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REVIEW ARTICLE

Cardio-anesthesiology considerations for the trans-catheter aortic valve implantation (TAVI) procedure☆,☆☆

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Abstract Transcatheter aortic valve implantation (TAVI) has become the mainstay for high-risk or inoperable patients with symptomatic aortic valve stenosis, and research regarding the use of transcatheter valves in intermediate or low-risk patients is currently ongoing. The aim of this article is to provide comprehensive insight into the anesthetic management of patients undergoing TAVI and to highlight possible gaps in the current knowledge. One important procedural characteristic that is imperative to consider is the type of anesthesia being used and its possible complications. Increasingly, experienced centers have changed from general anesthesia with endotracheal intubation to local anesthesia with sedation, especially when the transfemoral access route is used for TAVI. There is still debate regarding what type of anesthesia should be used in the procedure, and the lack of randomized data makes it even more challenging for the operators.

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☆☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented as well as its discussed interpretation.

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1. Introduction

Degenerative aortic valve stenosis (AS) is burdensome for Western societies given the continuously increasing population that reaches 70, 80 or even 90 years of age. For many decades, surgical aortic valve replacement (SAVR) has been, and still is, the gold standard for effectively treating patients with AS to ameliorate symptoms and extend life. Nonetheless, approximately 30% of patients are not offered SAVR due to increased surgical risk or anatomical variations.[1–4] Transcatheter aortic valve implantation (TAVI) has emerged in the last decade as an alternative to SAVR and has become the mainstay of treatment for inoperable or high-surgical-risk patients with severe AS.[5,6] As the technology and operator experience advances, even patients with a moderate surgical risk tend to undergo TAVI. Proper multidisciplinary pre- and peri-procedural patient evaluation and management is mandatory for achieving the best outcomes, especially in patients who could otherwise be effectively treated surgically. Cardiac anesthesiologists play an important role in the decision making[5] and peri-TAVI care of these patients in the catheterization laboratory. The aim of this review is to briefly discuss the TAVI procedure from an anesthetist's point of view, focusing on anesthetic management during TAVI, and to present the current data regarding the use of general anesthesia (GA) versus local anesthesia (LA) with conscious sedation, while highlighting the gaps in knowledge.

2. Pre-procedural evaluation

A Heart Team comprised of cardiologists, interventional cardiologists, heart surgeons and imaging specialists assesses the suitability of all patients with aortic valve stenosis for SAVR or TAVI. All patients are evaluated in a detailed fashion and undergo several examinations, including (but not limited to) an echocardiogram, coronary angiogram and computed tomography scan. The decision to perform TAVI is based on the severity of symptoms, evaluation of risks and consideration of special (relative) contraindications to open heart surgery, such as previous heart surgery, 'hostile' chest, and severe respiratory failure. Surgical risk scores, such as the EuroSCORE (1 and 2)[7,8] and STS score[9] are also considered, but they have many problems.[10] Functional capability (for example, determined with the Karnofsky index) can also provide valuable information for decision-making.[11] During the multidisciplinary meeting where the access route and valve type are considered, the input from the anesthesiologist regarding the risk of the procedure and the type of anesthesia that will be used is crucial.

The day before the procedure, the anesthesiologist has a separate, detailed conversation with the patient, explaining all anesthesia-related manipulations and possible complications. Afterwards, the Anesthesia Informed Consent form is signed. Pre-medication consists of omeprazole 40 mg and bromazepam, 1.5 mg per os the night before, and the patient fasts for 8 h regardless of the anesthesia technique that will be employed.

3. Available TAVI prostheses

TAVI is performed in the cardiac catheterization laboratory (i.e., cath lab) or in a hybrid operating room under strict sterile conditions. Cardiac surgical backup in the hospital, but not necessarily in the room, is mandatory.[5,12] Although the transfemoral route is considered to be the default and best option for the procedure,[13] other routes are available, including the subclavian,[14] trans-aortic[15] and trans-apical approaches.[16] In a minority of patients, the arterial vasculature is not accessible, and the trans-caval route is another option in these cases.[17,18]

The availability of transcatheter valves has radically increased in the past few years, and there is a vast selection of available sizes that can be selected according to patient's anatomical characteristics as well as the operator and center preference.[19,20] The two most widely used valves are the Edwards family (Edwards Lifesciences, Irvine, USA) and Medtronic family (Medtronic, Minnesota, USA) bioprosthetic valves. The Edwards SAPIEN XT and SAPIEN 3 prostheses are balloon-expandable and require aortic valve balloon predilatation and rapid ventricular pacing (RVP) during deployment. The Medtronic CoreValve and Evolut R prostheses are self-expandable, partially or wholly recapturable and repositionable.[21] The latter characteristic has reduced the incidence of implantation of a second valve as a bail-out maneuver.[22]

The Medtronic valves can also be safely implanted without balloon predilatation.[23,24] Both valves can be implanted with the trans-femoral approach, but the Edwards valves can also be implanted trans-apically, whereas the Medtronic valves can be implanted by the subclavian and direct aortic routes.

Large randomized trials, including the PARTNER[25–27] and CoreValve US[28–30] trials, have provided useful insight regarding the mortality and complication rates after TAVI with the two most widely used valves.

In recent years, even more TAVI devices have emerged, including the Lotus valve (Boston Scientific Inc, USA),[31] with promising results for various procedural outcomes.

4. Anesthetic considerations

Our center (1st University Department of Cardiology, Hippokration Hospital, Athens) was one of the very first TAVI centers in Greece and has performed more than 400 implantations since the beginning of 2009. At the start of the TAVI program, all transfemoral procedures were performed under GA. Subsequently, with gained experience and use of newer devices, we have opted to perform more than 90% of the implantations with only LA and mild sedation. When surgical access is necessary, for example, with use of the trans-subclavian route, GA is obviously mandatory.

All patients receive antibiotic prophylaxis (piperacillin-tazobactam and/or vancomycin, dosage according to renal function) 1 h before the procedure, and are on dual antiplatelet treatment (100 mg acetylsalicylic acid and 75 mg clopidogrel, daily).

4.1. General anesthesia (GA)

Invasive anesthesia monitoring consists of a three-lumen central line (standard jugular vein access) for the administration of

fluids, drugs and blood, if needed, as well as a radial arterial line for invasive blood pressure monitoring and/or blood gas control. A 5—6 French sheath is also inserted in the jugular vein, which can be used by the cardiologist to fluoroscopically position a temporary pacemaker wire in the right ventricle apex. All lines are inserted once the patient lies on the cath lab table. Basic non-invasive monitoring consists of pulse oximetry, capnography, continuous multiple channel ECG and hourly urine output through a bladder catheter.

Since the anesthetist controls the cardiac pacing, we will briefly provide details. During balloon inflation in cases of aortic valvuloplasty, a brief run of rapid ventricular pacing at 170—200 beats per minute is necessary to drop the blood pressure below 50 mmHg systolic and facilitate immobility of the expanding balloon. The same maneuver is performed during expansion of balloon-expandable prostheses, i.e., those of the Edwards family. After each run, the pacemaker is reverted to 50 beats per minute back-up pacing; in rare occasions (2—5%) where the valvuloplasty results in a severe aortic regurgitation, fast pacing of approximately 100—120 bpm is used to stabilize the patient during the few minutes that are necessary to deploy the prosthesis.

The choice of anesthetic agents varies. Induction is usually performed with the use of midazolam, ketamine, fentanyl and etomidate, or propofol, which are titrated accordingly; all but the last are considered cardiovascular stable drugs that do not cause a clinically significant drop in the blood pressure and/or pulse rate. However, some patients may require inotropic and/or vasopressor support before the induction of anesthesia; therefore, infusion drips of noradrenaline (and less often adrenaline or phenylephrine) are prepared and ready to be administered. Rocuronium is used to facilitate endotracheal intubation. Generally, however, the manner of drug administration (dosage, etc.), rather than which specific drug is used, is more important for achieving hemodynamic stability during anesthesia induction and endotracheal intubation. Hemodynamic collapse in an elderly, frail patient with significant aortic valve stenosis provides very little time and few options before full-blown cardiac arrest.

The maintenance of anesthesia is achieved with a target-controlled infusion of propofol. An added benefit of GA and endotracheal intubation is the option to perform trans-esophageal echocardiography (TEE) during the TAVI procedure, either routinely or on an as-needed basis. The latter is the protocol in our center.

4.2. Local anesthesia (LA) and sedation

All invasive lines are inserted in the same way as that described for the GA approach. Oxygen is administered with a partial rebreathing face-mask, and end-tidal carbon dioxide is measured (capnography). LA is performed by the interventional cardiologist per standard techniques (2% lidocaine injection bilaterally in the two groin areas). Sedation is performed by the anesthesiologist and consists of target-controlled administration of midazolam, propofol, fentanyl or remifentanil alone or in various dosage combinations. The dosage and rate of administration are individualized and titrated to the desired effect, according to clinically relevant factors, including concomitant medications, age, ASA physical classification, and level of patient debilitation. In all cases, access to the patient is such that the airway can be secured easily, if needed.

5. Choice of anesthesia

The most important anesthetic consideration in TAVI is the type of anesthesia that will be given to the patient. Trends vary within hospitals and countries, and numerous factors need to be considered before reaching a decision, including patient-related and operational factors as well as logistics.[32] In the early years of TAVI, GA was the default option[33—36]; as previously mentioned, this was also the standard in our hospital.

GA enables the use of either two- or three-dimensional TEE, which can theoretically assist in optimal valve deployment and prompt recognition of complications, such as tamponade, interference with the mitral valve or paravalvular leakage. Although the use of TEE with GA and sedation has been described,[37] most centers (including ours) with adequate experience do not perform TEE; instead, they rely on transthoracic echocardiogram (TTE), angiography and hemodynamic measurements. Multi-slice computed tomography is routinely utilized for valve size selection, whereas the probe from the TEE interferes with fluoroscopic imaging during valve deployment; however, a pigtail catheter in the non-coronary cusp is sufficient for guiding the procedure.[38]

Operators use GA in cases where the trans-femoral route is not possible and surgery is involved, including the subclavian,[14] trans-aortic[15] and trans-apical[16] routes. Although subclavian cases have been reported with LA, most centers still prefer GA for these TAVI cases.[39—41]

Another theoretical argument in favor of GA is the total immobility of the patient, which could decrease complications. However, available evidence does not support this concern, indicating that the type of anesthesia is irrelevant to the occurrence of vascular complications.[34,35,41—44]

The type of the anesthetic management has increasingly switched from GA to LA, especially in European centers.[45] Sedation shortens procedural time, time to ambulation and hospital stay duration.[34] In addition, the use of vasopressors in sedation is not as frequent as in GA procedures, which can be attributed to the vasodilating effects of the anesthetic agents.[46,47] Furthermore, emergency intubation and switching to GA can be achieved in the cath lab to surgically handle cardiac or vascular complications should they arise during TAVI.[48,49]

LA has the unique benefit of real-time evaluation of the patient's mental status and cognitive function. Favorable outcomes with a shorter implant procedure time, reduced stay in high dependency areas, and shorter time to hospital discharge have been reported in a series of patients who underwent TAVI under sedation with remifentanil.[34]

6. Post-procedural care

After the procedure, patients are transferred to the coronary care unit (CCU) for observation; GA patients are extubated in the cath lab and are then transferred to the CCU. For transfemoral TAVI, simple analgesics or low dose

opioids are usually given with good effect; intensive analgesia is only required when a surgical incision has been made. After the procedure, improvements in systolic and diastolic functions are often observed due to afterload lowering, thus allowing for reduction or even discontinuation of inotropic drugs.[50] Sometimes high levels of crystalloids (i.e., normal saline, 0.9%) are needed during the initial post-procedural hours to support a chronically hypertrophied small left ventricle.

In uncomplicated cases of the "modern" TAVI era that use 14 French devices, the patient is mobilized after 24 h. In cases where there is no need for ECG monitoring, for example, if a permanent pacemaker was in place prior to the TAVI procedure, the patient is discharged after 2 to 3 days. In experienced centers, early discharge after the procedure is becoming more prevalent; same-day discharge has been described in a patient who underwent transfemoral TAVI with LA.[51] However, it must be emphasized that same-day discharge is not yet safe or common.

7. Complications

From the available data, there is no difference between GA and LA in terms of mortality.[45,52] European data have shown that patients with high EuroSCORE levels undergoing TAVI with GA have a higher mortality, highlighting the need for better evaluation and the possible use of LA in these patients.[38]

It is also an important to monitor renal function after the procedure. Impaired renal function before TAVI is considered a prognostic factor for mortality after the procedure.[53] Many factors can influence renal function during the procedure, including the amount and type of contrast, the incidence of debris embolization during valvuloplasty and/or valve deployment and the occurrence of hypotensive episodes triggered by anesthetic agents.[38] Recent reports have shown higher rates of acute kidney injury in the GA population, which are attributed to episodes of hypotension.[52,54,55] However, there remains a lack of robust data regarding any possible effect the type of anesthesia might have on kidney function.

Pacemaker implantation after TAVI is another important consideration, and rates vary depending on the valve type that is being used, the depth of implantation and the existence of previous conduction defects.[56–59] While multiple TAVI registries have not found any difference between the anesthesia type and pacemaker implantation rates,[32,45] one single registry did.[52] Nonetheless, it is inconclusive whether the type of anesthesia impacts the incidence of pacemaker implantation.

One of the most feared complications during TAVI is the possibility of a stroke. It has been reported that patients are more worried about stroke than death.[50] Both PARTNER trial cohorts, comparing the Edwards TAVI with either SAVR or medical therapy, showed an increase in the rates of stroke in the TAVI population during the first year.[25,27] Longer follow-up data from this trial have shown that at 5 years, the rates of stroke in both the TAVI and SAVR populations are equal.[60] Data from available trials and studies have not shown any association between the types of anesthesia and the rates of stroke after TAVI.[45,52,61] In theory, because LA has the benefit of real-time evaluation of the patient's mental status and cognitive function, a stroke can be identified, and therefore treated, more easily and quickly.

From a financial point of view, frequent reports suggest that LA with sedation in TAVI is more cost-effective compared to GA since it requires less hospital staff and a shorter length of hospital stay; however, reliable data are still needed.[54,62,63]

8. Clinical implications

The rates of TAVI procedures have increased in the past decade, enabling more patients with symptomatic aortic stenosis to be successfully treated. Interestingly, this increase in the use of TAVI has not decreased the number of SAVR procedures performed, indicating the importance of TAVI in meeting a previously unmet need for these patients.[64] However, it is still unknown whether this might change in the future, as the number of TAVI procedures could eventually surpass SAVR procedures. The crucial determining factor for this shift will be newer indications for TAVI that we presume are forthcoming, including use in intermediate- and lower-risk populations and in patients with bicuspid aortic valves or failing bioprosthetic valves.[65]

The type of anesthesia during TAVI is an ongoing matter for debate. There is a wealth of data that can be found in various registries and studies, but no randomized controlled trials. There has been a steady change in practice with the ongoing trend to use local anesthesia with mild sedation more; this approach has many potential benefits, including shorter operative time, direct communication with the patient, potentially lower complication rates and reduced need for intra-procedural vasopressor support. However, there remains a need for GA, especially when unconventional access routes are indicated. The importance of the presence of a dedicated and experienced cardiac-anesthetist at the patient's head at all times during the TAVI procedure cannot be overemphasized. All described anesthesia steps should be meticulously followed to assist the interventional cardiologists in the procedure and to minimize complications and immediately help resolve them should they occur.

9. Conclusion

Transcatheter aortic valve implantation is a promising treatment strategy for high-risk surgical patients, and trials investigating its effectiveness in intermediate- and lower-risk patients are underway. Data are inconsistent regarding the superiority of using local anesthesia with conscious sedation alone versus general anesthesia as the anesthesia management of choice for elderly frail patients. Ultimately and at present, the choice of anesthesia is based on the personal experience and preference of the Heart Team involved in the TAVI procedure, which will dictate the best possible management plan for each patient.

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