greater prevalence of baseline lung disease (24.6% vs. 18.6%, $p = 0.03$), peripheral vascular disease (35.1% vs. 18.2%, $p < 0.05$), and atrial fibrillation (40% vs. 27.0%, $p < 0.05$).

Pre-matched baseline echocardiographic parameters

Of the 1092 patients that met the inclusion criteria for this study, 1085 had baseline echocardiograms available for review (Table 2). There were no significant differences in baseline LVEF (55% vs. 55%, $p = 0.08$), mean aortic valve gradient (42.0 mmHg vs 42.5 mmHg, $p = 0.53$), or degree of aortic insufficiency (22.6% vs. 20.4%, $p = 0.45$) between the NLS group and ALS group. The ALS group had a statistically, but not clinically, significant smaller aortic valve area (0.7 cm^2 vs. 0.8 cm^2, $p < 0.001$).

Matched patient characteristics

Using 2:1 propensity score matching, 407 patients who underwent TAVR under the Nurse Led Sedation protocol were matched with 243 patients who underwent TAVR under the monitored anesthesia care pathway. After matching, the absolute standardized difference was < 0.10 for most variables

Table 1. Unmatched demographic and clinic characteristics.

	Nurse Led Sedation	Anesthesia Led Sedation	P-value*	Standardized Difference**
	(n = 807)	(n = 285)		
Age	82.0 (76.0,86.0)	82.0 (75.0,86.0)	0.90	0.01
Male	491 (60.8)	169 (59.3)	0.65	0.03
Hypertension	787 (97.5)	280 (98.2)	0.48	0.05
Dyslipidemia	763 (94.5)	274 (96.1)	0.29	0.08
Diabetes mellitus	333 (41.3)	115 (40.4)	0.79	0.02
Serum Creatinine, mg/dL	1.1 (0.9,1.4)	1.1 (0.9,1.4)	0.79	0.03
Lung disease (≥moderate)	150 (18.6)	70 (24.6)	0.03	0.15
Immunocompromised	96 (11.9)	21 (7.4)	0.03	0.15
History of endocarditis	6 (0.7)	4 (1.4)	0.46	0.06
Cerebrovascular Disease	259 (32.1)	97 (34.0)	0.55	0.04
Prior Stroke	114 (14.1)	44 (15.4)	0.59	0.04
Peripheral vascular disease	147 (18.2)	100 (35.1)	<0.001	0.39
Prior MI	233 (28.9)	90 (31.6)	0.39	0.06
Prior CABG	211 (26.1)	63 (22.1)	0.18	0.09
Prior PCI	294 (36.4)	93 (32.6)	0.25	0.08
Atrial fibrillation	218 (27.0)	114 (40.0)	<0.001	0.28
NYHA Class IV	369 (45.7)	69 (24.2)	<0.001	0.46
STS-PROM, %	5.9 (4.1,8.9)	5.2 (3.8,7.9)	0.01	0.12

Note. MI = myocardial infarction; CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; NYHA = New York Heart Association; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

*For dichotomous outcomes, the *p*-value was based on the chi-square test (or Fisher's exact test, as appropriate); for continuous outcomes, the *p*-values was based on the two-sample t-test (or Mann-Whitney U test, as appropriate).

**The standardized difference is used in the propensity score literature to assess the comparability of two groups. Unlike the *p*-value, which depends on the sample size, the standardized difference is unaffected by the sample size, as it expresses the between-group mean difference in units of the pooled standard deviation. Standardized differences larger than 0.25 indicate meaningful imbalance in the baseline characteristic (Rubin 2001). In the unmatched sample above, three of the baseline variables have large standardized differences.

Table 2. Unmatched baseline echocardiographic parameters.

	Nurse Led Sedation	Anesthesia Led Sedation	P-value
Left Ventricular Ejection Fraction	57.5 (47.5,60)	55.0 (50,63)	0.18
Mean Aortic Valve Gradient	42.0 (36.0, 48.8)	42.5 (36.0, 50.5)	0.1
Aortic Insufficiency (>mild)	22.6%	20.4%	0.05
Aortic Valve Area (cm^2)	0.8 (0.6,0.9)	0.7 (0.6,0.8)	0.2

Note. *Quantitative variables are summarized using mean ± standard deviation [or mean (1st quartile, 3rd quartile). Categorical variables are reported using frequency (percentage).

(Table 3). For peripheral arterial disease, the standardized difference was 0.19. These standardized differences indicated an adequate match and no major imbalance between the groups at baseline. All outcomes presented in the following sections are for the matched cohort.

Matched clinical outcomes

In the NLS group, 2.2% of patients required conversion to general anesthesia, while 0.8% of patients in the ALS group underwent conversion ($p = 0.22$). Similarly, only 1.0% of the NLS and 0.8% of ALS patients required conversion to open surgery in both the NLS group and ALS group ($p = 0.99$). Both groups had comparable survival to discharge (98.3% NLS vs. 100% ALS, $p = 0.05$). While there were numerically more deaths in the NLS group, no deaths were directly attributable to the anesthesia method. The deaths are attributable to known complications of TAVR (coronary obstruction, tamponade, aortic root rupture).

There were also no significant differences in major vascular complications, minor vascular complications, life-threatening bleeds, minor bleeds, major stroke, new onset atrial fibrillation, permanent pacemaker implantation, or need for a second valve.

Notably, the NLS group had a significant reduction in procedure-room time (NLS: 138 minutes vs ALS: 160 minutes, $p < 0.01$), contrast volume (115 mL vs. 150 mL, $p < 0.01$), and length of ICU stay ($p = 0.003$). At 1 year, there was no difference in the combined endpoint of death or readmission between groups (Table 5).

Matched echocardiographic outcomes

Discharge echocardiographic assessment of procedural success was similar between groups. The ALS group had a statistically, but not clinically, significant higher ejection fraction at discharge (NLS: 60% vs. ALS: 58%, $p = 0.028$). Mean gradients were similar between groups (NLS: 11.5 ± 46 mmHg vs. ALS: 11.8 ± 5.0 mmHg, $p = 0.47$). There was no significant difference in the degree of AI between groups (Table 6).

Discussion

Our study shows that: 1) nurse-led sedation was performed safely and effectively, 2) procedural outcomes with nurse-led sedation are similar to those with anesthesia-led moderate sedation, 3) there are no clinically significant differences in post-deployment hemodynamics or valve area with nurse-led sedation compared to anesthesia-led moderate sedation 4) nurse-led sedation is associated with significantly less ICU and procedure-room time than anesthesia-led moderate sedation, and 5) there is no difference in 1 year readmission or death between groups. An important contribution of this report is a dedicated protocol for nurse-led sedation.

While not statistically significant, the finding of numerically higher death in the NLS group raises concern. Review of these cases is notable for the fact that death was not attributable to the method of anesthesia. The deaths were attributable to cardiac arrest following discharge from the catheterization laboratory, an aortic root rupture in an otherwise inoperative candidate, a coronary obstruction that was successfully transferred to the operating room, a ventricular

Table 3. Matched baseline demographics.

	ALS (n = 243)	NLS (n = 407)	95% CI	p	Std Diff
Age	82.0 (75.0,86.0)	81.0 (74.0,86.0)	−1.00 (−2.42, 0.41)	0.17	0.07
Male	143 (58.8)	235 (57.7)	1.05 (0.76, 1.45)	0.78	0.02
Body mass index	28.4 ± 6.4	28.5 ± 5.8	−0.05 (−1.01, 0.90)	0.92	0.01
Hypertension	242 (99.6)	406 (99.8)	0.60 (0.04, 9.57)	0.99	0.03
Dyslipidemia	235 (96.7)	385 (94.6)	1.68 (0.74, 3.83)	0.21	0.10
Diabetes mellitus	103 (42.4)	169 (41.5)	1.04 (0.75, 1.43)	0.83	0.02
Serum Creatinine	1.1 (0.9,1.4)	1.1 (0.9,1.4)	0.01 (−0.068, 0.088)	0.80	0.01
Dialysis	13 (5.3)	17 (4.2)	1.30 (0.62, 2.72)	0.49	0.06
Lung disease	61 (25.1)	89 (21.9)	1.20 (0.82, 1.74)	0.34	0.08
Immunocompromised	19 (7.8)	35 (8.6)	0.90 (0.50, 1.61)	0.73	0.03
History of endocarditis	3 (1.2)	2 (0.5)	2.53 (0.42, 15.26	0.37	0.08
Cerebrovascular Disease	85 (35.0)	147 (36.1)	0.95 (0.68, 1.33)	0.77	0.02
Prior Stroke	41 (16.9)	60 (14.7)	1.17 (0.76, 1.81)	0.47	0.06
Peripheral vascular disease	82 (33.7)	102 (25.1)	1.52 (1.08, 2.16)	0.02	0.19
Prior MI	81 (33.3)	127 (31.2)	1.10 (0.79, 1.55)	0.57	0.05
Prior CABG	52 (21.4)	104 (25.6)	0.79 (0.54, 1.16)	0.23	0.10
Prior PCI	81 (33.3)	150 (36.9)	0.86 (0.61, 1.20)	0.36	0.07
Atrial fibrillation	98 (40.3)	165 (40.5)	0.99 (0.72, 1.37)	0.96	0.004
NYHA Class IV	64 (26.3)	120 (29.5)	0.86 (0.60, 1.22)	0.39	0.07
STS-PROM, %	5.3 (4.1,8.1)	5.4 (3.9,8.6)	0.10 (−0.60, 0.80	0.78	0.03
WBC	6.8 (5.6,8.1)	6.3 (5.1,7.7)	−0.50 (−0.83, −0.10)	0.003	0.07
Platelet	199000.0 (155000.0,248000.0)	192000.0 (156000.0,235000.0)	−7000.0 (−19319.1)	0.27	0.11
LVEF, %	55.0 (50.0,62.0)	55.0 (50.0,60.0)	0.00 (−1.77, 1.77)	0.99	0.04
Mean aortic valve gradient	43.0 (37.0,51.0)	42.0 (37.0,48.5)	−1.00 (−2.44, 0.43)	0.17	0.10
Aortic insufficiency	45 (18.5)	86 (21.1)	0.85 (0.57, 1.27)	0.42	0.07
Aortic Valve Area	0.7 (0.6,0.8)	0.8 (0.6,0.9)	0.06 (0.03, 0.10)	0.001	0.09

Note. MI = myocardial infarction; CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; NYHA = New York Heart Association; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; WBC = white blood cell count; LVEF = left ventricular ejection fraction.
*Quantitative variables are summarized using mean ± standard deviation [or mean (1st quartile, 3rd quartile). Categorical variables are reported using frequency (percentage).

Table 4. Sensitivity analysis.

	Propensity-score matched dataset (n = 650)			Full Dataset (n = 1092)	
	Parameter Estimate	95% CI		Propensity Score Adjusted Parameter Estimate	Regression Adjustment Parameter Estimate
Major Vascular complications	−1.2977	−3.1633	0.0128	−1.1457	−0.7805
Minor Vascular complications	−0.3130	−1.0474	0.3644	−0.2871	−0.2945
Life-threatening bleeding	−1.9052	−4.8139	−0.2586	−1.7367	−1.1484
Major bleeding	−0.2546	−1.2298	0.6238	−0.1678	−0.0567
Minor bleeding	−0.2571	−0.8978	0.3439	−0.1954	−0.1204
Major or life-threatening bleeding	−0.6954	−1.5694	0.0705	−0.5151	−0.3538
Major stroke	−0.1782	−3.2494	2.1721	−0.5645	−0.8216
Minor stroke	−11.4816*	-	-	−11.6013	−11.4171
New-onset atrial fibrillation	−0.3362	−1.8783	0.9538	−0.2752	−0.5319
New pacemaker implantation	−0.7625	−1.5803	−0.0424	−0.6418	−0.5431
DC LVEF, %	0.00388	−0.0333	0.041	0.007	0.0110
DC Mean aortic valve gradient	0.0264	−0.0436	0.0964	0.05072	0.0490
DC Aortic insufficiency	−0.6521	−1.9296	0.4020	−0.5872	−0.6222
DC Aortic Valve Area	−0.0438	−0.0992	0.0116	−0.0650	−0.0691
Conversion to general anesthesia	−1.0022	−2.8887	0.3638	−0.9036	−0.9596
Conversion to open heart surgery	−0.1790	−2.1600	1.4624	0.0278	−0.0745
Need for a 2nd transcatheter valve	−1.1099	−2.9884	0.2336	−1.0186	−0.9642
Length of ICU stay	0.5496	0.2997	0.7995	0.48908	0.5216
Postoperative LOS	−0.0405	−0.1210	0.0399	−0.03447	−0.0262
In-hospital mortality	−11.4918*	-	-	−12.2902	−12.0454

Note. DC = discharge; LVEF = left ventricular ejection fraction; ICU = intensive care unit.

Table 5. Matched procedural and in-hospital outcomes.

Variable	ALS (n = 243)	NLS (n = 407)	95% CI	p
Total laboratory time	160.0 (144.0,176.0)	138.0 (118.0,162.0)	−22.0 (−27.8, −1.00)	**<0.01**
Fluoroscopy time	24.2 (19.6,28.5)	22.5 (18.1,28.8)	−1.7 (−3.0, −0.30)	**0.01**
Contrast volume	150.0 (115.0,177.5)	115.0 (90.0,150.0)	−35.0 (−45.69, −2.00)	**<0.01**
Major Vascular complications	2 (0.8)	12 (2.9)	0.27 (0.06, 1.23)	0.07
Minor Vascular complications	12 (4.9)	27 (6.6)	0.73 (0.36, 1.47)	0.38
Life-threatening bleeding	1 (0.4)	11 (2.7)	0.15 (0.02, 1.16)	0.07
Major bleeding	7 (2.9)	15 (3.7)	0.78 (0.31, 1.93)	0.58
Minor bleeding	16 (6.6)	34 (8.4)	0.77 (0.42, 1.43)	0.41
Major or life-threatening bleeding	8 (3.3)	26 (6.4)	0.50 (0.22, 1.12)	0.09
Major stroke	1 (0.4)	2 (0.5)	0.84 (0.08, 9.28)	0.99
Minor stroke	0 (0.0)	4 (1.0)	0.99 (0.98, 1.00)	0.30
New-onset atrial fibrillation	3 (1.2)	7 (1.7)	0.71 (0.18, 2.79)	0.75
New pacemaker implantation	9 (3.7)	31 (7.6)	0.47 (0.2, 1.00)	0.05
DC LVEF, %	60.0 (55.0,65.0)	58.0 (55.0,62.0)	−2.00 (−3.78, −0.200)	**0.03**
DC Mean aortic valve gradient (mmHg)	11.8 ± 4.9	11.5 ± 4.9	0.29 (−0.50, 1.09)	0.47
DC Aortic insufficiency (>mild)	4 (1.9)	13 (3.7)	0.52 (0.17, 1.62)	0.25
DC Aortic Valve Area	1.7 (1.4,2.1)	1.7 (1.5,2.2)	0.00 (−0.11, 0.11)	0.99
Conversion to general anesthesia	2 (0.8)	9 (2.2)	0.37 (0.08, 1.71)	0.22
Conversion to open heart surgery	2 (0.8)	4 (1.0)	0.84 (0.15, 4.60)	0.99
Need for a 2nd transcatheter valve	2 (0.8)	10 (2.5)	0.33 (0.07, 1.52)	0.23
Length of ICU stay	0.0 (0.0,25.8)	0.0 (0.0,0.0)	0.00 (0.00, 0.00)	**<0.01**
Postoperative LOS	2.0 (1.0,3.0)	2.0 (1.0,3.0)	0.00 (0.00, 0.00)	0.77
In-hospital mortality	0 (0.0)	7 (1.7)	0.98 (0.97, 0.99)	0.05
Home	234 (96.3)	377 (92.6)	2.07 (0.97, 4.44)	0.06
Extended care/rehab	6 (2.5)	20 (4.9)	0.49 (0.19, 1.24)	0.12
Other acute care hospital	0 (0.0)	2 (0.5)	0.99 (0.99, 1.00)	0.53
Nursing home	3 (1.2)	1 (0.2)	5.08 (0.53, 49.07)	0.15
Hospice	0 (0.0)	0 (0.0)		
Death	0 (0.0)	7 (1.7)	0.98 (0.97, 0.99)	0.050

Note. DC = discharge; LVEF = left ventricular ejection fraction; ICU = intensive care unit.
*Quantitative variables are summarized using mean ± standard deviation [or mean (1st quartile, 3rd quartile). Categorical variables are reported using frequency (percentage).

Table 6. Matched 30 day and 1 year outcomes.

Variable	ALS (n = 243)	NLS (n = 407)	95% CI	p
30d Mortality	2 (1.0)	8 (2.3)	0.43 (0.09, 2.04)	0.35
30d Readmission: Cardiac Related	12 (4.9)	22 (5.5)	0.89 (0.43, 1.84)	0.76
30d Readmission: All cause	20 (8.2)	34 (8.5)	0.97 (0.54, 1.72)	0.91
1 yr Mortality	20 (9.1)	40 (10.9)	0.82 (0.47, 1.45)	0.50
1 yr Readmission: Cardiac Related	35 (18.1)	49 (16.1)	1.15 (0.72, 1.86)	0.56
1 yr Readmission: All Cause	65 (35.1)	85 (29.0)	1.33 (0.89, 1.97)	0.16
1 yr Readmission or Death	0.4 ± 0.6	0.5 ± 0.6	0.06 (−0.06, 0.17	0.33

Note. *Quantitative variables are summarized using mean ± standard deviation [or mean (1st quartile, 3rd quartile). Categorical variables are reported using frequency (percentage).

wire perforation that survived to the operating room with mechanical circulatory support, and successfully treated vascular injuries that died during convalescence. Four deaths occurred in 2014, suggesting that this group may not be fully comparable to the devices and skill found in modern clinical practice. This study is notable not only for the above findings but also for the similar rate of conversion to general anesthesia and open surgery between groups. The rates of conversion to general anesthesia reported in this study (0.8–2.2%) are similar and comparable to other studies of minimalist TAVR.[5] Nonetheless, the rate of conversion to general anesthesia was numerically higher in the NLS group. The two conversion to general anesthesia in the ALS group were attributable to ventricular perforation requiring exploration. In the NLS group, only one conversion was attributable to an inability to sedate the patient. The other causes included a respiratory arrest requiring intubation, the previously described coronary obstruction, and ventricular perforations. With the exception of inadequate sedation, we feel that these conversions represent known complications of TAVR more so than limitations of NLS. The rate of conversion to open surgery in the NLS group (1.0%) is similar when compared

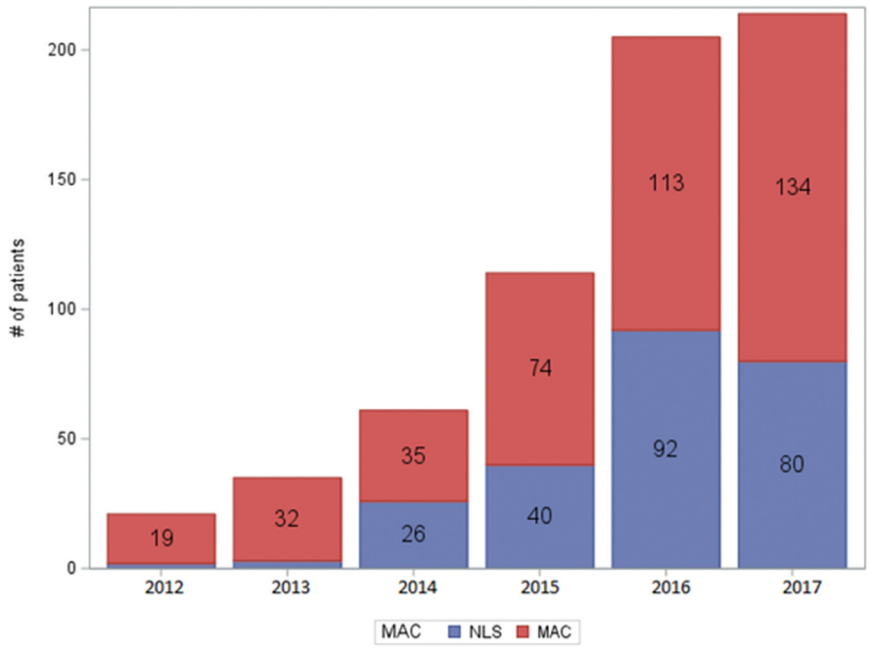

Figure 3. Changes in sedation practice by year. 2:1 propensity matched TAVR sedation cases by year. NLS has increased in frequency since 2012.

to prior reports (0.5%).[8] Of the 4 conversions to open surgery, three were attributable to left ventricular perforation and one was attributable to the previously described coronary obstruction. There was no significant delay in operative intervention. Similar to prior reports, only 50% of patients requiring conversion to open surgery survived to discharge. While the number of patients requiring second valve placement was numerically higher in the NLS group, the majority of these patients underwent TAVR prior to 2015. This likely reflects difficulty with sizing rather than an inherent limitation of NLS. Of the two contemporary NLS patients that required placement of a second valve, one had a predicted need prior to TAVR (given the significantly calcified annulus) and the second had an intentionally low placement of the first TAVR valve to avoid rupture of the sinotubular junction. Again, we feel that these findings are likely attributable to inherent limitation in TAVR more than NLS. The shorter procedure room time and ICU length of stay is likely attributable to the "less invasive" nature of NLS as well as different equipment and staffing needs.

NLS is not a new concept in the field of TAVR. The first case performed by Dr. Cribier in 2004 was completed under NLS with an anesthesiologist available on call.[9] The Emory TAVR program was initiated in 2007 with procedures performed with general anesthesia. With the commercialization of TAVR for inoperable patients in 2011, our program began to experience delays in care related to anesthesia availability. Cardiology procedural area nurses are familiar with administering sedation per protocol for patients undergoing cardiac catheterization/interventions and electrophysiology procedures. Given the history of sedation of TAVR and nurse experience, our team felt comfortable exploring NLS as an option for streamlining care in a safe and efficient manner. Initial conversations included all members of the Heart Team, including: Interventional Cardiology, Cardiac Surgery, Anesthesiologists, Imagers, and Nursing. The discussions included development of a standardized pathway inclusive of characteristics of patients who may benefit from NLS. Discussions also included examination of preexisting pathways utilized within interventional cardiology as well as training for nursing staff. The Anesthesiology department was integral in developing and refining these protocols.

The team relied upon existing moderate sedation protocols for standardization of orders. The orders included drug doses, monitoring parameters, and a reassessment of patient condition to ensure safety (see Figure 2).

In the procedural area there are a number of safety mechanisms in place: pharmacologic agents and an emergency code cart containing intubation supplies. The procedural area is also equipped with hemodynamic support including intra-aortic balloon pumps, percutaneously inserted left ventricular assist devices, and extracorporeal membrane oxygenation. The staff has been trained to initiate femoral hemodynamic support. In an airway emergency the staff is instructed to call the anesthesia emergency code. This allows for rapid anesthesia response to the procedural area to provide emergent intubation and assumption of airway management.

Training of staff was of high priority for the success of this program. NLS is performed under the supervision of an implanting physician. The implanting physician can request a deviation from the protocol at her or his discretion. The nurses who provide NLS must go through yearly skills verifications, which are documented within the employee record. They also participate in additional educational training sessions. The nurses are encouraged to participate in patient selection evaluations as well as provide feedback regarding patient care and outcomes. The state of Georgia requires 20 continuing nursing education (CNE), or continuing education credits per year. Twenty credits is approximately 20 hours of education for the staff. Figure 3

shows the relative change in the volume of nurse led sedation cases over time in this matched cohort.

We recommend the Emory protocol, as a minimum, to centers with an interest in implementing NLS; however, it should be modified based on an institution's needs and expertise.

Multiple studies have evaluated the predictors and outcomes of early discharge following TAVR.[3,10,11] Work by Konigstein suggests that the presence of an anesthesiologist in the catheterization laboratory during transfemoral TAVR did not significantly change 30 day outcomes.[12] In the 3M Study, 98% of patients underwent TAVR with no or minimal procedural sedation. Anesthesiologists, presence was implied per protocol but not mandated. Next-day discharge was achievable in 80.1% of the study population.[3] Our data suggest that nurse led sedation can be an iterative step in simplifying the minimalist TAVR pathway.

Limitations

This study has limitations. Though 2:1 propensity matched, it is a single-center, non-randomized, retrospective study conducted at an experienced TAVR institution and results may not be generalizable to lower-volume centers. Nursing privileges vary by state and while NLS is possible in Georgia, it may not be a viable option in all states. While the total number of adverse outcomes was higher in the NLS group this was not statistically significant. Larger studies are warranted to further assess these differences.

This study did not evaluate the total cost of care; however, based on resource utilization it is likely that given comparable outcomes, NLS is likely more cost effective and currently being evaluated.

Conclusion

Minimalist TAVR with nurse led sedation is feasible, safe, and effective. Patients undergoing NLS have similar clinical and echocardiographic outcomes to those undergoing anesthesia led sedation with decreased length of both procedure time and ICU stay. Further study is warranted to evaluate NLS in the low-risk TAVR population.

ORCID

Samuel Maidman http://orcid.org/0000-0002-1376-5526

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