Anesthetic Management of Percutaneous Aortic Valve Implantation: Focus on Challenges Encountered and Proposed Solutions

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Objective: To describe 6 months of experience in the anesthetic management of percutaneous aortic valve implantation.

Design: An observational, cohort study.

Setting: A university hospital.

Participants: Eighteen high-risk patients with relative contraindications to surgical valve replacement (78 ± 8.7 years, logistic EuroSCORE 26 ± 19.1). Intervention: An Edwards/Sapien Aortic Bioprosthesis (Edwards Lifesciences LLC, Irvine, CA) was implanted in patients with severe symptomatic aortic stenosis who underwent percutaneous retrograde aortic valve implantation without cardiopulmonary bypass. The procedure was performed using general anesthesia (15 patients) or sedation (3 patients).

Measurements and Main Results: The valve was successfully implanted in all patients. One patient had prolonged ventricular fibrillation that required advanced cardiopulmonary resuscitation, endotracheal intubation, and placement of an intra-aortic balloon pump. Six patients had vascular access site complications managed either percutaneously or surgically. Five patients were extubated in the catheterization laboratory. All patients were transferred to the intensive care unit for monitoring, and all but one were discharged to an intermediate care unit within 24 hours. Early postoperative complications included acute renal failure (1 patient), arrhythmias (1 atrial fibrillation and 1 transient heart block), and stroke (1 patient). One patient died 58 days after the procedure for noncardiac reasons.

Conclusions: Transcatheter aortic valve implantation is possible in selected high-risk patients. Anesthesiologists must be aware of current technology in order to have an active role in patient selection, to develop monitoring and standards of care in the cardiac catheterization laboratory, and to plan postoperative management.

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TODAY, SURGICAL AORTIC valve replacement (AVR) is the treatment of choice for a vast majority of patients with aortic stenosis.1 However, in a subset of patients, mainly elderly patients with declining overall health status or severe comorbidities, AVR is considered either too high risk or contraindicated. Given the limited therapeutic options in these patients, there has been interest in the development of a transcatheter aortic valve implantation (TAVI) technique. The rationale is to minimize the overall surgical trauma by avoiding sternotomy and the use of cardiopulmonary bypass (CPB) and implanting the prosthesis in the beating heart, thereby avoiding cardiac arrest.2 Economic considerations will contribute to the implementation of this technique if safety and efficacy can be confirmed.

The aim of this report is to present the results of the authors’ initial TAVI experience in selected high-risk patients and to focus on challenges encountered in the anesthetic management of this procedure.

METHODS

The authors prospectively collected data on patients with severe symptomatic aortic stenosis referred for TAVI at a single Institution from November 2007 to May 2008. The study was approved by the ethics committee, and all patients signed informed, written consent. Patient selection was performed on the basis of an increased perioperative risk profile documented by a EuroSCORE ≥20% in 10 patients or by conditions not included in the score, such as porcelain aorta, prior thoracotomy, liver cirrhosis, and chest wall radiation in 8 patients. The therapeutic option of percutaneous aortic valve implantation also was discussed extensively for the individual patient and approved on the basis of a consensus that conventional surgery was excessively high risk in terms of anticipated mortality and morbidity.

Patients underwent transathoracic echocardiography, coronary and aortofemoral angiography, and/or a multidetector computed tomography scan to determine iliofemoral anatomy and suitability for TAVI. Patients were excluded if the aortic annulus diameter was <18 or >25 mm, if there was severe iliofemoral or aortic disease/tortuosity, or if a reasonable quality or duration of life was considered unlikely because of comorbidities. Patient preference alone for TAVI was not considered adequate if surgery was an option.
All TAVI procedures were performed in the cardiac catheterization laboratory with operating room–like sterile precautions using the transfemoral retrograde approach and the Edwards/Sapien Aortic Bioprosthesis (Edwards Lifesciences LLC, Irvine, CA). A vascular surgeon was on call and aware of the ongoing procedure. A cardiac surgeon actively took part in the procedure, and a perfusion technician was present to institute emergency CPB in the catheterization laboratory.

The surgical technique has been described in detail. The prosthesis consists of a bovine pericardial trileaflet valve (Fig 1) mounted in a balloon-expandable stainless steel stent. A standard balloon valvuloplasty was performed before prosthesis deployment to provide an enlarged passageway for the subsequent insertion of the prosthesis. A deflectable guiding catheter was used to actively direct the prosthesis from the femoral or iliac artery, through the aorta, within the calcified native aortic valve leaflets. The prosthesis was positioned under fluoroscopic (Figs 2 and 3) and angiographic guidance, and it was deployed by balloon inflation. Both balloon valvuloplasty and prosthesis deployment were performed during rapid ventricular pacing. After removal of the balloon catheter, the venous puncture sites were closed by manual compression, whereas the arterial entry sites were closed by closure devices (Prostar XL; Abbot Vascular, Redwood City, CA) or with a surgical approach.

Acetylsalicylic acid (100 mg/d) was administered before the procedure and continued indefinitely. In addition, all patients received clopidogrel (300 mg loading dose) the day before followed by 75 mg daily for at least 3 months. During the intervention, patients received intravenous heparin to achieve an activated coagulation time of 250 seconds for the duration of the procedure. Intravenous cefazolin was administered immediately before the procedure.

All patients were monitored with a 5-electrode electrocardiogram, pulse oximetry, urinary catheter, and radial artery catheter (20-G). All patients undergoing general anesthesia underwent transesophageal echocardiography (TEE) at the end of the procedure, whereas those patients receiving local anesthesia plus sedation had transthoracic echocardiographic evaluation.

A triple-lumen central venous catheter and a pulmonary artery catheter introducer were placed in the right internal jugular vein, providing access to transvenous pacing in case of postprocedural bradycardia and atrioventricular heart block, and supplementary routes for fluids. Pulmonary artery catheterization was not performed routinely and was

Fig 1. The Edwards/Sapien Aortic Bioprosthesis, a xenograft consisting of 3 bovine pericardial leaflets mounted in a balloon-expandable stainless steel stent. (Color version of figure is available online.)

Fig 2. A properly positioned prosthetic valve.

Fig 3. A balloon-mounted prosthetic valve positioned adjacent to a native valve calcification.
The deployment of the device before defibrillation. An aortic root fibrillation occurred during device deployment, the authors completed dynamic instability after the procedure. If pacing-induced ventricular arterial pressure before further pacing. Intravenous boluses of phenylephrine were maintained ideal valve position, another person initiated pacing, and a third one confirmed reliable pacemaker capture and effective reduction in arterial pressure before rapidly inflating and then deflating the stent-deployment balloon.4

During balloon valvuloplasty and during the implantation of the bioprosthesis, a transient partial cardiac standstill was induced to minimize cardiac motion and pulsatile transaortic flow, which would otherwise have acted to eject the inflated device-deployment balloon.4 Rapid ventricular pacing was used to induce atrioventricular asynchrony, left ventricular dyskinesis, compromised ventricular filling, and reductions in stroke volume and cardiac output.4,5 An external pacemaker with the capability of rapid onset and rapid offset of pacing at rates in excess of 200 beats/min was used. Ventricular pacing was performed at 220 beats/min, and, if necessary, the rate was reduced until reliable capture was achieved and a reduction in systolic arterial pressure below 50 mmHg was observed. A coordinated approach was developed wherein one person observed the fluoroscopic image and maintained ideal valve position, another person initiated pacing, and a third one confirmed reliable pacemaker capture and effective reduction in arterial pressure before rapidly inflating and then deflating the stent-deployment balloon. The pacing terminated only when the balloon was fully deflated.1

Because tachycardia in the presence of severe aortic stenosis and left ventricular hypertrophy could cause myocardial ischemia, the authors limited the episodes and the duration of rapid pacing to less than 15 seconds in most patients. Rest periods of 1 to 2 minutes were allowed to ensure adequate recovery of left ventricular systolic function and arterial pressure before further pacing. Intravenous boluses of phenylephrine (up to 2-3 mg) were used as required in the presence of persistent hypotension. Low-dose epinephrine (0.03 µg/kg/min) was used in patients with a preoperative low ejection fraction and hemodynamic instability after the procedure. If pacing-induced ventricular fibrillation occurred during device deployment, the authors completed the deployment of the device before defibrillation. An aortic root angiogram was performed at the end of the procedure to assess perivalvular or transvalvular aortic regurgitation and proper positioning of the prosthesis and to ensure normal flow into both main coronary arteries. Iliac and femoral angiography were performed to assess vascular complications.

At the end of the procedure, patients were transferred to the ICU for early extubation and/or monitoring or to an intermediate care unit. Given the limited incisions associated with these endovascular procedures, postoperative pain was managed with nonsteroidal anti-inflammatory agents/paracetamol and low-dose opioids. A device specialist and a medical expert from the manufacturer attended the first 5 procedures in the authors' center. Cardiologists, cardiac surgeons, and anesthesiologists involved in these procedures visited other hospitals and attended theoretic and practical courses.

Results are presented in a standard fashion. Continuous variables are expressed as mean ± standard deviation or as median when appropriate, and categoric variables are expressed as proportions.

**RESULTS**

Between November 2007 and May 2008, 69 consecutive patients underwent clinical evaluation for TAVI at the authors’ institution. In 51 patients, TAVI was not performed (screening/treatment ratio 4:1) (Table 1). A total of 18 symptomatic patients (11 men and 7 women) were deemed suitable for TAVI (Table 2). Age was 78 ± 8.7 years (range, 62-92 years), logistic EuroSCORE was 25% ± 18.5%, and 12 patients (66%) were New York Heart Association functional class III or IV.

All patients left the catheter laboratory alive, with a properly positioned prosthetic valve. The procedural time was 204 ± 54 minutes. The radiation dose was 297 ± 132 Gy/cm², and the contrast volume was 358 ± 111 mL. No patient required conversion to surgical valve replacement. Prosthesis deployment was performed during rapid ventricular pacing without CPB, recovering good hemodynamic stability in almost all cases. Fourteen patients received elective general anesthesia, whereas 4 patients received local anesthesia in combination with mild sedation. Two patients experienced rapid pacing–induced ventricular fibrillation that was easily managed with electrical defibrillation. One additional patient had prolonged ventricular fibrillation that required advanced cardiopulmonary resuscitation, endotracheal intubation, and placement of an intra-aortic balloon pump for 12 hours. The patient was discharged from the ICU after 36 hours and from the hospital 6 days later.

Hemodynamics of the implanted valve were satisfactory in all patients, with abolishment of the gradients and a mean aortic regurgitation grade of 1.17/4.0 on echocardiographic evaluation (either transthoracic or transesophageal), with no patient

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<th>Table 1. Consecutive Patients Who Underwent Clinical Evaluation for Transcatheter Aortic Valve Implantation at the Authors’ Institution in a 6-Month Period</th>
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<td>Died during the screening period</td>
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<td>Refused any invasive treatment and were addressed by medical therapy</td>
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<tr>
<td>Noncritical aortic stenosis</td>
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<td>Large annulus with diameter &gt;25 mm</td>
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<td>Small or diseased peripheral vessels</td>
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<td>Low cardiac output and end-stage cardiac disease</td>
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<td>Indication for conventional valve replacement</td>
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<td>Transcatheter aortic valve implantation</td>
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<td><strong>Total</strong></td>
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<th>Table 2. Major Comorbidities of 18 Consecutive Patients Who Underwent Transcatheter Aortic Valve Implantation</th>
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<td>Recent pulmonary edema requiring hospitalization</td>
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<td>Coronary artery disease</td>
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<td>Previous myocardial infarction</td>
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<tr>
<td>Previous percutaneous coronary intervention</td>
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<td>Previous coronary artery bypass graft surgery</td>
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<td>Chronic renal insufficiency (creatinine clearance &lt;50 mL/min)</td>
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<td>Chronic dialysis</td>
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<td>Chronic obstructive pulmonary disease on medical therapy</td>
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<td>Cirrhosis and previous orthotopic liver transplantation</td>
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<td>Disabling rheumatoid arthritis</td>
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<td>Myasthenia gravis</td>
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<td>Porcelain aorta</td>
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<td>Previous chest wall radiation</td>
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having severe aortic regurgitation. Nine patients had mild-to-moderate aortic regurgitation; in 7 of them, it was perivalvular regurgitation, and in 2 it was intravalvular.

No pericardial tamponade, aortic dissection, misplacement of the valve, or procedural coronary flow impairment were observed in the entire study population. Femoral access was obtained percutaneously in 13 patients, whereas a surgical approach was performed in 5 patients. Five patients experienced vascular access site complications, managed either percutaneously or surgically; 3 patients required endovascular treatment because of common iliac artery complications, a peripheral femoral embolization was resolved with balloon angioplasty in 1 patient, and a common femoral artery complication was surgically repaired in 1 patient. Nine patients required periprocedural transfusions of blood products (≤2 U of packed red blood cells in all patients except 1 who received 5 U of red blood cells, 6 U of fresh frozen plasma, and 6 U of platelets because of preoperative hepatic and renal dysfunction), most of them at the beginning of the implantation program. A pulmonary artery catheter was not used in the catheterization laboratory, whereas it was used twice during ICU stay.

At the end of the procedure, 15 patients were transferred to the ICU for early extubation and/or monitoring. Five patients were extubated in the catheterization laboratory, and 3 were transferred to an intermediate care unit. All but 1 patient had a short ICU stay and were discharged to an intermediate care unit at day 0 or 1. Hospital stay was 11 ± 10.5 days (range, 1-58 days). Major early postoperative complications included acute renal failure requiring renal replacement therapy (1 patient), atrial fibrillation and transient heart block, and stroke occurring on the first postoperative day (1 patient). All patients were alive 30 days after the procedure. All patients were discharged from the hospital. At the 6-month follow-up, 15 patients were alive. One patient with a history of previous orthotopic liver transplantation and immunosuppressive therapy died 2 months after the procedure from sepsis and multiorgan failure. The patient on chronic dialysis and the one with a postoperative stroke died of pneumonia after 2 and 3 months, respectively.

**DISCUSSION**

A favorable outcome was obtained in the first 18 patients undergoing TAVI in the authors’ center, suggesting that the technique is feasible in selected high-risk patients and that it represents a unique challenge for the anesthesiologist. TAVI is a novel technique developed to deal with an increasing risk profile of patients with aortic stenosis. The goal of this procedure is to decrease the invasiveness of surgical AVR, which is the current gold standard.

All TAVI procedures in this series started with conventional balloon aortic valvuloplasty to provide an enlarged passageway for the subsequent insertion of the prosthesis and were performed with the retrograde approach requiring transfemoral artery access; negotiation of femoral, iliac, and aortic vasculature; retrograde crossing of the calcified aortic valve; and meticulous valve deployment in the subannular region.

All patients in the present study received the balloon-expanding Edwards/Sapien Bioprosthesis. Other technologies are being developed or were used in large clinical series such as the self-expanding CoreValve ReValving System (CoreValve, Paris, France).

According to the recent literature, the authors reserved TAVI for patients with severe calcific aortic stenosis, a standard indication for surgical AVR, but at “high risk” for CPB and/or an open sternotomy procedure. The authors used the EuroSCORE as a predictive risk model. Because the predictive tools for operative risk assessment are imprecise, especially at high levels of risk, and omit important risk factors, such as severe thoracic aorta calcification, previous chest wall radiation, or liver cirrhosis, the authors believe that the best characterization of the individual risk should be a combination of objective quantitative predictive models and subjective assessment by experienced surgeons, cardiologists, and anesthesiologists. The authors extensively discussed the therapeutic option of TAVI for each individual patient and reached a consensus that conventional surgery was excessively high risk in terms of anticipated mortality and morbidity. Patients were excluded if a reasonable quality or duration of life was considered unlikely despite valve replacement because of comorbidities. In the authors’ center, patient selection and preoperative diagnostics have been safely and effectively managed on an outpatient basis. Because this new procedure is moving toward clinical practice, a multidisciplinary approach is required, and the “valve team” should include a trained cardiac surgeon, interventional cardiologist, and cardiac anesthesiologist. With the maturing of the technology, all cardiac surgeons, cardiologists, and anesthesiologists will become familiar with this procedure.

The prevention of contrast media-induced nephrotoxicity (normosaline plus sodium bicarbonate in the authors’ experience) and preoperative lung optimization (with physiotherapy and bronchodilators) are major concerns in these patients. The authors considered an ICU stay before the procedure in severely decompensated patients. The opinion of the anesthesiologist as well as that of cardiologists and cardiac surgeons was always considered in the authors’ center. Moreover, the authors preoperatively planned the strategy for treatment in case of complications, determining the potential of surgical bailout in advance.

In the authors’ experience, the anesthesiologist took a participatory role in developing monitoring and standards of care in the catheterization laboratory for this procedure, together with cardiac surgeons and cardiologists. It is important to note that the environment of the catheterization laboratory is designed to satisfy the needs of cardiologists, since the role of the anesthesiologist was not taken into consideration when the laboratory was designed. Basic monitoring equipment and setup items that are considered standard in operating rooms may therefore not be present in the catheterization laboratory. The catheterization laboratory has to be stocked with the additional equipment and medications that anesthesia providers typically require to manage difficult airways and hemodynamically unstable patients. The authors’ center is building a hybrid operation room (ie, a standard operative room with an additional angiography system equivalent to any standard catheterization laboratory).

The authors also established a strategy of communication among the specialists about the case so that patient safety and
care were optimized. The procedure table and fluoroscopy equipment frequently moved during the case without warning because the cardiologist had the table control. The anesthesiologist had to face this problem, trying to solve it with the use of long intravenous catheters and breathing circuits.

Blood transfusions were not frequent in the authors’ experience, even if they were required at the beginning of the operators’ learning curve. A steady loss through the valve access sheath may be appreciated when there are catheters or wires inserted into the vessels, compromising the valve closure. A sudden unexplained decrease in blood pressure, particularly on sheath removal, should alert all to the possibility of a major vascular rupture, perforation, or avulsion, which may require an urgent repair. Usually, arterial guidewires are left in place so that if vascular damage occurs the defect can be immediately fixed endoluminally without the need for open surgery. Besides aortic dissection, aortic rupture, and access-related complications, periprocedural complications may include prosthesis embolization, paravalvular insufficiency, and coronary obstruction.

Stroke is a known risk of routine balloon valvuloplasty and TAVI atheroembolism resulting from manipulation of the native valve or aortic arch may play a role. The authors observed no operative stroke in their experience and only one postoperative stroke on the first postoperative day.

Even if an experienced team could perform TAVI under local anesthesia with a simplified setup, the anesthetic preparation must take into account the risk of neurologic complications and hemodynamic instability requiring emergent CPB and cardiac surgery. A perceived excess of prophylactic anesthetic preparations has to be interpreted in the light of possible severe periprocedural complications.

The role of TEE in a setting in which fluoroscopy is very informative has to be further evaluated. TEE may provide useful information about the results of balloon valvuloplasty (leaflet mobility and aortic regurgitation) and the position of the prosthetic valve during deployment with respect to the aortic valve plane and the left ventricular outflow tract; the immediate prosthetic valve assessment after implantation (prosthetic valve area and gradient, leaflet mobility, regurgitation grade, and location); and additional information about left ventricular function, mitral regurgitation, and thoracic aorta anatomy. Moreover, it may identify procedure-related complications such as pericardial effusion, permitting prompt management of these problems. TEE could be of particular value with valve calcification and fluoroscopic imaging is difficult. However, it may have some drawbacks when incorporated into TAVI; it is sometimes limited in its ability to clearly distinguish the prosthesis while mounted on the balloon catheter, and it may increase the operator’s preferences for general anesthesia. Furthermore, it may interfere with the fluoroscopic imaging, necessitating TEE probe withdrawal at the time of implantation. However, TAVI guided by “online” TEE in anesthetized patients may facilitate training for an interventionalist embarking on percutaneous aortic valve implantation. The authors used TEE for selected high-risk cases (aortic disease and concomitant heart valve problems) and when complications were suspected.

Hemodynamic stability was the principal objective of the anesthetic management during percutaneous aortic valve implantation. Goals of hemodynamic management were those typical of aortic stenosis. Low heart rates (50-70 beats/min) were preferred to rapid heart rates (>90 beats/min). Supraventricular arrhythmias and ventricular ectopy were managed aggressively. Transient hypotension not responding to preload augmentation was managed with phenylephrine boluses. Persistent hypotension before completing the procedure was treated with a continuous infusion of norepinephrine. A concern with rapid pacing was the risk of provoking ventricular arrhythmias; of particular concern were patients with aortic stenosis and coronary artery disease. In the authors’ center, CPB was not used because the procedure appeared to be well tolerated without extracorporeal support in most patients. The authors suggest that an experienced cardiac surgeon and a perfusionist should be present in case of rapid cardiovascular deterioration that necessitates the emergency use of CPB.

Anesthetic techniques for TAVI may vary according to the patient’s characteristics, coexisting diseases, and procedural issues. General anesthesia or local anesthesia plus sedation were both used in the present patients with good results. Elective general anesthesia with endotracheal intubation has many advantages, facilitating sheath placement and the removal and eventual surgical repair of the arterial access site, immobility during valve deployment, periprocedural TEE, airway management in case of hemodynamic or neurologic complications, and rapid CPB institution when necessary. It is important that, at present, sheaths used for Edwards/Sapien Bioprosthesis implantation (22F or 24F internal diameter) have external diameters of 8.5 or 9.3 mm, respectively, and vascular access site complications are quite frequent. The authors used preoperative evaluation of aortofemoral angiography or computed tomography imaging (small vessels, peripheral artery disease, stenosis, and calcification) to plan anesthetic strategies for TAVI. A potential advantage of local anesthesia may be that overstretching the arterial system by the delivery sheath induces discomfort, which alerts the physician to the risk of injury or rupture. In the authors’ experience, the passage of relatively large and stiff deployment catheters through the iliac arteries was well tolerated with local anesthesia. General anesthesia was the preferred technique at the beginning of the authors’ implantation program, accompanying the operator’s learning curve. The physicians were more comfortable operating on an anesthetized patient. With increasing team experience, a shift was seen toward the use of local anesthesia plus sedation. Operators may advocate the use of general anesthesia with neuromuscular paralysis to minimize patient movement and to induce short periods of apnea, thus avoiding breathing artifacts that would interfere with prosthesis placement. Moreover, despite intravenous sedation, some patients may become restless lying completely still for an hour or more. General anesthesia may be more suitable when the patient is unable to maintain the same position through the entire procedure. Lastly, local anesthetic techniques can be problematic because of high dosage requirements for local anesthetics. This places patients with decreased metabolic capacity at increased risk for neurologic and cardiac toxicity. A preoperative ilioinguinal/iliohypogastric nerve block could be performed with the aim to reduce the total dose of lidocaine. In the authors’ experience, if local anesthesia with sedation was used, the anesthesiologist was ready to employ
full general anesthesia at any moment to preserve the patient’s conditions. Patients with anticipated difficulty in airway access were obviously unsuitable for performing TAVI under local anesthesia with sedation (the risk of delay in airway access during emergent situations was worse than the potential benefits of a less invasive anesthetic technique). A study to evaluate whether the choice of anesthetic technique affects outcome of TAVI may be useful to determine the ideal anesthetic technique for this procedure. There is also a need for well-conducted large randomized controlled clinical trials to compare percutaneous with surgical replacement of the aortic valve for calcific aortic stenosis.

One of the limitations of the transfemoral approach is that some patients are not candidates for this procedure. In 8 patients, TAVI was not performed because of low cardiac output and end-stage cardiac disease. Even if it is argued that these are the very patients who could benefit from this procedure, the authors performed a balloon valvuloplasty to reduce afterload and evaluate improvements in ventricular function. More details could have been collected to describe this cohort of patients such as ejection fraction, mitral regurgitation, aortic regurgitation, medical therapy, past history of a neurologic event, evaluation of carotid arteries, history of diabetes, serum creatinine before and after the operation, inotropic and vasopressor medication, cardiac output, hemodynamic, TEE, blood gas analysis, intravenous fluids, arrhythmia data, and use of anesthetic drugs. Even if the ICU stay of these patients was short, the overall hospital stay averaged 11 days. These data could be attributed to the comorbidities, to the safety concerns for this new procedure, and to a chronic lack of intensive care unit beds in Europe.14

CONCLUSIONS

TAVI is an emerging alternative to surgical aortic valve replacement. The technique is feasible in selected high-risk patients in the authors’ experience. Anesthesiologists must be aware of current technology, have a participatory role in developing standards of care for these high-risk patients, and support continuous refinement toward a minimally invasive approach.

REFERENCES


