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Minimalist approach for transcatheter aortic valve replacement

Abordagem minimalista para implante transcatheter de válvula aórtica

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DOI: 10.31160/JOTCI201927A201827

ABSTRACT – Transcatheter aortic valve replacement became a routine interventional procedure worldwide, together with improvements in valve technology and optimized implant techniques. The concept of minimalist approach became relevant, aiming at optimal technical implant, fewer perioperative comorbidities, and consequently faster recovery and less associated risks. Compared with surgical aortic valve replacement, reduction of hospital and intensive care unit stay and fewer rates of procedural complications offset the high costs of transcatheter aortic valve replacement valves. The principles of the minimalist approach consist on top performance by experienced structural interventionists, a complete transcatheter basis under local anesthesia and conscious sedation, together with bedside transthoracic echocardiography to access hemodynamic features. It is necessary to customize transcatheter aortic valve replacement optimal procedure by revising how to simplify each aspect of the patient's care process, without losing focus on safety and best outcomes based on individualized patient characteristics, center's expertise, and multidisciplinary care. This review aimed to summarize the current evidence for a minimalist approach to transfemoral transcatheter aortic valve replacement and provide information for its safe and successful implementation and customization.

Keywords: Transcatheter aortic valve replacement; Aortic valve/surgery; Aortic valve stenosis; Heart valve prosthesis implantation/methods

RESUMO – O implante transcatheter de válvula aórtica tornou-se uma intervenção de rotina em todo o mundo, acompanhando as melhorias na tecnologia das válvulas e a otimização das técnicas de implante. O conceito de abordagem minimalista tornou-se relevante, visando obter um implante tecnicamente ideal, menos comorbidades perioperatórias e, consequentemente, recuperação mais rápida e com menos riscos associados. Em comparação à cirurgia de troca da válvula aórtica, a redução no tempo de hospitalização e na unidade de terapia intensiva, e a menor incidência de complicações do procedimento acabam por compensar os custos mais altos das válvulas para o implante transcatheter de válvula aórtica. Os princípios da abordagem minimalista consistem em desempenho superior de intervencionistas estruturais experientes, uma base estrutural completa sob anestesia local e sedação consciente, juntamente da ecocardiografia transtorácica à beira do leito, para avaliar características hemodinâmicas. É necessário customizar um procedimento ideal do implante transcatheter de válvula aórtica, procurando simplificar cada um dos aspectos da atenção ao paciente, sem perder o foco na segurança e na obtenção dos melhores desfechos, com base nas características individuais na experiência do centro e no atendimento multidisciplinar. Esta revisão teve como objetivo sintetizar as evidências atuais para uma abordagem minimalista do implante transcatheter de válvula aórtica transfemoral, e fornecer informações para garantir a segurança e o sucesso da implementação e customização desse procedimento.

Descritores: Substituição da valva aórtica transcatheter; Válvula aórtica/cirurgia; Estenose aórtica; Implante de prótese de valva cardíaca/métodos

How to cite this article:

Dallan LA, Ichibori Y, Attizzani GF. Minimalist approach for transcatheter aortic valve replacement. J Transcat Interv. 2019;27:eA201827. <https://doi.org/10.31160/JOTCI2019A201827>

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Submitted on:

Nov 19, 2018

Accepted on:

Jan 14, 2019

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INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has been widely accepted as an alternative therapeutic option to surgical aortic valve replacement (SAVR) in severe aortic stenosis patients with moderate or high risk of death in surgery.^{1,2} Ongoing improvements in both devices and techniques have enabled successful dissemination of TAVR procedure with high reproducibility. TAVR is now a reality as routine interven-

tional procedure worldwide. Hence, the concept of optimizing the procedure became relevant, since it is necessary to reduce perioperative comorbidities, with consequent early recovery, and overall better post-procedural outcomes in the elderly frail population. Efforts such as reduced length of hospital stay (LOS) and fewer resource utilization offset high material cost of TAVR as compared with SAVR.^{3,4}

Metanalysis and registry data suggest that minimalist TAVR may provide lower mortality, lower morbidity, shorter intensive care unit (ICU) and hospital stay, shorter procedure times with local anesthesia (LA).⁵

As demonstrated by data from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry,^{6,7} there has been a constant increase in the rate of conscious sedation (CS); increasing from 2.2% in 2012 to 17.2% in 2015, whereas general anesthesia decreased from 97.6% to 82.6% during the same period (Figure 1). In 2015, more than 85% (58.7%, 2014) of patients were treated via transfemoral access with predominant percutaneous approach (compared with surgical cutdown). As a result of these trends, LOS following TAVR decreased from a median of 6 days in 2012 to 4 days in 2015.

Figure 1. Trends toward a less invasive approach for transcatheter aortic valve replacement – conscious sedation vs. general anesthesia. Proportion of conscious sedation has gradually increased yearly, and 59% of patients had percutaneous approach in 2014 on the data from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) Transcatheter Valve Therapy Registry.

France 2 and France TAVI registries showed a similar trend. General anesthesia was used in 70.3% of patients in 2010, and decreased to 47.2% in 2015, along with a decrease in the use of transesophageal echocardiography (TEE) guidance (64.1% in 2010 to 26.7% in 2015).⁸ LOS after implantation has also gradually decreased over time as shown in figure 2. Nonetheless, the minimalist approach has not become an established strategy for patient care. There are many issues to be addressed by clinical studies, and the utilization of minimalist approach continues to be largely dependent on center preference.

Figure 2. Trends toward a less invasive approach for transcatheter aortic valve replacement (TAVR): length of stay, general anesthesia and transesophageal echocardiography (TEE) guidance.⁸ Data from France 2 registry and France TAVI registry showed decreased rates of general anesthesia, TEE guidance, and a shorter length of hospital stay (LOS) after TAVR.⁸

This review aimed to summarize the current evidence for TAVR minimalist approach, and provide information for its safe and successful implementation and customization.

TRANSCATHETER AORTIC VALVE REPLACEMENT MINIMALIST APPROACH

The principles of TAVR minimalist approach are summarized in figure 3 that shows procedure performance under LA and CS, along with transthoracic echocardiography

Pre procedure	
On-site cardiovascular surgery	Non on-site cardiovascular surgery
CT with standard contrast volume	CT with reduced contrast volume
Intra procedure	
Hybrid operating room	Catheterization laboratory
General anesthesia	Local anesthesia/conscious sedation
Transesophageal echocardiography	Transthoracic echocardiography
Anesthesiologist attending	No anesthesiologist attending
Surgical cutdown approach	Percutaneous approach
Ballon predilation	No ballon predilation
Pulmonary artery catheter	No pulmonary artery catheter
Urinary catheter	No urinary catheter
Post procedure	
Intensive care unit	Telemetry floor
Temporary PM	Early removal of temporary PM if possible
Standard LOS after TAVR	Short LOS (within 3 days) after TAVR

Standard

Simplified

Figure 3. Components related to optimization pre-, intra-, and post-procedurally in transcatheter aortic valve replacement (TAVR). CT: computed tomography; PM: pacemaker; LOS: length of hospital stay.

(TTE) after its conclusion to assess hemodynamic status, valve positioning and paravalvular leak (PVL).⁹⁻¹¹ Other clinical components may include no pulmonary artery or urinary catheter placement, precocious mobility and early discharge, 1 to 3 days following the procedure, ideally on the next day.¹¹

There must be a concerted team effort to simplify care and reduce invasiveness in every step of the process. This includes detailed pre-procedural planning, multidisciplinary team training, intra-procedural focus and post-procedural care, never compromising patient safety and outcomes. TAVR components optimization algorithm shown in figure 4.

MINIMALIST TRANSCATHETER AORTIC VALVE REPLACEMENT: POTENTIAL RISKS AND BENEFITS

Minimalist TAVR provides benefits to both patients and hospitals, since this approach has demonstrated to minimize resource utilization and mitigate the high costs associated with TAVR. Multicenter trials demonstrate that minimalist approach had similar results to standard TAVR in terms of mortality and stroke. Shorter procedure time and hospital stays were seen in the minimalist group, demonstrating that it is as safe and as effective.^{5,10}

Regarding cost-effectiveness,³ TAVR has showed to lower hospitalization costs with the minimalist approach when compared to standard procedure (\$45,485.00±\$14,397.00 vs. \$55,377.00±\$22,587.00; $p<0.001$). This reduction correlates with shorter ICU and hospital LOS. Attizzani et al.⁴ also reported that minimalist approach saved \$16,000.00/case. Similarly, TAVR under LA/CS¹² or post-TAVR early discharge¹³ has been advantageous regarding fewer resource use as well as hospitalization costs. TAVR in the inoperable or high surgical risk patients also provides good cost-effectiveness with favorable outcomes compared with SAVR or medical management.¹⁴⁻¹⁶ The shorter LOS is an important factor to compensate the expensive costs of transcatheter valve systems; TAVR reduced LOS by an average of 4.4 to 6.2 days, as compared to SAVR. Reduction in LOS may be even more meaningful regarding cost-effectiveness when TAVR is performed in lower surgical risks patients, since the survival and quality-of-life benefits of TAVR compared with SAVR may be reduced in high surgical risk patients. Reductions in LOS is also reported regarding LA/CS TAVR.⁹

The minimalist approach can also reduce intra-procedural burden in elderly patients with multiple comorbidities, then facilitating earlier recovery and mitigating functional decline with a better patient comfort.¹⁷ LA/CS was shown to achieve greater improvement of patient's quality of life at 30 days post-TAVR, as assessed by Kansas City Cardiomyopathy Questionnaire compared with general anesthesia.¹² Additionally, for elderly patients, shorter LOS is beneficial, considering the potential reduction

Figure 4. Suggested algorithm for optimization in transfemoral transcatheter aortic valve replacement (TAVR). GA: general anesthesia; NYHA: New York Heart Association; MI: myocardial infarction; PPM: permanent pacemaker.

in known negative outcomes of longer hospitalization, including reduced functional status, infection, or delirium.¹⁸ There is also lower 1-year mortality rates among patients with severe chronic obstructive pulmonary disease undergoing minimalist approach when compared to the standard procedure.¹⁷

Even though, some arguments have been raised about the safety of minimalist TAVR regarding the increased trend of this approach.¹⁹ TAVR is still associated with major complications that may lead to severe complications, such as cardiac tamponade or ventricular valve embolization, although this is getting less frequent. Complications requiring immediate surgical interventions and LA/CS conversion to general anesthesia are not very frequent. Performing TAVR at the cath lab may be disadvantageous from this point-of-view, but there is still not enough evidence to completely support the safety of this approach. Shorter LOS may not be enough for the detecting conduction disturbances, which require permanent pacemaker. Strengths and weaknesses of minimalist TAVR are summarized in table 1.

Table 1. Comparison between standard and minimalist transcatheter aortic valve replacement approaches

	Favors minimalist approach	Favors standard approach
Invasiveness	x	
Learning curve		x
Patient recovery, experience	x	
Simplicity of the procedure	x	
Approach of complications		x
Paravalvular leak assessment		x
Early discharge	x	
Hospital costs, resource use	x	
Overall safety	Unknown	Unknown

Therefore, it is necessary to customize each step of the procedure, by simplifying or reducing invasiveness based on patient-specific characteristics, center's experience, and multidisciplinary involvement. Interventionists must be comfortable regarding cardiac computed tomography (CT) to be matched with clinical information for predicting possible procedure complications.

CLINICAL STUDIES

There is no standardized strategy for minimalist TAVR, so there is few data available regarding general outcomes. Nonetheless, multiple studies have investigated each component related to TAVR optimization.

Local anesthesia/conscious sedation

After European and US centers, the safety and feasibility of TAVR with LA/CS compared to general anesthesia has been widely investigated in many clinical studies.^{4,20,21} Although the strategy varies among studies,^{21,22} the most common approach consists of infiltration of lidocaine at the access site, and administration of remifentanyl or fentanyl associated with propofol and/or midazolam. Transfemoral approach is the most commonly used and preferred access site. Trans-subclavian or trans-carotid TAVR has been performed under LA/CS in only limited cohorts.^{20,23} Many studies have confirmed similar 30-day mortality rates between LA/CS and general anesthesia,^{3,4,20,24} with even better 30-day outcome of LA/CS shown by recent large meta-analysis (mortality, relative risk – RR: 0.73; 95%CI 0.57-0.93; $p=0.01$),⁵ including 26 studies and 10,572 patients. Another meta-analysis published in the same year, with 19 studies, showed no differences between the two anesthetic techniques (RR: 0.91; 95%CI 0.70-1.18; $p=0.48$).²⁵ One-year or long-term survival, as well as procedure-related complications, such as stroke, myocardial infarction, acute kidney injury, vascular and bleeding complications also did not differ between LA/CS and general anesthesia in several studies.^{21,26}

LA/CS were associated with lower rates of systemic hypertension and subsequent intra and post-procedural inotropic support, and potentially lower pulmonary complications rate, like the incidence of respiratory failure and pneumonia associated with mechanical ventilation.^{22,23} As a result, early recovery after the procedure can be achieved, leading to a shorter length of post-procedural ICU stay and LOS,^{12, 20,22,25,27} e.g. mean 1.5-2.1 days shorter in LOS under LA/CS than under general anesthesia.^{5,25} However, emergent conversion from LA/CS to general anesthesia is not rare, showing a wide range of incidence rates between 2.9% and 12% in large clinical studies.²² The predominant reasons for the conversion are patient uncooperativeness or discomfort, as well as procedural complications, such as vascular complications, hemodynamic compromise, and cardiac tamponade. This emphasizes the importance of preparedness for swift conversion to general anesthesia, with the capacity of the emergent management of catastrophic complications.

The largest and most recent report²⁸ from the STS/ACC TVT registry with 10,997 patients undergoing elective transfemoral TAVR, compared LA/CS vs. general anesthesia and showed that, despite the slightly lower procedural success in LA/CS (97.9% vs. 98.6%; $p<0.001$), they reduced rates of 30-day mortality (2.3% vs. 4.0%; $p<0.001$) and a composite of 30-day mortality or stroke (4.8% vs. 6.4%; $p<0.001$). TAVR under LA/CS also achieved a lower rate of intra-procedural inotrope requirement and shorter length of ICU and hospital stay (6.0 vs. 6.5 days; $p<0.001$), after adjustment using propensity analyses. Crossover rate from

CS to general anesthesia was 5.9%, which was consistent with previous reports.²⁸

According to these prior reports,^{12,20,22,25,27} transfemoral TAVR under LA/CS seems to be feasible and safe with the merit of shorter LOS. However, majority of these studies are observational, and randomized, controlled trials are scarce,²⁹ a potential caveat of which is patient selection bias, e.g. some patients may have received general anesthesia due to heart failure symptoms precluding flat positioning during the procedure under LA/CS. Furthermore, generally, proportions of LA/CS increase with an institution's growing experience of TAVR. In other words, at the initial phase of the learning curve, general anesthesia is more commonly used, and structural interventionists gradually convert to LA/CS, which contributes to the performance bias leading to favorable outcomes in LA/CS.

Limited clinical studies have reported results on TAVR without intra-procedural anesthesiologist attendance. A comparison between procedures with vs. without anesthesiologist attendance in patients undergoing transfemoral TAVR under LA/CS showed comparable procedure-related complication rates and 30-day mortality rates were observed between the groups.²²

The 3MTAVR (Multidisciplinary, Multimodality, But Minimalist Approach to Transfemoral Transcatheter Aortic Valve Replacement) study showed considerable heterogeneity in the degree of procedural sedation, however the level of anesthesia did not impact procedural variables, length of stay, or cardiac readmission rates. It concluded that LA only or procedural sedation are both reasonable anesthetic strategies when utilizing the Vancouver Transcatheter Aortic Valve Replacement Clinical Pathway.²⁷

The SOLVE-TAVI³⁰ (SecOnd-generation seLf-expandable Versus Balloon-expandable Valves and gEneral Versus Local Anesthesia in TAVI) trial randomized 447 patients undergoing TAVR to either the procedure under LA/CS or general anesthesia. In patients at high risk for surgery who undergo TAVR, self-expanding and balloon expandable devices are associated with similar safety at 30 days, with no differences between procedures done under local or general anesthesia. LA with CS was equivalent to general anesthesia with respect to the composite of all-cause mortality, stroke, myocardial infarction, infection requiring antibiotic treatment, and acute kidney injury (25.5% vs. 27.0%; $p=0.02$ for equivalence), as shown in figure 5. The composite outcome was driven by a high but similar rate of infection in both arms (21% for both; $p=0.005$ for equivalence). General anesthesia was associated with a higher rate of catecholamine use but does not affect procedure times, valve related outcome, or clinical outcome. In conclusion, results from large, long-term randomized trials are still needed to fully elucidate the safety, efficacy and indication of LA/CS in TAVR.

Figure 5. SOLVE-TAVI Trial (SecOnd-generation seLf-expandable Versus Balloon-expandable Valves and gEneral Versus Local Anesthesia in TAVI): combined primary outcome of all-cause mortality, stroke, myocardial infarction, infection requiring antibiotics, and acute kidney injury at 30 days among patients receiving general anesthesia and conscious sedation.³⁰

Transthoracic echocardiography guidance

Intra-procedural assessment of TAVR utilizes TEE for: device size selection by the measurement of aortic valve anatomy, including annular dimensions; evaluation of complications, such as cardiac tamponade, mitral regurgitation, or left ventricular dysfunction; evaluation of performance in implanted TAVR valves, including location, transvalvular gradient or PVL.³⁰⁻³²

Due to the increased rate of TAVR under LA/CS, TTE has been replacing TEE for intra-procedural guidance. As CT is currently the gold standard modality for pre-procedural planning of valve type and size selection, more attention is drawn to the capability and accuracy of PVL evaluation by TTE, driven by the robust association between PVL (including mild) and worse prognosis following TAVR, demonstrated by large clinical trials and meta-analysis.³⁰⁻³²

The TAVR outcomes utilizing intra-procedural TTE instead of TEE have been evaluated in studies that compared LA/CS vs. general anesthesia, yielding conflicting results. Some studies^{8,21} show TEE guidance as being more commonly used in general anesthesia than in LA/CS (76.3% vs. 16.9%; $p<0.001$), and LA/CS was associated with an increased incidence of post-procedural aortic regurgitation $\geq$ mild (15.0% for general anesthesia vs. 19.1% for LA/CS; $p=0.015$). After propensity score matching, with TEE use included in the adjustment model, the rate of aortic regurgitation became non-different (12.7% for general anesthesia vs. 16.2% for LA/CS; $p=0.19$). A Brazilian registry³³ demonstrated that TTE guidance was associated with increased hazard of mortality compared with TEE guidance (hazard ratio – HR: 1.75; 95%CI 1.10-2.78; $p=0.018$). These registries seem to support the use of TEE guidance during procedure, whereas reports from other registries^{10,20} and single-site studies,⁴ as well as meta-analysis from seven

studies⁵ have shown similar risk of PVL between the two anesthetic approaches. Notably, most of these studies consistently used TTE for LA/CS and TEE for general anesthesia, and showed similar short-term mortality rates between the two approaches.^{4,10} In another report investigating procedural TTE performance, intra-procedural TTE was able to properly obtain the information of procedural complications and PVL with sufficient image quality (fair or better in 89.6%), when performed by specialized echocardiographers.³⁴

With the current evidence, no consensus has been reached regarding TTE safety during a procedure. TTE image quality can be suboptimal, especially for obese patients, and those with lung disease or chest deformities. Therefore, patients with inappropriate imaging windows should be carefully evaluated for intra-procedural TTE. A multi-modality approach, such as pre-procedural CT, and intra-procedural angiographic and hemodynamic evaluation is recommended to optimize TTE utilization. Specifically, pre-procedural CT enables the prediction of possible intra-procedural complications (i.e. coronary obstruction, annulus rupture etc.) and provides information on calcium quantity and distribution in the aortic valve that have been associated with significant PVL after TAVR.³⁵

There is also data regarding the use of intracardiac echocardiography to guide various structural heart interventions, including TAVR. Intracardiac echocardiography has historically been used to guide a limited number of transcatheter cardiac interventions. However, the advances in structural heart disease interventions in the last decade led to its growing application as a potential alternative to TEE that mitigates the need for endotracheal intubation. Nonetheless, the scarcity of data, the imperfection of the current probes, and the limited experience among operators still prevents a wider adoption of this technology.³⁶

Percutaneous approach

As a consequence of a smaller delivery profile, percutaneous approach has now become the preferred option, as compared with surgical cutdown for transfemoral TAVR in many centers. For percutaneous approach, structural interventionists use pre-closure technique with two Perclose ProGlide or Prostar® XL devices Abbott Vascular, Santa Clara, CA, USA).³⁷ Percutaneous approach has shown similar in-hospital or 30-day mortality rates compared with surgical cutdown approach in several reports.³⁶⁻⁴¹ Vascular complications were also compared between the two approaches, demonstrating varying incidence rates across studies ranging from 2.4% to 27.1% for major vascular complications when the percutaneous approach is used.⁴⁰ The wide variation is due to discrepancy regarding definition of complications, the type and the generation of the transcatheter heart valve, and the study periods. Most studies have shown similar major vascular complication rates,⁴¹ whereas some reports have shown higher minor vascular

complications rates with the percutaneous approach.⁴⁰ Percutaneous approach was associated with more pronounced localized stenosis, dissection, or pseudoaneurysm at the access site.³⁹ Of note, 4% to 14%^{38,42} of patients experienced percutaneous closure device failure contributing to approximately half of vascular complications.

There is a real requirement to overcome the learning curve for better outcomes with percutaneous approach, shown by rapid decrease of vascular complications without improvement in device technology.⁴² Regarding bleeding complications,^{38,39} a major study demonstrated a significantly lower incidence of major bleeding complications with a percutaneous approach at 30 days (RR: 0.43; 95%CI 0.20-0.93; $p=0.03$).⁴⁰ Additionally, percutaneous approach was associated with a shorter LOS compared with surgical cutdown approach in several studies,^{36,37} and a meta-analysis including 9 studies and 4,280 patients.⁴³ However, LA/CS tends to be more often used in percutaneous approach, which may have affected the LOS. Surgical approach enables better control of the access site with direct visualization, but has more complications, such as pain, wound infections and lymphatic complications.³⁹

In summary, percutaneous approach in transfemoral TAVR is a feasible and a safe alternative to surgical cutdown approach, especially in cases with LA/CS procedure. A higher success rate will be expected by operator experience together with knowledge of favorable anatomical characteristics, including severity of calcification and tortuosity, vessel size and depth, and femoral bifurcation position.⁴²

Early discharge

Shorter post-TAVR LOS can be effortlessly achieved as a consequence of fewer complications and the less invasive aspect of TAVR; however, there is an intention to shorten LOS in many centers for the reduction of resource utilization, costs, and the improvement of patient experience. Many reports have shown that early discharge (within 2 or 3 days) after transfemoral TAVR does not compromise safety, i.e. a similar 30-day mortality or rehospitalization rate compared with late discharge (>2 or 3 days),^{11,44,45} while carrying the advantage of reduced hospitalization costs.^{13,14} Recently, the safety of next day discharge was directly evaluated in comparison with non-next day discharge,¹⁴ demonstrating comparable 30-day mortality and rehospitalization rates between the two groups. In the largest study,⁴⁶ next day discharge ($n=132$) was not associated with an increased hazard of the 30-day composite of mortality or rehospitalization compared with non-next day discharge ($n=117$; HR: 0.62; 95%CI: 0.20-1.91; $p=0.41$), and at one year, next day discharge even showed better composite outcome (HR: 0.47; 95%CI: 0.27-0.81; $p=0.006$).

However, these studies are limited by their retrospective, non-randomized design, and early discharge patients had fewer risk factors associated with adverse outcomes,

which consequently indicates the existence of selection bias affecting outcomes of these studies. New York Heart Association (NYHA) class IV,⁴⁴ baseline renal dysfunction,^{13,46} atrial fibrillation,⁴⁶ previous balloon aortic valvuloplasty, bleeding or vascular complications,^{13,44,45} blood transfusion,^{13,45} peri-procedural stroke,¹³ mechanical circulatory support devices,¹³ new permanent pacemaker implantation,^{13,45} and acute kidney injury were negatively associated with the early discharge, whereas male sex, younger age, pre-TAVR permanent pacemaker, and TAVR under LA/CS were associated with a higher probability of early discharge.^{13,44-46}

Early discharge seems to be safely performed in selected patients who have favorable baseline characteristics (younger age, stable symptoms, preserved renal function, etc.) and procedural outcomes (no bleeding or vascular complications, no severe conduction disturbances, etc.). However, there is no clear definition of the ideal candidate for early discharge after TAVR. The 3MTAVR study showed no impact of LA/CS in procedural variables, length of stay, or cardiac readmission rates. It concluded that LA only or procedural sedation are both reasonable anesthetic strategies when utilizing the Vancouver Transcatheter Aortic Valve Replacement Clinical Pathway.²⁷

Predilation and postdilation

Predilation has been a routine step before transcatheter valve deployment to facilitate the delivery and expansion of the device across the native valve with stable hemodynamics. Several studies^{47,48} have evaluated the outcomes of direct implantation of transcatheter valve, i.e. no predilation prior to the implantation. A large registry including 5,887 patients⁴⁷ demonstrated similar adverse event rates, such as 30-day mortality, stroke, and moderate/severe regurgitation, among patients with and without predilation. These results are consistently in line with previous reports including recent meta-analyses,⁴⁹ in addition to longer-term safety data of direct implantation from observational studies.⁴⁸ Reduced incidence of permanent pacemaker implantation was also suggested in direct implantation,⁵⁰ partially supported by the Brazilian registry,⁴⁸ which demonstrated a lower rate of new-onset persistent left bundle branch block in patients with direct implantation. Direct implantation can lead to reduction of procedure or fluoroscopy time and contrast volume by skipping one procedural step in the treatment flow.⁴⁹ However, direct implantation seems to require more frequent postdilation⁴⁹ that may theoretically affect prosthesis durability, and is reportedly associated with an increased risk of cerebrovascular events, also detected by diffusion-weighted magnetic resonance imaging, when compared with implantation with predilation. Although not clearly explained in the report, postdilation might be one of the reasons of this finding. Thus, future studies are warranted to establish the safety of direct implantation

in TAVR, together with the results from ongoing randomized trials.

In the absence of clear evidence thus far, balloon predilation before implantation should be determined by the experience of the operator, as well as clinical (e.g. chronic kidney disease or left ventricular function) and anatomical (i.e. aortic valve calcification severity and distribution, bicuspid valve, or aortic valve area; these may be associated with postdilation) characteristics utilizing multimodality assessment, such as CT and echocardiography.

Surgical backup

There were reported outcomes of TAVR in centers without an on-site cardiac surgery backup,⁵¹ suggesting that in-hospital complications, such as neurologic events, myocardial infarction, vascular complications, and mortality did not differ among patients at centers with and without on-site cardiac surgeons. Even among patients with intra-procedural complications and likely to benefit from emergent open surgery (e.g. annular rupture, aortic dissection or pericardial tamponade), in-hospital mortality was similar between the two groups (62.5% for on-site surgery vs. 50% for non on-site surgery; $p=0.7$).⁵¹

Another studies compared TAVR performed in a catheterization laboratory with those in a hybrid operating room directly, and concluded that midterm mortality after TAVR was similar between the cath lab and the hybrid operating room. These findings support the performance of TAVR in either location, which has important implications on health care organization and costs.^{3,4}

Contrast injection

Several studies evaluated the strategy aiming to reduce contrast volume administered not only intra-procedurally, but also for pre-procedural planning such as CT and coronary angiography. Significant reduction of intra-procedural contrast volume was achieved by utilizing co-registration of pre-procedural CT angiography with real-time X-ray for the fusion image guidance, or synchronized diastolic-injection method of aortography for the aortic regurgitation assessment.⁵² In pre-procedural CT planning, dedicated contrast injection or acquisition protocol, and new technologies such as the third-generation dual-source CT have reduced contrast volume while preserving diagnostic image quality.⁵²

Cardiac monitoring

Until now, evidence-based strategy is lacking for the post-TAVR electrocardiogram monitoring duration. Procedure-related high-degree atrioventricular block (HAVB) occurs mainly in the peri-procedural period of ≤ 24 hours following TAVR; however, 2% to 7% of patients reportedly experience delayed HAVB ≥ 48 hours after the procedure, which supports current recommendation of continuous

rhythm monitoring up to 72 hours.⁵³ There is also data showing that no patients with normal post-TAVR electrocardiogram had delayed HAVB up to 8 days after TAVR, indicating possibility of omitting a temporary pacemaker wire or continuous rhythm monitoring following TAVR in these selected patients.⁵⁴ Post-TAVR care without ICU may be optional in selected low-risk patients.

Debriefing

Periodically, it is important to get all the multidisciplinary team together to discuss past procedures, with success and complications, and what could have been done in a different way for better outcomes and better patient experience. With this approach, the whole team can really understand what is going on, the new ideas for upcoming patients, and everybody felt important and understand its role in the TAVR procedure.

So debriefing is an important step in the hospital system, valuing the cath lab staff, allowing them to get their questions answered and permitting that all professionals give their opinion and work together to improve outcomes.

PERSPECTIVES

Transcatheter valve system evolution, together with the operators' experience including pre-procedural planning, has enabled substantially reduced TAVR-related complications. Future technologies will further improve it to be easier procedures with higher success and reduced complications. Therefore, it is a natural transition that more centers are currently moving toward simplifying and minimizing the procedure to reduce patient's burden and resource use, and mitigate the high costs associated with TAVR. However, robust evidence for these approaches to assure patient safety is still needed. New studies are currently being awaited to fully elucidate the feasibility, safety, and ideal candidates for individualized approach. Therefore, these studies will provide clear strategy of optimized approach for all the patients undergoing TAVR procedures.

CONCLUSION

Minimalist approach involves different efforts to simplify the transcatheter aortic valve replacement procedure and patient care, therefore reducing invasiveness at every step of treatment flow, always prioritizing safety and better outcomes. Minimalist approach has developed with new data and better technologies; however under the current lack of robust evidence, it should be performed carefully on an individualized basis by institutional multidisciplinary team discussion and expertise structural interventionists.

FUNDING

There is none.

CONFLICT OF INTEREST

Dr. Attizzani is on the advisory board, and serves as a consultant and a proctor for Edwards Lifesciences and Medtronic, and is a consultant for Abbott Vascular. The remainder of the authors have no disclosures.

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