Supplement to Cath Lab Digest

CardioVascular Learning Network

Cost Analysis of TAVR Procedure Using

Nurse-Led Sedation in the Cath Lab

In order to fulfill this educational activity, please visit https://www.naccme.com/program/NurseLedSedation to complete the post-test/evaluation and obtain your certificate.

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This activity is designed for interventional cardiologists, cardiologists, nurses, technicians and all involved in the treatment of patients in the cardiac catheterization lab.

LEARNING OBJECTIVES

After completing this activity, participants should be able to:

- Identify the economic value of nurse-led sedation for a TAVR procedure.
- Evaluate and deduce whether to perform a TAVR procedure in the Cath Lab or in a Hybrid/Surgical Suite.
- Understand how these efficiencies can improve the patient experience and reduce the length of hospital stay, and rate of readmission.

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To be eligible for credit, participants must read the CME Supplement, complete the post-test online with a score of 70% or better, and complete the evaluation. Upon completing the activity, there will be instructions on how to complete the evaluation and print a certificate or other documentation of credit.

Release Date: September 1, 2021
Expiration Date: September 1, 2022
Estimated time to complete: 1 hour

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Overview

The goal of this educational article is to help readers identify best practices for nurse-led sedation (NLS) during transcatheter aortic valve replacement (TAVR) procedures. We have identified experts in the field, from a variety of sites, who explain how to transition to NLS, evaluate appropriate patients, and staff NLS TAVR procedures. The experts also discuss the impact of NLS on patient outcomes, resource utilization, and facility costs.

General anesthesia (GA) was used in the first clinical TAVR cases performed in the US to provide the ability to convert to open aortic valve replacement if needed.[1,2] With evolving TAVR technology, complications, such as stroke and vascular access site bleeding, have declined.[2] Lower-profile devices have enabled less-invasive transfemoral TAVRs, allowing the procedure to be performed in cardiac catherization laboratories (CCLs) instead of operating rooms (ORs).[1] This has also enabled the use of monitored anesthesia care (MAC) and conscious sedation (CS) instead of GA. The use of MAC or CS by some centers is another way to make TAVR even less invasive and to reduce the amount of time the patient spends in the intensive care unit (ICU).[1, 2]

MAC, which is traditionally performed by an anesthesiologist, includes the continuous monitoring of patient response as well as ventilation, oxygenation, circulation, capnography, and temperature. In MAC, the anesthesiologist must be prepared to address an obstructed airway or to convert the case to GA, if needed.[3] According to the American Society of Anesthesiology (ASA), CS can be used in select patients by non-anesthesiology healthcare providers (HCPs) in certain procedures. CS, which is also known as moderate sedation, is characterized by the patient being able to respond purposefully to verbal commands or light physical stimulation. The ASA recommends that non-anesthesiology HCPs receive training in sedation and analgesic pharmaceuticals, be able to establish an open airway (if necessary) and provide positive pressure ventilation. Patient selection is key, as a variety of patient characteristics, such as significant obesity, a short neck, atypical airway anatomy, and sleep apnea, may increase the risk for adverse events.[4]

The minimalist approach to TAVR, which was adopted by some centers as early as 2012, includes use of CS and transthoracic echocardiography (TTE), instead of GA and transesophageal echocardiography (TEE). The early experience with the minimalist approach showed similar outcomes and reduced time in ICU for patients undergoing minimalist TAVR compared to those treated prior to the adoption of a minimalist approach. Some centers have expressed concern that the use of TTE (instead of TEE) could underestimate the severity of paravalvular leak (PVL) after TAVR. However, early experience with minimalist TAVR did not show a significant increase in mild to moderate PVL.[5]

An analysis of the Transcatheter Valve Therapy (TVT) Registry showed that CS accounted for 15.8% of TAVR procedures performed during April 2014–June 2015. CS compromised an increasing percentage over this period from 11% in April–June 2014 to 20% in April–June 2015. In-hospital and 30-day mortality was significantly less frequent in patients treated with CS compared to GA. In addition, time in ICU and length of stay (LOS) in the hospital were significantly lower in CS patients. Conversion to GA was needed in 5.9% of patients.[1]

A more recent analysis of the TVT Registry of patients undergoing transfemoral TAVR showed that CS was used in 33% of cases in January 2016, which increased to 63% in September 2018. Compared to patients undergoing GA, CS was associated with better in-hospital and 30-day mortality rates, decreased use of inotropic agents, and shorter hospital LOS. Moderate and severe PVL rates were similar between the minimalist approach and standard TAVR at 3.0% and 5.8%, respectively.[6]

The Minneapolis Heart Hospital has quantified the effect on costs of a minimalist approach to TAVR. Patients undergoing non-urgent/non-emergent transfemoral TAVR and who did not require surgical cut-down technique for vascular access receive CS. CS patients were less likely to require time in the post-anesthesia care unit (PACU) compared to those receiving GA for TAVR at 49.5% and 100%, respectively (P<0.001). CS patients also were significantly less likely to require an ICU stay at 0.9% versus 31.8% for GA patients (P<0.001) and had shorter LOS at two days versus three days for GA patients (P<0.001). The minimalist TAVR approach decreased variable procedural costs by 17.9% compared to GA TAVR. The cumulative two-year cost savings for the hospital was $3.6 million.[7]

There is wide variation among centers in the frequency of CS in TAVR procedures, with 13% of centers not using CS for any TAVR procedure and 26% of facilities using CS in >80% of TAVR cases.[6] It's unclear to what extent facilities are adopting the most recent trend in anesthesia during TAVR: NLS. The purpose of this article is to describe practices developed by four facilities to assist healthcare providers (HCPs) who are seeking to establish or refine a TAVR program using NLS. Screening processes, evaluation by anesthesiology, staffing levels, and ways to maximize throughput while maintaining patient satisfaction are presented.

Abbott Northwestern

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What motivated your program to move toward TAVR procedures in the cath lab using NLS?

Prior to February 2016, all transfemoral TAVRs at Abbott Northwestern Hospital were exclusively performed with

Figure 1. Procedural Characteristics and Clinical Outcomes of Minimalist TAVR vs. Standard TAVR7

	Minimalist TAVR (N=107)	Standard TAVR (N=107)	*P* Value
Transfemoral Access	100%	100%	—
Conversion to Open Sternotomy	0%	1.9%	0.50
ICU Utilization	0.9%	31.8%	<0.001
LOS (Days), Median	2.0	3.0	<0.001
Cerebrovascular Accident	0%	2.8%	0.25
Bleeding >2 units	0%	0.9%	1.00
Major Vascular Complications	0%	0%	—
Minor Vascular Complications	1.9%	2.8%	1.00

GA, TEE, and full surgical preparedness (Foley catheters, invasive monitoring lines, cardiovascular operating room team, and supply present).

Our program adopted a minimalist approach to transfemoral TAVR as early as February 2016. Accompanying the shift to minimalist-focused TAVR, staffing modifications were made, and CS and TTE replaced GA and TEE, respectively. In addition, open heart surgical heart instruments and related supply chain items were omitted. Our experience to include the clinical and economic outcomes is well described.[7] However, moderate/conscious sedation in this study was primarily directed by physician anesthesiologists and certified registered nurse anesthetists (CRNAs).

Expanding procedural volume coupled by the inability to achieve patient throughput and turnaround time to the level we desired, further adaptations to our minimalist TAVR approach were required. Following a comprehensive review, a multidisciplinary group of stakeholders — hospital administration, physician leadership, anesthesia, and the cardiac catheterization laboratory team — MDs, Advanced Practice Providers (APPs), RNs, cardiovascular technicians (CVTs) — ultimately made the decision to move forward with the NLS pathway.

Prior to establishing the purposed change, focused education, and training in compliance with current Joint Commission standards fueled the development of a specific nursing protocol. The transition to NLS was incorporated gradually using carefully selected cases prior to wide-scale adoption. Our stakeholder group met regularly following the practice change to ensure patient satisfaction, as well as safety and regulatory measures, were upheld.

What would you consider to be the biggest barriers to the transition?

Change is always hard at first. However, our program had gone through the transformation to a minimalist approach a number of years previously, so many logistical barriers were already removed. Adequately training our nursing staff and having them develop a particular level of comfort and familiarity represented the largest challenge. Ensuring patient tolerability and achieving consistently excellent outcomes were core principals we needed to uphold. Overtime, the nurses became empowered and truly championed the process.

What role did anesthesia play in the transition?

Involving anesthesia throughout the entirety of the process was critical. Their contributions to training and mentorship during the transition to NLS was fundamental in the success of our program. Insight into suitable patient selection, an in-depth understanding of ASA's classifications, and Mallampati scoring (which predicts the ease of intubation) helped to guide our current protocol. To date, ongoing engagement continues to ensure safety.

When did you begin your NLS in the cath lab? What was the decision process to transition to NLS?

The NLS pathway was first implemented in August 2018. As mentioned previously, a multidisciplinary group of stakeholders met prior to implementa-

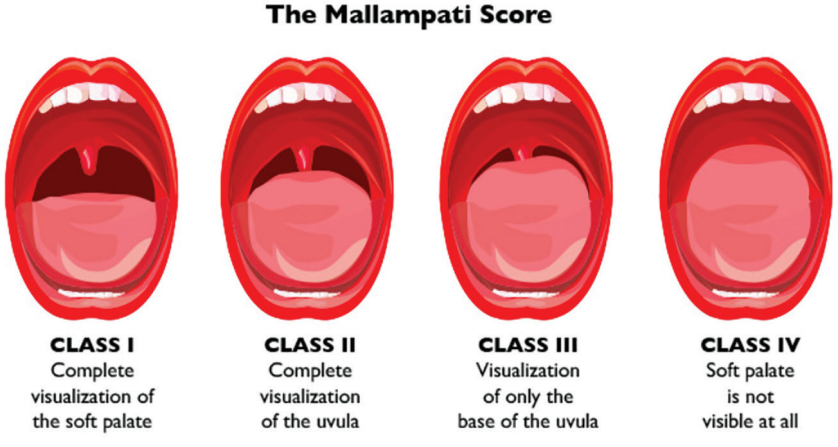

Figure 2. Mallampati Scoring.

tion to strategize, as well as to discuss the potential clinical and programmatic benefits. Capitalizing on our prior experience with the minimalist approach, the shift to NLS came somewhat naturally.

What has been the impact on your overall procedure times going from the hybrid room/OR to the cath lab?

Procedure time — room in to room out — was significantly shortened from a median length of 114 minutes to 85 minutes after NLS was established.

What has been the impact on costs when comparing TAVR procedures done in the cath lab versus those performed previously in the hybrid OR?

Overall, the implementation of minimalist TAVR was associated with significant cost savings. Our facility reported cumulative cost saving of $3.6 million over a two-year period. The introduction of the NLS pathway has led to further cost savings, including:

a. Length of stay. We have observed a reduction in LOS (0.68 reduction) with implementation of NLS. Our median length of stay currently is one day. Prior to NLS, the median LOS was 2.0 days.
b. ICU utilization. Our ICU utilization decreased from 21% to 10%. It should be noted that the TVT Registry counts any PACU recovery as ICU utilization.
c. Procedure staffing. The following team members participate in a TAVR procedure at our facility: two RNs (one primarily responsible for patient care/sedation and the other circulating and documenting), one interventional cardiologist, one cardiac surgeon, one structural heart fellow, one APP and two cath lab techs – a cardiovascular technologist (CVT) and a radiation technologist (RT). A sonographer is also available on standby for a limited echo after valve deployment to check for effusion, PVL, etc.
d. Overall procedure-based direct costs. There was an average total variable CV lab/OR cost reduction of 20%, with a 2% reduction in average total variable cost. These reductions are in addition to the substantial cost savings reported when our program adopted the minimalist approach to TAVR.7
e. Volume throughput per TAVR day. We do not have "dedicated TAVR days." Every day is a TAVR day, and we try to accommodate four to five procedures per day if needed.
f. Patient complications. Serious complications are in the low single digits and were not affected by implementing an NLS approach.
g. Patient readmissions. We observed no significant difference after implementation of NLS (12% vs 10%).

What is your patient algorithm for patient stratification with regard to location of procedure (cath lab vs OR) and/or anesthesia choice (GA, MAC, NLS)?

Proper patient selection in a systematic manner can lead to more efficient resource utilization. If a patient was deemed adequate for NLS, any cath lab resource can be used. These are often standard transfemoral cases or patients in the absence of high-risk features or potential intolerances/barriers to moderate sedation. Conversely, any of our high-risk patients or those deemed not NLS candidates (involving GA, MAC, or alternative access/necessitating surgical cut-down) would be appropriately triaged to a hybrid surgical suite.

What is your program's process for conversion to open surgery? What is your open conversion ratio?

Reflecting our stratification protocols, typically high(er)-risk procedures are specifically performed within a hybrid suite, which has the full capabilities of a traditional OR room. Thus, should complications ensue, a designated OR team would then rapidly assume care and perform surgical intervention without having to modify rooms. Should catastrophic complications occur in a standard cath lab room, swift transportation to the CVOR would need to occur. Our CCL team is trained in advanced circularity support methods (ECPR, ECMO). Thus, in the event an OR was not immediately available, the team would then take every measure possible to provide hemodynamic support until an OR was free.

Conversion to open sternotomy is currently <1%, or approximately a 1:400–1:500 occurrence. Albeit rare, our team periodically reviews and rehearses for emergent surgical and hemodynamic bailouts. A dedicated perfusionist (with primed pump) is available for all cases unless a patient declared an unwillingness to proceed with open heart surgery.

Now that you've converted to NLS, what do you wish you knew before you started?

Having seen the positive effects, it would've been beneficial to have prepared for the change much sooner.

What would you consider to be the biggest benefits of NLS?

Broadly, the use of NLS for transfemoral TAVR appears to be associated with improved length of stay, shorter procedure duration, and significant reduction in overall cost, with comparable procedural success and complication rates. In an effort to further optimize care for patients undergoing TAVR, NLS represents a forward-thinking solution to circumstances that may challenge a program's sustainability and programmatic success.

What are the biggest drawbacks of NLS?

While it's hard to draw upon the disadvantages of NLS, interpretation can often be misguided by the ease at which "said" change can be adapted. I would caution that implementation of an efficient, established NLS protocol takes considerable effort prior to widescale

adaptation. Moreover, I would encourage inexperienced programs to adapt a stepwise, methodical adaptation.

How are your nurses trained? What is their history/background when establishing their role in conscious sedation?

Nurses administer protocol-driven sedation, as prescribed by a physician, in the majority of procedures in the CCL. Many, if not all, of our nurses have extensive critical care or ICU experience. Nursing staff are expected to have an in-depth knowledge regarding the safe and effective use of moderate sedation, including being credentialed by the hospital for providing moderate sedation. Famously Benjamin Franklin stated: "By failing to prepare, you are preparing to fail." This principle holds true with the concept at hand.

When the NLS program was launched, we identified two to three "champions" who believed in the concept, had previous experience with structural heart disease (SHD) procedures, and welcomed the challenge. We felt that concentrating the early experience in a few hands was desirable before broader adoption. These champions then trained the remainder of the CV lab staff over the ensuing months, which allowed for greater efficiency while maintaining safety.

Riverside Methodist

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What motivated your program to move toward TAVR procedures in the cath lab using NLS?

As experience and refinement of the TAVR technology increased over the past decade, the procedure became much safer. The motivation was to simplify the procedure to continue improving patient outcomes, decrease hospital LOS, improve patient throughput, and reduce unnecessary procedure-related costs.

Figure 3. Minimalist TAVR vs. Standard TAVR[2, 5]

	Minimalist TAVR	Standard TAVR
Setting	CCL or hybrid suite	OR or hybrid suite
Sedation	MAC or NLS	GA
Interventional Field	Groin	Groin and chest
Access	Transfemoral	Multiple access sites, some of which require surgical techniques
Echocardiography	TTE	TEE
Cardiopulmonary Bypass	Perfusionist available	Primed support pump
Recovery	CCL recovery unit, PACU, or telemetry	ICU or Cardiac Care Unit

We formed a committee composed of CCL staff, OR staff, anesthesia, cardiothoracic surgeons, interventional cardiologists, and hospital administration. We discussed institutional outcomes, hospital readmission rates, complications, procedure conversion rate to open heart surgery, unnecessary resources available during each procedure, such as OR staff, perfusionist, surgical instrumentation, and primed cardiopulmonary support pumps.

The goal was to move to a full minimalist TAVR approach composed of nurse-led minimal conscious sedation, local anesthesia, fully percutaneous access site and closure, and TTE performed in a standard CCL. In the post-procedure setting, the patient would be recovered in a cath lab recovery unit rather than a cardiac ICU. The entire committee made the decision as a group aligned with the same focus to improve TAVR cost efficiencies and patient care.

The transition was performed in a step-wise approach with one change at a time and close monitoring of patient outcomes through pilot programs.

What would you consider to be the biggest barriers to the transition?

The cultural change of the all parties involved in the process. For example, nursing recovery units would now need to be trained on TAVR, large bore arterial access, TAVR-related rhythm abnormalities, and any complications associated with it.

What role did anesthesia play in the transition?

Anesthesia was part of the committee and provided important constructive criticism during the transition process. It is important that all committee members are aligned and understand the purpose with clarity of what the goals are as the transition happens to NLS. At the forefront of all discussions, the focus should be on improving TAVR-related patient outcomes.

When did you begin your NLS in the cath lab? What was the decision process to transition to NLS?

We started providing NLS in the cath lab four years ago. The decision process was based on developing a cost-effective TAVR program, decreasing ICU use, cost, and LOS. We have done over 1,000 cases with NLS.

The patient's clinical experience has been very positive. Patients who have had NLS during TAVR have been able to get out of bed and receive physical therapy even the same day of the procedure. Additionally, patients have a reduced ICU stay and LOS, with 85% of our TAVR patients now having next-day discharge.

What has been the impact on your overall procedure times going from

the hybrid room/OR to the cath lab? Have there been cost savings?

Reduction in procedure time is one of the major benefits of NLS. Our cath lab turnaround time is around 45 minutes between TAVR cases allowing us to complete four to five TAVR cases per TAVR day. Patient throughput and scheduling has been more efficient, as patients get scheduled quicker with less wait times for their TAVR procedure.

Cost is significantly less in the NLS protocol due to decreased resource utilization, such as OR personnel, unused surgical trays with surgical equipment, no need for a perfusionist or a primed cardio-pulmonary support pump in the room, anesthesiologist, or use of TEE. Additionally, decreases in ICU stay and LOS also lower initial hospital cost.

What has been the impact on costs when comparing TAVR procedures done in the cath lab versus those performed previously in the hybrid OR?

a. Length of stay. Next-day discharge is now done for the majority of our TAVR patients.
b. ICU utilization. We have completely eliminated the use of ICU utilization, except on hemodynamically unstable patients.
c. Procedure staffing. We have reduced the number of staffing in the cath lab to: two RTs and two RNs (one at the head of the patient bed administering medications and one helping with charting).
d. Overall procedure-based direct costs. We have seen cost savings per TAVR case averaging $6,000 to $8,000 per case with NLS and next-day home discharge.
e. Volume throughput per TAVR day. We perform four to five cases per TAVR day.
f. Patient complications. Complication rate has been relatively unchanged compared to TAVR performed with GA. One advantage of using CS is the rapid identification and treatment of stroke complications that lead to quicker interventional management by performing periprocedural neurological assessments.
g. Patient readmissions. We have seen a decrease in readmission rates, as we have also implemented a reduced readmission program in parallel with NLS.

What is your patient algorithm for patient stratification with regard to location of procedure (cath lab versus OR) and/or anesthesia choice (GA, MAC, NLS)?

The algorithm is very simple. Every transfemoral TAVR access is now performed under the NLS protocol. Alternative TAVR access, such as subclavian approach or transcaval access, is performed under GA.

What is your program's process for conversion to open surgery? What is your open conversion ratio?

The conversion rate to open heart surgery is <1% each year. Typically, conversion to open heart surgery is related to procedural complications, and the most important thing to keep in mind is preserving a patient's life. For that, the first priority is to stabilize the patient using mechanical circulatory support if necessary and inserting arteriovenous cannulas for ECMO support. Then, the life-threatening condition, such as pericardiocentesis in cases of pericardial tamponade, must be treated. Thus, teamwork coordination is important: one operator cannulates the patient in preparation for ECMO while the other performs lifesaving interventions such as pericardiocentesis. Once the patient is stable on mechanical circulatory support, we transfer the patient to the OR for open heart surgery if it is a viable option for the patient.

As long as the patient's hemodynamic stability is achieved with either mechanical support or lifesaving interventions, a proper plan of care — including open procedure to be performed and seeking OR availability — should be discussed as soon as possible.

Now that you've converted to NLS, what do you wish you knew before you started?

I wish we had the data to support a minimalist TAVR approach with NLS. It wasn't available then. The advantage of NLS for TAVR is cost efficiency, decreased length of stay, and improved patient satisfaction without compromising the safety and efficacy of the procedure.

What would you consider to be the biggest benefits of NLS?

Performing TAVR procedures with shorter procedure and quicker recovery times with early ambulation, and patients returning home within 24 hours of the procedure with good outcomes. Patient throughput is also important, as it allows us to complete more cases per TAVR day with more flexibility.

What are the biggest drawbacks of NLS?

There is no big drawback with using NLS. One possible minor disadvantage is peri- and post-procedural use of TEE for early recognition of procedural complications and to evaluate the presence and severity of PVLs.

How are your nurses trained? What is their history/background when establishing their role in conscious sedation?

Our nurses are critical care or emergency room nurses. They complete structural heart training, including TAVR orientation in addition to their cath lab orientation. Our cath lab nurses worked with our interventional cardiologists and anesthesiologists to create a medication algorithm for potential patient response or complications to the procedure and work under the direct supervision of the performing operator. We have created an emergency medication kit for TAVRs for the sedating RN to have everything readily available to them during the procedure.

Heart Hospital of Lafayette
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Figure 4. Role of Anesthesiology in NLS
• Key to development of NLS goals and protocols, including inclusion/exclusion criteria for NLS
• Train HCPs involved in NLS TAVR
• Evaluate patients in TAVR preassessment to determine whether patient is eligible for NLS
• Available on standby during procedure to assist if necessary

What motivated your program to move toward TAVR procedures in the cath lab using NLS?

Our TAVR program started in October 2015. At that time, Sapien XT was the valve in practice and required a 18Fr system. Our initial plan was to complete several cases with GA and TEE. Central venous lines were used, as well as arterial lines. We completed 36 cases with this procedure plan. Alternative access via transapical approach was completed if femoral arterial access was not appropriate caliber. In 2016, we transitioned from TEE to TTE and used MAC without endotracheal intubation. Improvements in the valve technology occurred and sheath diameters improved, resulting in increased transfemoral access success rates.

Our team was given the opportunity to visit Emory Medical Center in 2017 and observe their minimally invasive program. We returned to our hospital and continued to educate staff and other providers on the feasibility of the NLS protocol. We had multiple meetings with the providers involved in the procedure, including anesthesia, CV surgery, and interventional cardiology. The decision to proceed with NLS was entirely directed by the clinicians. In late 2017, we completed our first NLS case without complications. We have continued to transform the TAVR program into a minimalist program with >98% of cases completed with NLS. GA is only used for alternative access cases via transcarotid or transaxillary artery.

What would you consider to be the biggest barriers to the transition?

Comfort levels of the team members became the biggest barriers. Once the team was comfortable with the TAVR procedure that we initially implemented, change out of that comfort zone was difficult. Any time we decided to remove a specific part of the procedure, members of the team had questions. These included questions about their changing role in the procedure, as well as protocols in the event complications occurred. Over many conservations and educational moments, we were able to improve of comfort level and proceed successfully.

What role did anesthesia play in the transition?

We continue to involve anesthesia in the TAVR team. They are no longer present during the case, but they do continue to evaluate the patients in the preop setting. During this evaluation one to days days prior to the procedure (and at the time of preoperative lab testing), an anesthesia team member will meet with the patient and ensure NLS is the appropriate route to take to ensure a successful procedure. Concerns are then communicated to the interventional cardiologist and modifications to the sedation plan are completed, if required, prior to the patient arriving on the procedure day.

When did you begin your NLS in the cath lab? What was the decision process to transition to NLS?

We have completed 216 NLS cases to date. We have not had any complications, such as airway management issues, related to the sedation plan. The procedure times have decreased with the patient being in the procedure room for shorter periods. Patients can quickly be assessed for neurological changes throughout the procedure. They remain comfortable and usually have amnesia during the procedure. No one is discharged with narcotic pain medications, given the lack of significant patient discomfort. This results in a decreased LOS and early ambulation in the postop period.

What has been the impact on your overall procedure times going from the hybrid room/OR to the cath lab? Have there been cost savings?

Procedure times have been reduced with increased experience. The timeframe from large bore sheath insertion to removal has decreased and can be as low as 13 minutes in our experience. Additional reduction in valve deployment times or duration of sheath insertion is limited without a change in patient outcomes. The cost savings is directly related to removing specific aspects of the procedure, such as intubation, central venous line placement, Foley catheter placement, preparation of the chest for low-risk patients, and TEE. The TAVR procedure can be safely completed without these additions, which were held over from traditional CV surgery/OR protocols.

What has been the impact on costs when comparing TAVR procedures done in the cath lab versus those performed previously in the hybrid OR?

a. Length of stay. LOS averages 1.2 days. Delays in discharge are usually related to heart failure management with continued intravenous diuretic therapy. With GA, it was not uncommon that delays also were related to urinary retention from GA and/or Foley catheter placement, delirium

from sedatives in this advanced age population, and/or lack of progression in ambulation.

b. ICU utilization. Patients are admitted to telemetry floors. ICU times have decreased and are measured in a duration of hours. Telemetry nurses can appropriately take care of several TAVR patients in addition to other cardiac patients with ratios of 1:4 or 1:5. This, therefore, reduces nursing staffing issues.
c. Procedure staffing. The number of staff required in TAVR procedures has decreased. Staff currently include one RN, one radiation/scrub tech, echocardiogram technologist, and monitor (RN or RT) in addition to interventional cardiology and cardiovascular surgery. OR staff is available but not present during the case.
d. Overall procedure-based direct costs. Perfusion equipment and a perfusionist are no longer present in the case. A perfusionist is on call in the event of complications needing surgical bailout. Operating rooms are no longer held while TAVRs are being completed. This allows for increased utilization. Telemetry nurses have reduced tasks to complete as well and no longer have radial arterial and venous central lines to remove.
e. Volume throughput per TAVR day. We routinely complete three TAVRs before 11:00am (start time is 7:30am). Our average turnaround time is 30 minutes between cases using only one cath lab. The interventional cardiologist completes routine outpatient cardiology clinic starting at 1:00pm. The cardiovascular surgeon proceeds to scheduled OR cases following the completion of TAVRs.
f. Patient complications. No patient complications related to NLS.
g. Patient readmissions. No patient readmission related to NLS.

What is your patient algorithm for patient stratification with regard to location of procedure (cath lab versus OR) and/or anesthesia choice (general, MAC, NLS)?

Protocols have been developed to inform patients who can undergo NLS. Anesthesia evaluates the patient prior to arrival on the TAVR day. Examples of limitations to NLS include the inability to position supine, weight >100kg, OSA history, and severe gastroesophageal reflux disease (GERD) or aspiration risk.

What is your program's process for conversion to open surgery? What is your open conversion ratio?

Complications that require surgical bailout are best treated in the OR. If the patient is stable, we would proceed with moving the patient to the OR for emergency sternotomy. Our OR and cath lab are 20 feet apart. If the OR is occupied or the patient is too unstable, emergency sternotomy is completed in the cath lab/hybrid suite. This has never been completed for a TAVR patient. We have had two conversions for pericardial effusions, but this occurred several hours after the procedure therefore, allowing for pericardial drain placement and utilization of the OR for repair in a more controlled fashion. We have regular meetings regarding surgical bailout protocols for all cath lab cases, including wire perforation from coronary intervention cases, right ventricle perforation from pacemaker implantation, and other procedures. The rates of surgical bailout are low in TAVR patients, but every lab needs a protocol for complications related to TAVR and other cases.

Now that you've converted to NLS, what do you wish you knew before you started?

We should have progressed quicker from GA to MAC to NLS.

What would you consider to be the biggest benefits of NLS?

Patient satisfaction, staff satisfaction, cost savings, decreased LOS, and increased productivity of the providers as well as the hospital/cath lab.

What are the biggest drawbacks of NLS?

Reduced resources in the event of a rare complication. However, the risk of procedural complications is assessed to the best of our ability prior to procedure.

How are your nurses trained? What is their history/background when establishing their role in conscious sedation?

Each nurse has more than five years of experience as a nurse prior to taking a role in TAVR procedures. Nurses also undergo advanced cardiac life support (ACLS) training, as well as annual training for moderate sedation per cath lab protocols.

Bassett Medical Center

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What motivated your program to move toward TAVR procedures in the cath lab using NLS?

The desire to start a patient-friendly, safe, and sustainable TAVR program was modeled on the premise that a transfemoral TAVR procedure can be approached very similarly to a transfemoral complex PCI procedure if performed by the most experienced and highest-volume operators in an institution.

Having a high-volume interventional cardiologist with vast TAVR and complex PCI experience and an experienced cardiothoracic surgeon was step one in deciding how to build the TAVR program algorithm. The fundamental mindset was to approach TAVR in many of the same ways as a complex PCI procedure. Keeping our focus patient-friendly and safe (single-groin access, cerebral embolic protection use in appropriate cases, avoiding alternate-access TAVR cases, etc.) formed the underlying philosophy.

The cardiovascular service line director (an experienced interventional

Figure 5. Impact of NLS on Facility Metrics and Outcomes

	Abbott Northwestern	Riverside Methodist	Heart Hospital of Lafayette	Bassett Medical Center
LOS	Reduction of 0.68 days	Next-day discharge for most TAVRs	LOS averages 1.2 days	>85% have next-day discharge
ICU Utilization	Decreased to 10% from 21%*	No ICU utilization except for hemodynamically unstable patients	Patients admitted to telemetry; ICU stay has decreased, measured in hours, not days	Only used for procedurally complex patients and whose with high-risk comorbidities
TAVR Staffing	1 IC, 1 CTS, 1 structural heart fellow, 2 RNs, 1 CVT, 1 RT	Non-physician staffing: 2 RNs, 2 RTs	1 IC, 1 CTS, 1 RN, 1 RT, 1 echocardiogram technologist	1 IC, 1 CTS, 1 CVT, 2 RNs, 1 monitoring staff member
Conversions to Open Surgery/GA	<1%	<1%	<1%	<1%; None related to NLS
Procedure Direct Costs	Variable cost reduction of 20%	Cost savings of $6,000-$8,000 per case with NLS and next-day home discharge	Reduction in utilization of standard TAVR costs, e.g., perfusion equipment	TAVR device cost plus standard CCL costs
TAVR Throughput	4-5 TAVRs/day	4-5 TAVRs/day	3 TAVRs before 11AM; surgeries start at 1PM	4-6 TAVRs and 4-6 PCIs/day
Patient Complications	None related to NLS	Relatively unchanged vs standard TAVR	None related to NLS	None related to NLS
Patient Readmissions	No significant difference after NLS	Decrease in readmission rate	None related to NLS	None related to NLS

*Includes cases admitted to post-anesthesia care unit.
IC – Interventional cardiologist, CTS – Cardiothoracic surgeon, CVT – Cardiovascular technologist, RT – Radiation technologist.

cardiologist — Mun Hong, MD), the experienced interventional cardiologist (myself), and the experienced CT surgeon (John Kelley, MD), with administrative support made the decision to transition to NLS.

What would you consider to be the biggest barriers to the transition?

Keeping the NLS TAVR program unique and selective is the most important barrier. It's natural for every procedural physician to want to partake in an exciting leap in cardiovascular care, but a Jack of all trades can sometimes be a master of none. High-volume experienced operators with good outcomes are the right folks to spearhead — and maintain good outcomes — using NLS in a high-profile niche, such as a constantly evolving TAVR program.

Major stakeholders may lack an understanding of TAVR as a procedure and TAVR as a jewel in the crown of any community heart program. This can represent a barrier to adoption, and stakeholders may need education on the current evidence to address this obstacle.

What role did anesthesia play in the transition?

We always value the input of our anesthesia colleagues, but we were also coming off a decade or more of high-volume complex interventional cardiology cases using NLS in the cath lab.

When did you begin your NLS in the cath lab? What was the decision process to transition to NLS?

We are closing in on 200 cases, less than two years since program initiation. We started our program using NLS in the cath lab, which is not very different from complex PCI.

What has been the impact on your overall procedure times going from the hybrid room/OR to the cath lab? Have there been cost savings?

The vast majority of our TAVR cases go home the day after TAVR using NLS. The case volume and work flow on a TAVR day is very similar to any cath-lab PCI day, as the approach is similar. The cost savings for TAVR performed in a cath lab, with mostly single-groin access and mostly next-day discharge is immense, but varies based on the institution's reimbursement structure.

What has been the impact on costs when comparing TAVR procedures done in the cath lab versus those performed previously in the hybrid OR?

a. Length of stay. Most outpatient-elective TAVRs (>85%) go home the next day.
b. ICU utilization. ICU is only in cases that were procedurally complex, those that need transvenous pacing overnight (which in our experience has been <3%), and those with high-risk comorbid conditions.
c. Procedure staffing. In an NLS TAVR procedure, there is one interventional cardiologist, one cardiothoracic surgeon, one CVT, two circulating RNs, and a monitoring staff member.
d. Overall procedure-based direct costs. Standard valve apparatus costs and standard cath lab case costs.
e. Volume throughput per TAVR day. We do four to six TAVRs and four to six PCIs per day.
f. Patient complications. There have been no patient complications related to NLS in the cath lab.
g. Patient readmissions. There have been no patient complications related to NLS in the cath lab.

What is your patient algorithm for patient stratification with regard to location of procedure (cath lab versus OR) and/or anesthesia choice (general, MAC, NLS)?

Not applicable to our facility.

What is your program's process for conversion to open surgery? What is your open conversion ratio?

There have been no conversions related to NLS in the cath lab. Overall, conversions have been <1% with an emergent need for open surgery.

Now that you've converted to NLS, what do you wish you knew before you started?

Just how impactful it can be to overall patient care. We started down this path with patient care, as our focus, but it has grown to be more than that — it's an overall immensely satisfying patient experience.

What would you consider to be the biggest benefits of NLS?

Low complications, patient-friendly, low LOS, streamlined care.

What are the biggest drawbacks of NLS?

The inability to perform alternate-access TAVR.

How are your nurses trained? What is their history/background when establishing their role in conscious sedation?

Many of our cath lab nurses have ICU or special cardiac care experience, and the majority have been in the cath lab setting for at least two years. We don't have an established protocol for qualifications besides the ability to administer conscious sedation and the ability to monitor patients in this setting.

Summary

NLS has been shown to have similar outcomes as standard TAVR in select transfemoral procedures. It is associated with faster procedure times, reduced ICU stays, lower LOS, and improved TAVR throughput. Conversion rates to GA are low. NLS can obviate the cost of surgical trays and equipment, thereby reducing procedural costs. In addition, NLS may optimize hospital resources by lowering the number of HCPs who participate in TAVR procedures, not requiring a "hold" on ORs during TAVR, and reducing ICU stays.

Developing a TAVR program requires a multidisciplinary team, including hospital administration, interventional cardiology, cardiothoracic surgery, anesthesiology, sonography, nursing, and technologists. The transition to NLS requires a similar approach to develop protocols, guide patient selection, and define the roles and responsibilities of HCPs. Anesthesiology plays a critical role in refining patient selection and assisting with patients who require bailout. Nurses may need training on sedation and analgesic pharmaceuticals, as well as garnering a comfort level with a new role. ■

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