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ORIGINAL ARTICLE

Percutaneous aortic valve implantation: the anesthesiologist perspective

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ABSTRACT

Percutaneous aortic valve implantation is an emergent technique alternative to surgical aortic valve replacement in high risk patients with aortic stenosis. Percutaneous aortic valve implantation techniques are undergoing rapid development and currently represent a dynamic field of research. Perioperative optimal strategies keep on evolving too. At a review of the literature, only three previous papers on Pubmed focused specifically on anesthesiological challenges of percutaneous aortic valve implantation. In one of them our first 6 months experience was reported. In this new paper we describe the anesthesiological management of percutaneous aortic valve implantation at our Centre, reporting the results of our implantation program from November 2007 to February 2009.

Keywords: *percutaneous aortic valve implantation, aortic stenosis, general anesthesia, local anesthesia.*

INTRODUCTION

Rapid progress in interventional cardiology has recently seen the rate of percutaneous coronary intervention overtake that of coronary artery bypass surgery. Now attention is directed towards the treatment of valvular heart diseases, with exciting developments in balloon and stent technology having the potential to transform the management of many common heart conditions, such as aortic stenosis (1). Aortic stenosis is the most common form of valvular heart disease in adults, affecting thousands of patients every year and causing significant morbidity and mortality in case of advanced disease. Surgical aortic valve replacement is the treatment of choice for a vast majority of patients (2). However, in a subset of patients, mainly elderly patients with declining overall health status or severe comorbidities, aortic valve replacement is considered either too high risk or contraindicated (3).

The size of this cohort is expected to increase in the next several years, reflecting the aging population and the improving therapeutic options in patients with multiple and advanced medical conditions. Moreover, prognosis with medical management is poor (2), and effects of percutaneous balloon aortic valvuloplasty (BAV) are modest and short-lived (4, 5). Given the limited therapeutic options in these patients, there has been interest in the development of transcatheter aortic valve implantation (TAVI) techniques. The rationale is that of minimizing the overall surgical trauma by avoiding sternotomy,

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aortotomy, use of cardiopulmonary bypass (CPB), and by implanting the prosthesis on the beating heart, thereby avoiding cardiac arrest.

LITERATURE REVIEW

To the best of our knowledge, only three groups focused on the anesthesiological management of TAVI so far.

Ree et al. (6) described both the evolution and the main associated complications in the anesthetic management of the initial 40 patients undergoing percutaneous retrograde aortic valve replacement at St. Paul's Hospital (Vancouver, Canada). The first four patients received monitored anesthesia care, while the subsequent 36 underwent general anesthesia.

There were no anesthesia-related adverse events. The prosthetic valve was placed successfully in 33/40 patients (83 %). Median anesthetic time was 3.5 hours (range, 1.25-7.25 hours).

Thirty-two/40 patients required vasopressor support. The most common, serious procedural complications were myocardial ischemia and arrhythmia following rapid ventricular pacing, hemorrhage from vascular injury secondary to the placement and removal of the large-bore sheath in the ilio-femoral artery, aortic rupture, and prosthetic valve maldeployment; 30-day mortality was 13 % (n = 5/40).

Behan M et al. (7) described the experience of the Sussex Cardiac Centre (Brighton and Sussex University Hospital, Brighton, UK) performing TAVI procedures in 12 patients Three of them underwent the procedure under general anesthesia and nine under remifentanil-based sedation. There were no differences between the groups in terms of comorbidities and clinical characteristics. The procedure was visualized using fluoroscopic aortic calcification coupled with multiple small volume aortograms. One patient converted from sedation to general anesthesia. One patient in the general anesthesia group died from respiratory complications. They concluded that TAVI can, in the majority of cases, be performed under remifentanil-based sedation resulting in a shorter implant procedure time, reduced stay in high dependency areas, and shorter time to hospital discharge

We recently published our initial six months experience in anesthesiological management for TAVI (8). In our experience updated to February 2009, 50 patients (79 + 7.3 years, logistic EuroSCORE 25.4 + 15) underwent TAVI using a balloon expandable (34 patients) or a self-expandable (16 patients) prosthesis.

Valve deployment was visualized by high-resolution fluoroscopy and contrast angiography. Nineteen patients received general anesthesia, and 31 received local anesthesia plus sedation.

Two patients had to be converted from local anesthesia to general anesthesia (1 refractory ventricular fibrillation and one pt was resteless). Procedural complications included prosthesis embolization (1 patient), ascending aorta dissection (1 patient), arrhythmias following rapid ventricular pacing (5 patients) and vascular access site complications (8 patients). One valve-in-valve implantation because of severe aortic regurgitation after the first procedure was performed.

Five patients in the general anesthesia group were extubated in the theatre and mechanical ventilation time in intensive care unit (ICU) was 12 hours. Mean ICU stay in the general anesthesia group was 34 + 3 hours vs 15 + 3 hours in the local anesthesia group (p = .009). Postoperative complications included acute renal failure (7 patients), III° atrio-ventricular block (12 patients), sepsis (9 patients) and

stroke (1 patient). All 50 patients were alive 30 days after the procedure. At the 6 moths follow-up 4 out of 30 patients died for non-cardiac reasons.

PROCEDURES

Two technologies, the balloon-expandable Edwards/Sapien Bioprosthesis (Edwards Life-sciences Inc., Orange, CA), and the self-expandable CoreValve ReValving System (CRS TM, CoreValve Inc., CA, USA) have been used in the largest clinical series (9). These technologies present differences in design and implantation technique. Several other technologies are being developed and have entered or are expected to enter an active phase of clinical testing in the next future.

All current TAVI procedures start with conventional BAV to provide an enlarged passageway for the subsequent insertion of the prosthesis. Although initial procedures were performed using the so-called "antegrade" approach (10), via transfemoral vein access, this procedure has been complication-prone and has been largely abandoned. Most commonly, the preferred "retrograde" approach requires transfemoral artery access (percutaneously, surgically or hybrid) negotiation of femoral, iliac and aortic vasculature, retrograde crossing of the native aortic valve and valve deployment in the subannular region (9, 10). A vascular access via subclavian artery (11) and the hybrid "transapical" approach (12), through the left ventricular apex, provide an alternative route to retrograde transfemoral access in patients with diseased femoral, iliac and aortic anatomy. The positioning of the prosthesis is mostly aided by high-resolution fluoroscopy, contrast angiography and transesophageal echocardiography. After the final assessment of device position and function, the delivering system is removed and vascular access sites are closed either surgically or percutaneously. Iliac and femoral angiography is advocated to ensure the integrity of vessel repair and the absence of vascular complications such as perforation, dissection and occlusion. Surgical repair of these complications may be required; endovascular stenting can be beneficial in selected cases.

PATIENT SELECTION AND PREOPERATIVE EVALUATION

A number of predictive risk models have been employed to ascribe an objective quantitative risk profile for the purpose of patients selection for TAVI. The two risk models most commonly used are the Europen System for Cardiac Operative Risk Evaluation (EuroSCORE) (13) and the Society of Thoracic Surgeon (STS) database (14). Notably, these predictive tools for operative risk assessment are imprecise, especially at high levels of risk, not entirely consistent from model to model, and generally omit important risk factors, such as severe thoracic aorta calcification, previous chest wall radiation or liver cirrhosis (15-17).

Most appropriately, the best characterization of individual risk should be a combination of objective quantitative predictive models and subjective assessment by experienced surgeons, cardiologists and anesthesiologists.

The therapeutic option of TAVI has to be discussed extensively for the individual patient and approved on the basis of a consensus that conventional surgery is excessively high risk in terms of anticipated mortality and morbidity. The definition of the "inoperable" patient remains a pivotal consideration. Patients are excluded if a reasonable quality or duration

of life (> 1 year) are considered unlikely despite valve replacement because of comorbidities. A comprehensive evaluation of patients'overall medical condition and non-cardiac comorbidities is essential and follows the same algoritm as used in surgical patients. Besides comorbidities, older age arises special anesthesiological concerns. Some patients may have unrealistic expectations regarding the risk and degree of invasiveness of the procedure.
An honest and appropriate explanation of the anesthetic management of the procedure and the risks involved is an essential feature of the preoperative encounter.
A thoughtful management planning requires that the specialist opinion of the anesthesiologist, and not just that of cardiologists and cardiac surgeons, should always be sought early. Moreover, it is imperative for the "valve team" to plan preoperative strategies of treatment in case of procedural complications, determining the potential for surgical bailout in advance of the procedure.

MONITORING AND ANESTHESIOLOGICAL SETUP

The anesthesiologist has to take a participative role in developing monitoring and standards of care in the cath lab for this kind of procedures. It is important to note that physical environment of the cath lab is mostly designed to accommodate the needs of cardiologists, having an anesthesiologist taking an active role in patient care was not a primary concern when designing the cath lab (18).
Basic monitoring equipment and setup items that are considered standards in operative rooms, may therefore not be present in the cath lab. The cath lab has to be stocked with additional equipment and drugs that anesthesia providers typically require to manage difficult airways and hemodynamically unstable patients. Ideally, all operations should be performed in a hybrid operation theatre, i.e. a standard operative room with an additional angiography system.
Since the risk of hemodynamic instability and the need of emergent CPB and open surgery decreases with increasing equipe's experience, given the proven feasibility of performing the procedure under local anesthesia plus sedation, may be a tendency to simplify the anesthesiological setup. The perceived excess of prophylactic anesthetic preparations versus a more relaxed, confident and less complex approach has to be interpreted in the light of possible severe periprocedural complications.
At our Institution, all patients are monitored with five-electrodes EKG, pulsoxymetry, urinary catheter, bladder temperature, arterial and central venous lines. Two external adhesive pads are attached to the patient, for early management of arrhythmias.
Maintenance of normothermia is accomplished by an external convective warming system, an under body blanket and an intravenous fluid heater system. Pulmonary artery catheterization is not routinely performed and reserved to specific situations, such as left ventricular dysfunction and/or pulmonary hypertension.
A pulmonary artery catheter sheath may be placed at the time of initial central venous cannulation, allowing for further monitoring and providing a ready access to transvenous pacing routes in case of atrioventricular block, besides an adjunctive access for fluids.
Periprocedural transesophageal echocardiography (TEE) during PAVI may provide useful informations (19, 20). It aides the advancement of guidewires and delivery system and it allows to evaluate the effects of BAV (leaflet mobility, aortic regurgita-

tion), the position of the prosthesis at deployment, and post-implant valve assessment (area and gradient, leaflet mobility, regurgitation grade and location). TEE is of particular value when valve calcification are mild and fluoroscopic imaging difficult. Moreover it provides informations about preload and ventricular function, thoracic aorta anatomy and procedure-related complications, such as pericardial effusion and iatrogenic mitral regurgitation, thus guiding a prompt management of these events.

Drawbacks of periprocedural TEE may be the fact that it requires general anesthesia, it is sometimes limited in its ability to clearly distinguish the prosthesis while crimped on the delivery system and it may interfere with fluoroscopic imaging, necessitating probe withdrawal at the time of implantation.

At our Institution, all patients receive a transthoracic or transesophageal (if general anesthesia is used) echocardiographic evaluation at the end of the procedure, while periprocedural TEE evaluation is usually performed in selected high risk cases (aortic disease, concomitant heart valve problems) and when complications are suspected.

Newer modalities including intra-cardiac and three dimensional echocardiography, and CT angiography may further assist these procedures.

HEMODYNAMIC MANAGEMET

Hemodynamic stability is the main objective of anesthesiological management during TAVI. Goals of hemodynamic management are those typical of aortic stenosis. Intravenous fluid administration should be carefully titrated to provide adequate preload to a hypertrophied left ventricle. Tachycardia should be avoided to allow adequate diastolic filling time, and sinus rhythm should be maintained to preserve the contribution that atrial contraction adds to ventricular filling.

The systemic blood pressure must be maintained at a level to ensure coronary perfusion.

This may be accomplished through the use of vasopressor drugs, such as ethilephrine or norepinephrine. Since a significant proportion of the left ventricular afterload is produced by the stenostic aortic valve, vasopressor agents may be used without concern of adversely affecting ventricular performance, even in patients with poor left ventricular function.

Moreover, TAVI poses significant specific periprocedural challenges. Performing a BAV first allows easier passage of the prosthesis through the severely stenotic native aorti valve. Furthermore, the dilated aortic valve permits cardiac ouput circumventing the delivery system and better hemodynamics especially in patients with critical aortic stenosis. During BAV and the balloon-expandable prosthesis implantation, a transient partial cardiac standstill is induced to minimize cardiac motion and pulsatile transaortic flow, which would otherwise act to eject the inflated balloon, resulting in balloon slippage and device embolization and malpositioning. In earlier cases, CPB has been used to unload the left ventricle and to support the circulation during the deployment (21).

Pharmacologic agents such as adenosine and beta-blockers have also been employed; however, with inconsistent result. At present rapid ventricular pacing (RVP) is the preferred method to achieve this purpose (22), with suggested mechanism of action including induced atrio-ventricular asynchrony, left ventricular dyskinesis, compromised ventricular filling and reduction in stroke volume and cardiac output. RVP is performed at 220 bpm, and in case of

the presence of exit block, the rate is lowered by 20 bpm sequentially until reliable capture is achieved and a reduction in systolic arterial pressure to below 50 mmHg is observed.
A coordinated approach has been developed wherein one operator observes the fluoroscopic image and maintain the ideal valve position, a second operator starts pacing, and a third confirms reliable pacemaker capture and effective reduction in arterial pressure before rapidly inflating and then deflating the balloon.
Only when the balloon is fully deflated the pacing ends. While RVP is advantageous for valve positioning, the combination of rapid heart rate, myocardial hypertrophy and low coronary perfusion pressure produces an ischemic deficit in the myocardium. In most cases this ischemic deficit is well tolerated, most likely because of the brief duration of the RVP (12 seconds on average). However, it is prudent to minimize the number and duration of rapid pacing episodes during the procedure, and allow hemodynamic recovery before further pacing.
A bolus dose of a vasopressor such as etilephrine administered just prior or immediately after the rapid pacing episode will allow coronary perfusion pressure to be regained sooner. If the blood pressure does not recover promptly after an episode of RVP, myocardial ischemia must be suspected. The ischemic insult is usually caused by pacing, but coronary artery embolism from disruption of the calcified native aortic valve, or obstruction of one or both coronary ostia by the prosthetic valve or the displaced native valve leaflets must be considered.
Treatment of post-pacing myocardial ischemia is based initially on the restoration of coronary perfusion pressure through the use of vasopressor agents. In case of ischemia-induced ventricular fibrillation during valve deployment, consideration should be given to complete valve deployment before electrical cardioversion, thus avoiding prosthesis malpositioning or embolization when sinus rhythm is restored.
If the hemodynamic status fails to improve and the valve has not yet been deployed, the deployment of the prosthesis is the next step in management.
The main benefit of valve deployment is that it reduces left ventricular afterload, ventricular wall tension and myocardial oxygen demand, as well as it improves cardiac output. In the patient with acute aortic insufficiency following BAV, valve deployment may be the definitive management. If the patient remains unstable following valve deployment, femoral-femoral CPB can be rapidly instituted.
By intention CPB has been used in some centres during the first TAVI procedures, but it has been largely abandoned because the procedures appear to be well tolerated without extracorporeal support in most patients. Still, we suggest that an experienced cardiac surgeon and a perfusionist should be present or on call, in case of rapid cardiovascular deterioration requiring emergent CPB.
In case of hypotension during TAVI, besides ischemia ad aortic regurgitation, differential diagnosis must include cardiac tamponade, acute mitral regurgitation and major arterial bleeding/rupture.
Cardiac tamponade causing cardiovascular collapse may result from perforation of the right ventricle during pacing wire placement, and aortic or left ventricular perforation by guidewires or catheters. If tamponade occurs, it is easily detected by an associated increase in central venous pressure, visualization of the pericardial fluid and right-sided collapse on TEE, and abnormal movement of the heart on fluoroscopy.
The management may consist of percuta-

neous needle drainage of the pericardial blood or surgical intervention.

Acute mitral regurgitation may result from mitral impingement by the delivery catheters and the valve prosthesis. It can be readily diagnosed by continuous TEE monitoring.

Major arterial bleeding/rupture may complicate transfemoral artery procedures. A steady loss of blood through the valved sheath may be appreciated when catheters or wires in the vessels compromise the valve closure. A sudden unexplained decrease in blood pressure, particularly on decannulation, should alert to the possibility of a major vascular rupture which may require prompt intervention, whether by open or endovascular route.

Blood loss may be not readily apparent, as significant volumes may be lost retroperitoneally, but it is easily detected by contrast aortography.

An occlusion balloon may be deployed proximal to the perforation to attenuate the hemorrhage, and vigorous volume resuscitation with fluid and blood products may be required in addition to the use of vasopressor agents to maintain coronary perfusion. Usually an arterial guide wire is left in situ during the decannulation process so that if a vascular damage occurs the defect may be immediately fixed endoluminally without the need for open surgery.

Mild-to-moderate aortic regurgitation, mostly paravalvular, is observed in 50% of cases (23). However, the availability of larger prostheses and their careful matching with the size of the aortic annulus led to the decrease in the incidence of severe aortic regurgitation to 5%.

Further dilatation of the valve stent and valve-in-valve procedures have been suggested, but a severe periprosthetic aortic regurgitation with cardiogenic shock may require emergent surgery (24).

ANESTHESIA TECHNIQUES

Anesthesia techniques for TAVI may vary according to patient's characteristics and coexisting diseases, and procedural instances. Advantages of general anesthesia are easily clear. First, general anesthesia facilitates positioning of the valve prosthesis by maintaining patient immobility during fluoroscopy.

Neuromuscolar paralysis allows the anesthesiologist to control respiratory motion during radiographic filming and program short periods of apnoea, thus avoiding breathing artifacts interfering with prosthesis placement.

Moreover, some patients undergoing TAVI with local anesthesia may become restless lying completely still for an hour or more, which is usually the time required for the procedure.

Thus, general anesthesia may be more favorable when the patient is unable to tolerate the operation secondary to fatigue or having to maintain the same position through the entire procedure. Second, general anesthesia facilitates introducer sheaths placement and removal and eventual surgical repair of arterial access sites, which can be potentially complicated and prolonged. Third, it allows the use of TEE as an adjunctive imaging modality. Finally, it facilitates management of procedural complications.

Induction of general anesthesia can be done with a variety of agents. In patients undergoing TAVI anesthetic requirements are reduced because of advanced age and decreased cardiac output due to the severely stenotic aortic valve. The procedure itself does not produce a significant amount of surgical stimulation.

The choice of induction agents seems to matter less than the manner in which they are administered, which should be slowly and titrated to effect carefully. Mainte-

nance of anesthesia may be accomplished with inhalational agents, intravenous agents, or a combination of both. Inhalational agents may have some advantage offering some protection from the ischemic insult produced during the procedure by myocardial preconditioning.
Short acting agents that are rapidly cleared are preferred to facilitate extubation at the end of the procedure. Airway management is usually performed by endotracheal intubation. Because of the possible prolonged procedure and the use of TEE, use of laryngeal mask airway is not advised.
Yet general anesthesia is associated with important potential complications, particularly respiratory, which high risk patients who are unfit for surgical aortic valve replacement may tolerate poorly (25). On the basis of the EUROSTAR data, high-risk patients in particular attain important advantages from minimally invasive anesthetic techniques during endovascular aortic aneurysm repair: mortality, morbidity, hospital stay and intensive care unit (ICU) admission are significantly lower for regional and local versus general anesthesia in the EUROSTAR registry (26).
Similar benefits could be expected in high-risk patients undergoing TAVI with local anesthesia.
A trend for shorter procedure time, time to ambulation, high-dependency unit stay and overall hospital stay has been observed in our experience (8). Each of these factors is of significance both for patient morbidity and satisfaction, and for hospital efficiency and costs.
In our experience, general anesthesia has been the preferred technique at the beginning of our implantation program, accompanying operator's learning curve. With increasing equipe's experience, since the technique became straightforward and the feasibility of local anesthesia plus sedation became apparent, a shift was seen towards almost exclusive use of local anesthesia plus sedation.
At our Institution the anesthetic regimen for local anesthesia technique consists of 1% lidocaine injected subcutaneously at the arterial and venous access sites (maximum dose 4 mg/kg). In adjunct, sedation is accomplished with remifentanil infusion adjusted according to response (target level: score 2-3 with modified Wilson sedation scale (27); starting dose 0.02 mcg/kg/min, maximum dose 0.2 mcg/kg/min). Combined use of remifentanil and propofol (range dose 2-5 mg/kg/h) may be used according to patient's and procedural requirements in order to reach the above mentioned sedation level. Operator-delivered sedation is unlikely to be successful for these patient whose hemodynamics are brittle and tolerance of invasive procedures may be limited.
A potential advantage of local anesthesia may be the fact that overstretching the arterial system by the delivery sheath induces discomfort which alerts the physician of the risk of vascular injury or rupture.
In our experience, the passage of relatively large and stiff deployment catheters through the arteries is well tolerated with local anesthesia, and concerns of patients tolerance for vascular repair with local anesthesia are perhaps unfounded, since intravenous sedation is used to maximize comfort rather than to provide analgesia.
A preoperative ilioinguinal/iliohypogastric block can be performed to reduce the total dose of infiltration local anesthetics in patients with reduced metabolic capacity, at increased risk for neurologic and cardiac toxicity.
If local anesthesia plus sedation is employed, the anesthesiologist must be ready to institute full general anesthesia at any moment. This concept of "standby" general anesthesia appears to offer enhanced flexibility in scheduling patients for these

procedures. Patients with anticipated difficult airway are obviously unsuitable for this technique, because the risk of delay in airway access during emergent situations may be worse than the potential benefits of a less invasive anesthetic technique.
Notably, fluoroscopy equipment regularly limits access to patient's head which may be difficult once the procedure has started.
We are planning a large randomized trial of general versus local anesthesia to evaluate whether the choice of anesthetic technique affects the outcome of patients undergoing TAVI.

POST-PROCEDURAL COURSE

Most patients undergoing TAVI with general anesthesia are able to be extubated in the theatre at the end of the procedure, unless they are hemodynamically compromised or difficult airways. It is imperative to continuously evaluate the patient for the appropriateness of fast tracking as the operation progresses.
Patients who require mechanical ventilation postoperatively are usually able to be extubated within a few hours. Pain management is accomplished in most patients by nonsteroidal agents/paracetamol and opioids low rescue doses. It is important to note that these high risk patients are prone to complications at any time during hospital stay, with a pattern of complications substantially different from standard cardiac surgery.
According to single Institution organization, an early transfer to an intermediate care unit provided with bedside telemetry, could be a suitable strategy in selected patients with uneventful operative course. Ideally, all patients should stay in ICU for at least 24 hours and be closely monitored for several days especially as regards hemodinamics, vascular access, rhythm disturbances and renal function.
In this regard, main concerns may be arised by atrioventricular block (4-8%), necessitating pacemaker implantation in up to 24% with self-expandable devices (23).
The transvenous pacing lead is routinely left in situ after the procedure if self-expandable device is implanted. Moreover, acute renal injury remains a frequent cause of morbidity in patients undergoing TAVI. General risk factors include diabetes mellitus, pre-operative renal insufficiency, age, volume depletion-hypotension-low cardiac output, nephrotoxic drugs and high volume of contrast media.
Among others, specific risk factors comprise transapical access, number of blood transfusions, post-interventional thrombocytopaenia and severe inflammatory response syndrome (SIRS). Preventive measures pre-procedure, as well as careful post-procedure management, should be routine in all patients.

CONCLUSIONS

Six years after the first-in-man, TAVI technique is undergoing rapid development and dissemination.
As this new procedures is on its way towards clinical practice, perioperative optimal strategies keep on evolving.
Anesthesiologists must be aware of current technologies, playing a participative role in developing standards of care for these high risk patients and supporting the continuous refinement toward a more and more minimally invasive approach.

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