

Case Reports/Case Series

Case series: Anesthesia for retrograde percutaneous aortic valve replacement – experience with the first 40 patients

[Présentation de cas : L'anesthésie pour un remplacement valvulaire aortique percutané rétrograde : notre expérience avec les 40 premiers patients]

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Purpose: To describe both the evolution and the main associated complications in the anesthetic management of the initial 40 patients at our centre who underwent percutaneous retrograde aortic valve replacement, a novel technique utilizing a catheter-guided femoral artery approach.

Clinical features: With institutional Research Ethics Board approval, we retrospectively reviewed the medical records of the first 40 patients who underwent percutaneous retrograde aortic valve replacement between January 2005 and March 2006. Information obtained included patient characteristics, anesthetic management, details of the procedure, and complications. All procedures were scheduled to be performed in the cardiac catheterization laboratory. The first four patients received monitored anesthesia care, and 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 hr (range, 1.25–7.25 hr). 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% ($n = 5/40$).

Conclusions: Percutaneous retrograde aortic valve replacement is a novel procedure that presents the anesthesiologist with unique challenges. Careful preoperative assessment, intraoper-

ative monitoring appropriate for a major vascular procedure, and meticulous management of hemodynamics are imperative for a successful outcome. Serious complications, including major hemorrhage from vascular injury as well as arrhythmia and myocardial ischemia following rapid ventricular pacing, must be anticipated and managed in an expeditious fashion.

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Objectif : Décrire l'évolution et les principales complications associées à la prise en charge anesthésique des premiers 40 patients de notre centre à subir un remplacement valvulaire aortique percutané rétrograde, une technique innovante utilisant une approche échoguidée par l'artère fémorale.

Éléments cliniques : Une fois le consentement du Comité d'éthique de la recherche obtenu, nous avons révisé de façon rétrospective les dossiers médicaux des 40 premiers patients à avoir subi un remplacement valvulaire aortique percutané rétrograde entre janvier 2005 et mars 2006. Les caractéristiques des patients, la prise en charge anesthésique, les détails de l'intervention et les complications faisaient partie des renseignements obtenus. Toutes les interventions étaient prévues dans le laboratoire de cathétérisation cardiaque. Les quatre premiers patients ont reçu une sédation sous surveillance, et les 36 suivants une anesthésie générale. Il n'y a pas eu d'événements indésirables provoqués par l'anesthésie. La

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prothèse valvulaire a été positionnée avec succès chez 33/40 patients (83 %). Le temps d'anesthésie médian était de 3,5 h (extrêmes, 1,25 – 7, 25 h). Un vasopresseur a été nécessaire chez 32/40 patients. Suite à l'intervention, les complications graves les plus fréquentes étaient l'ischémie myocardique et l'arythmie à la suite d'un entraînement ventriculaire rapide, l'hémorragie provoquée par une lésion vasculaire due au positionnement et au retrait de la gaine à grand diamètre dans l'artère ilio-fémorale, la rupture aortique et le mauvais déploiement de la prothèse valvulaire. La mortalité à 30 jours était de 13 % (5/40).

Conclusion : Le remplacement valvulaire aortique percutané rétrograde est une intervention nouvelle qui présente à l'anesthésiologiste des défis spéciaux. Une évaluation préopératoire attentive, un monitoring opératoire adapté à une intervention vasculaire majeure et une prise en charge méticuleuse de l'hémodynamie sont absolument nécessaires à un devenir réussi. Des complications graves, notamment une hémorragie majeure causée par une lésion vasculaire ainsi que de l'arythmie et une ischémie myocardique suite à un entraînement ventriculaire rapide doivent être anticipés et pris en charge rapidement.

AORTIC stenosis is the most common cardiac valvular lesion in the developed world.¹ Its etiology may be congenital or acquired. Both forms of stenosis result in a valve with calcified, restricted leaflets. Once aortic stenosis becomes symptomatic, it carries a poor prognosis and is poorly managed with medical therapy.² Surgical aortic valve (AV) replacement is effective in prolonging life and improving symptoms; however, the procedure can be associated with significant perioperative risk, especially in the elderly with decreased functional reserve and multiple co-morbidities.^{3,4} Surgery may also carry an unacceptable risk due to extensive calcification of the ascending aorta. Whereas balloon valvuloplasty represents an alternative therapeutic option, the reduction in stenosis is modest and temporary.^{5,6}

Percutaneous approaches to AV replacement have been investigated since 1992.⁷ In 2002, Cribier *et al.*⁸ reported a successful percutaneous valve replacement via an antegrade transseptal approach through the femoral vein. However, due to arrhythmias and possible mitral valve injury, the antegrade approach is technically challenging and not well tolerated by some patients.^{9,10} A percutaneous retrograde approach for replacing the AV has been developed at our centre by Webb *et al.*¹¹ Vascular access is achieved through the femoral artery. The prosthesis, which is mounted on a catheter-guided stainless steel mesh stent, is maneuvered in a retrograde fashion into the ascending aorta

and placed through the native AV before deployment. Here, we report on the evolution in the anesthetic management of the initial 40 patients undergoing this novel procedure, and we summarize the associated major perioperative complications encountered.

Methods

With approval of the institutional Research Ethics Board, we retrospectively reviewed the charts, anesthetic records, and procedural database of the initial 40 patients who underwent percutaneous retrograde aortic valve replacement at our centre (St. Paul's Hospital, The University of British Columbia, Vancouver, B.C.) between January 2005 and March 2006. Patient characteristics, anesthetic management, details of the procedure, and complications were noted. Prior to the calculation of descriptive statistics and data comparisons, we used the Kolmogorov-Smirnov test and assessed kurtosis and symmetry of continuous data to test if values came from a Gaussian distribution. Unless otherwise stated, data are presented as mean \pm SD or median [interquartile range], as appropriate. Descriptive data on AV area and mean transaortic gradient, before and after prosthetic valve placement, were compared with the Mann-Whitney test; $P < 0.05$. Descriptive statistics and comparisons were calculated using Microsoft Excel 2003 (Microsoft Corporation, Redmond, WA, USA) and Prism version 4 (Graph-Pad, San Diego, USA) software.

Patient selection

The Therapeutic Products Directorate (Health Canada, Health Products and Food Branch; Ottawa, Ontario, Canada) approved the procedure for compassionate clinical use in patients considered unsuitable for conventional surgery by a team of cardiologists and cardiac surgeons. Patients with severe symptomatic aortic stenosis were referred for a percutaneous procedure due to multiple comorbidities and/or surgical risk (logistic EuroSCORE $\geq 20\%$, indicating a 30-day predicted mortality $\geq 20\%$ with operative management).¹²⁻¹⁴ Patient preference for a percutaneous procedure was not considered an indication. The interventional cardiology team obtained informed consent for the procedure from all patients.

Percutaneous valve replacement procedure

A detailed description of the technical aspects of this procedure, from an interventional cardiology perspective, has recently been published.¹¹ Patients received clopidogrel 600 mg and aspirin 325 mg orally prior to the procedure. Antibiotic prophylaxis with either intravenous vancomycin (1 g) or cefazolin (1 g) was

TABLE I Preoperative patient characteristics

Patients	<i>n</i> = 40	(100%)
Age (yr)	81 ± 8	
Female gender	15	(38%)
Body mass index (kg·m ⁻²)	27 ± 6	
Hypertension	23	(58%)
Diabetes mellitus	9	(23%)
Coronary artery disease	28	(70%)
Severe chronic obstructive lung disease	15	(38%)
History of cerebral ischemic event	3	(8%)
Peripheral vascular disease	8	(20%)
Atrial fibrillation	15	(38%)
Smoking		
Current	5	(13%)
Ex-smoker	16	(40%)
Never smoked	19	(48%)
Estimated GFR < 60 mL·min ⁻¹ ·1.73 m ⁻²	20	(50%)
Permanent pacemaker	7	(18%)
Aortic calcification	15	(38%)
Prior thoracotomy	14	(35%)
Symptoms		
NYHA 3 or 4	37	(93%)
Angina	16	(40%)
Syncope	3	(8%)
Aortic valve area (cm ²)	0.6* (range, 0.3–1.2)	
Transaortic mean gradient (mmHg)	46 ± 18	
Mitral regurgitation grade 3 or 4	18	(45%)
Ejection fraction < 50%	9	(23%)
Logistic EuroSCORE (%)	25 ± 15	
≥ 20	23	(58%)

Data are presented as mean ± SD, where appropriate; *median. GFR = glomerular filtration rate; NYHA = New York Heart Association.

administered. All procedures were performed by an interventional cardiologist in the cardiac catheterization laboratory. Femoral access was achieved percutaneously, and the ilio-femoral artery was progressively dilated to accommodate either a 22 or a 24 Fr sheath, depending on the size of the prosthesis to be placed. Heparin 70 U·kg⁻¹ *iv* was administered following arterial cannulation. The femoral vein was also cannulated to allow a pacing lead to be positioned in the right ventricle. Balloon valvuloplasty of the AV was then performed in a standard manner.¹¹ A Cribier-Edwards valve was mounted on a balloon at the tip of a deflectable steering catheter (Edwards Lifesciences Inc., Irvine, CA, USA). The guiding catheter was used to guide the device up the abdominal and thoracic aorta to the AV. Prior to deployment, the correct placement of the prosthesis across the AV was confirmed by fluoroscopy, aortography, and also, after the initial patients (who received transthoracic echocardiogra-

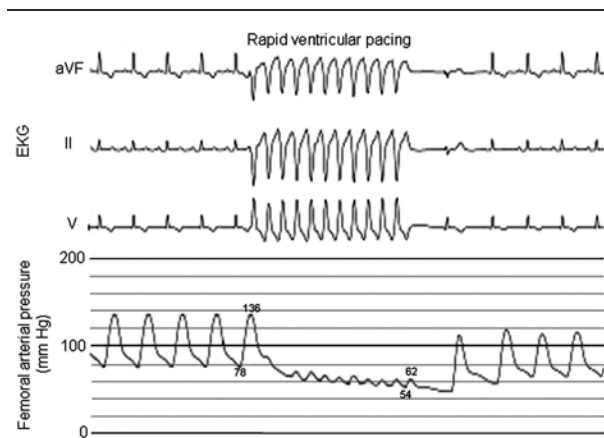


FIGURE 1 Femoral arterial pressure tracing showing marked hypotension and decreased pulsatile flow during rapid right ventricular pacing. EKG = electrocardiogram.

phy; *cf.* below), routine transesophageal echocardiography.

To prevent movement and possible ejection of the device during valve deployment, rapid right ventricular pacing was used to minimize pulsatile flow through the AV at the time of prosthesis implantation.¹⁵ Test pacing was first performed at a rate of 220 min⁻¹. The rate was reduced until reliable capture was observed and a reduction in systolic arterial pressure less than 60 mmHg was achieved (Figure 1). Following placement of the valve prosthesis, angiographic (and later also transesophageal echocardiographic; *cf.* below) examinations were performed to assess prosthetic valvular function and coronary artery patency. If a significant paravalvular leak was identified, balloon dilatation of the prosthesis was performed to further expand the mesh stent.

Anesthetic management

The anesthetic management underwent a significant evolution during the initial multidisciplinary learning curve associated with this novel procedure. On the day of the first scheduled procedure, the anesthesiologist on call was asked to help in the administration of conscious sedation in the cardiac catheterization laboratory. The initial four procedures were then carried out under monitored anesthesia care. As it became evident that patients regularly required surgical vascular repair at the access site (*cf.* below), the following 36 procedures were performed under general endotracheal anesthesia. It also became evident that endotracheal intubation facilitated the use of routine intraoperative transesophageal echocardiography (not done in the first four patients) to aid in the confirmation of accurate prosthetic valve function and placement. In

TABLE II Anesthetic management and intraoperative characteristics

Patients		<i>n</i> = 40 (100%)	
Type of anesthetic	Monitored anesthesia care*	4	(10%)
	General anesthesia	36	(90%)
Maintenance agent(s)	Desflurane	18	(46%)
	Sevoflurane	7	(18%)
	Desflurane & propofol	3	(8%)
	Desflurane & propofol & remifentanyl	3	(8%)
	Desflurane & remifentanyl	5	(13%)
	Sevoflurane & propofol	1	(3%)
	Sevoflurane & remifentanyl	2	(5%)
Duration	< 2 hr†	2	(5%)
	2–3 hr	7	(18%)
	3–4 hr	16	(40%)
	4–5 hr	10	(25%)
	> 5 hr	5	(13%)
Vasopressors used	Phenylephrine	30	(75%)
	Ephedrine	12	(30%)
	Dopamine	1	(3%)
	Epinephrine‡	3	(8%)
	Calcium chloride‡	2	(5%)
Minimum intraoperative systolic blood pressure§	70–79 mmHg	3	(8%)
	80–89 mmHg	3	(35%)
	90–99 mmHg	14	(35%)
	100–109 mmHg	3	(8%)
	110–119 mmHg	3	(8%)
> 119 mmHg	3	(8%)	
Intraoperative transfusion	1 U packed red blood cells	1	(3%)
	2 U packed red blood cells	2	(5%)
	3 U packed red blood cells	1	(3%)
	> 3 U packed red blood cells	1	(3%)

*Two (of the first four) patients received monitored anesthesia care for the valve placement, then general anesthesia for vascular repair. †The two patients whose procedure lasted less than two hours both suffered an intraoperative cardiac arrest. ‡Epinephrine and calcium chloride were used as resuscitative agents during the intraoperative cardiac arrests. §Indicates blood pressure in the pre-pacing stage of the procedure. ||One patient underwent massive transfusion (19 U of packed red blood cells, 20 U of platelets, 9 U of fresh frozen plasma, and 10 U of cryoprecipitate; *cf.* body text).

all patients, large-bore peripheral intravenous access, radial arterial catheters, and defibrillator pads were placed preoperatively.

Following induction of general anesthesia, the next 36 patients were maintained with an inhalational agent or a combination of inhalational and intravenous agents (Table II). All of these patients were paralyzed with a non-depolarizing muscle relaxant. Transjugular central venous catheters were inserted by the anesthesiologist in five patients, and all patients had femoral venous access placed by the cardiologist (*cf.* above).

As mentioned, transesophageal echocardiography, performed by a dedicated specialized cardiologist, was introduced as a routine monitoring modality in these patients. Intraoperative hypotension (systolic arterial pressure < 90 mmHg) was treated with intravenous crystalloid infusion as well as phenylephrine and/or ephedrine boluses. For persisting hypotension, phenylephrine, norepinephrine, and/or dopamine infusions were prepared and administered as indicated.

Following the procedure, tracheal extubation was undertaken when the patients were awake in the cardiac catheterization laboratory, whereas others were transferred, ventilated, to the cardiac care unit (CCU). All patients were monitored overnight in the CCU.

Results

The patients' preoperative baseline characteristics are listed in Table I. Fifty-eight percent of patients had a logistic EuroSCORE $\geq 20\%$ (*cf.* Methods: Patient selection); the mean logistic EuroSCORE was $25 \pm 15\%$ [95% confidence interval (CI), 20.2–29.8%]. The remainder were accepted due to significant comorbidities, including advanced age (> 85 yr), involvement of more than one valve, severe chronic obstructive pulmonary disease, multiple cerebrovascular accidents and carotid atherosclerosis, marked pulmonary hypertension, and debilitating arthritis that was felt to preclude rehabilitation after open heart surgery.

The prosthesis was placed successfully in 33/40 patients (83%). The reasons for an unsuccessful procedural outcome included an inability to deliver the prosthesis to the correct position in five patients and deployment in the aortic arch in two patients (Figure 2).

Patients tolerated general anesthesia well, with no anesthesia-related complications. Table II summarizes details on the anesthetic management of these patients. Reduced doses of anesthetic agents appropriate for the advanced age, multiple co-morbidities, and severe valvular disease of these patients were used and carefully titrated. For the management of hypotension, phenylephrine was administered to 30 patients, while ephedrine was used in 12 patients. Dopamine was used in a single individual as an adjunct to phenylephrine and ephedrine. Eight patients required no vasopressors. Epinephrine and calcium chloride were used in two instances during resuscitation following cardiac arrest.

Two patients sustained complications related to rapid ventricular pacing. Both occurred after pacing for balloon valvuloplasty, but prior to placement of the prosthetic valve. Ventricular fibrillation occurred in one patient who responded immediately to external

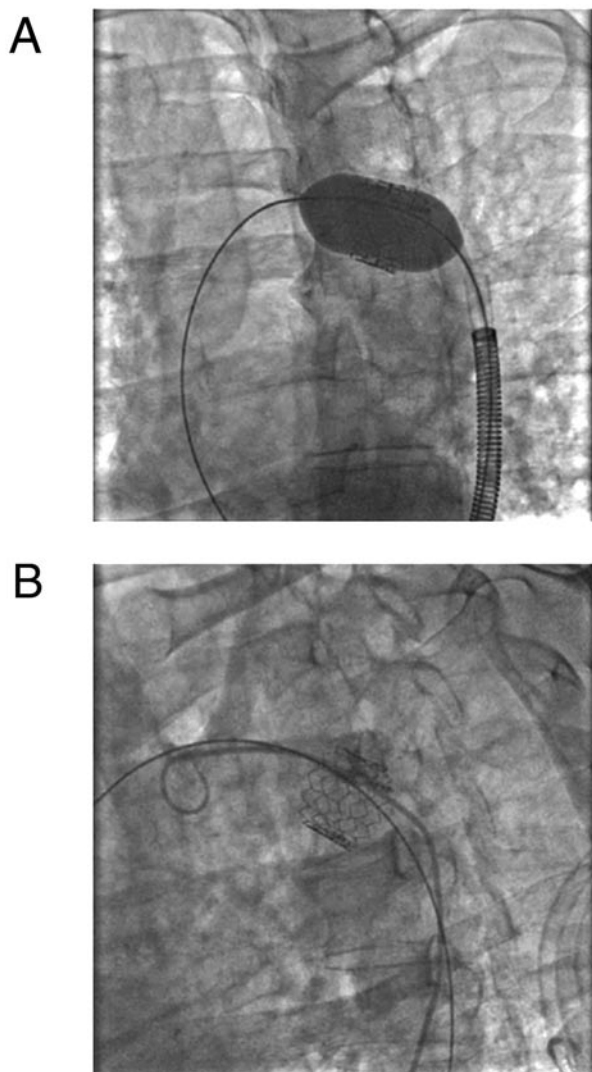


FIGURE 2 A) Prosthetic valve deployment in the aortic arch after valvuloplasty and subsequent unsuccessful initial deployment within the native aortic valve due to prosthesis embolization. B) Aortogram after valve deployment in the aortic arch. From an anesthetic perspective, the patient tolerated the procedure well with no obvious perioperative complications from the prosthesis placement in the aortic arch. With a good result from the balloon valvuloplasty, the patient subsequently underwent an uneventful colectomy for obstructing colorectal cancer and then an elective open aortic valve replacement three months later.

defibrillation. The second patient developed profound hypotension. Asystolic cardiac arrest ensued and, despite attempted resuscitation with epinephrine (3 mg), calcium chloride (1 g), and pacing, the patient died.

Following successful placement of the prosthetic valve, patients' hemodynamic parameters improved,

with the median calculated AV area increasing from 0.6 cm² (interquartile range, 0.5–0.7 cm²) to 1.7 cm² (interquartile range, 1.4–2.0 cm²; Mann-Whitney test, $P < 0.0001$; patients with available post data on the AV area, $n = 32$) and the mean transaortic gradient decreasing from 49 mmHg (median; interquartile range, 32–60 mmHg) to 11 mmHg (interquartile range, 9–16 mmHg; Mann-Whitney test, $P < 0.0001$; patients with available post data on the mean transaortic gradient, $n = 32$). Paravalvular aortic insufficiency, when present, was graded mild in severity. In association with improved hemodynamics, five patients required intravenous antihypertensive therapy after deployment of the prosthesis. Upon completion, all patients who had experienced no procedural complications were extubated and transported to the CCU. The median anesthetic time for the procedure was 3.5 hr (range, 1.25–7.25 hr).

Significant morbidity and mortality developed from vascular complications secondary to the placement and removal of the large-bore sheath in the ilio-femoral artery. One of the early patients in this case series died intraoperatively due to aortic rupture from the steering catheter. Another death resulted from postoperative multi-organ failure following a hemorrhagic cardiac arrest after femoral sheath removal and subsequent massive transfusion (*cf.* Table II). Overall, procedural blood loss was variable. Five patients required intraoperative transfusion of packed red blood cells, while eight additional patients were transfused during their hospital stay (*cf.* Tables II and III). As a result, the routine availability of a vascular surgeon to repair the femoral access site in the cardiac catheterization laboratory was incorporated as part of the standard management of these procedures.

Table III summarizes the in-hospital, post-procedure outcomes. The 30-day mortality was 13% (5/40 patients). Infection occurred in four patients. These included one case of *Staphylococcus aureus* septicemia, one case of infection at the access site after complex vascular repair, and urinary tract infections in two patients. All of these patients recovered with antibiotic therapy.

One patient experienced a postoperative cerebrovascular event. This individual made a full neurologic recovery.

Discussion

In this case series, we report on the first experiences with anesthesia for patients undergoing percutaneous retrograde AV replacement. Although surgical AV replacement is beneficial for improving patient symptoms and increasing life expectancy, it poses a

TABLE III In-hospital complications

Patients	n = 40	(100%)
Inability to deliver the prosthetic valve	5	(13%)
Prosthetic valve malposition	2	(5%)
Ventricular fibrillation	1	(3%)
Blood transfusion	13	(33%)
Postoperative infection	4	(10%)
Access site	1	
<i>Staphylococcus aureus</i> septicemia	1	
UTI	2	
TIA/CVA within 30 days	1	(3%)*
30-day mortality	5	(13%)
Intraprocedural mortality	1	(3%)

*Complete resolution with no neurologic sequelae.

TIA = transient ischemic attack; CVA = cerebrovascular accident;

UTI = urinary tract infection.

significant risk to the elderly with multiple medical problems, rendering these patients poor operative candidates.⁴ Patients may also be nonsurgical candidates due to marked aortic calcification or previous cardiac surgery. In these individuals, percutaneous AV replacement may become an alternative in the management of aortic stenosis. Other inherent potential advantages of the percutaneous approach compared to open heart surgery include avoidance of cardiopulmonary bypass and aortic cross clamping, avoidance of sternotomy and minimization of surgical stimulation, reduction in the need for postoperative ventilation and intensive care unit stay, and possible associated cost savings.

The anesthetic management of the initial four procedures carried out at our institution consisted of monitored anesthesia care with conscious sedation, in accordance with the original plan of the interventional cardiology team. We found, however, that performing the procedure under general endotracheal anesthesia offered distinct advantages. These include the facilitation of routine intraoperative transesophageal echocardiography to assist in the precise placement of the prosthesis prior to deployment and to assess for complications following placement. General anesthesia also allowed for improved patient tolerance of prolonged procedures and eased the process of surgical repair of the access site at the end.

The anesthetic risks for patients with severe aortic stenosis are well documented.^{16,17} We found that percutaneous AV replacement, however, carries with it unique additional challenges. Rapid ventricular pacing used during this procedure assists with the precise placement of the valve prosthesis. Induced ventricular tachycardia, however, does not allow sufficient diastolic

time for the hypertrophied ventricle to fill, producing a temporary state of decreased coronary perfusion in the face of increased myocardial oxygen demand. This has the potential of inducing profound arrhythmias and myocardial ischemia. Although rapid ventricular pacing was tolerated by most, two patients sustained significant complications. Our current practice, therefore, is to minimize pacing duration and to stabilize the patients' blood pressure with vasopressors prior to repeat pacing. We have found that close communication between the cardiologist and the anesthesiologist is critical during this part of the procedure. Alternative methods of temporarily reducing cardiac output during valve deployment include administration of adenosine,¹⁸ balloon occlusion of venous return to the right or left atria,¹⁹ as well as electrically inducing ventricular fibrillation.²⁰ However, each of these techniques is associated with its own set of complications.

Vascular injury was a significant cause of morbidity and mortality. All patients now undergo preoperative imaging of their vascular access sites to determine if the ilio-femoral artery lumen is sufficient to allow placement of the guiding catheter. Imaging also delineates the extent of any arterial calcification and tortuosity that may impair catheter advancement or surgical repair. Thirty-three per cent of our patients experienced procedural blood loss significant enough to warrant perioperative transfusion of red blood cells. Major vascular trauma must be anticipated as an intraoperative complication of this procedure. Hemorrhage also should be anticipated postoperatively, however, since ongoing bleeding from ilio-femoral vascular injury may be insidious and present in a delayed fashion (e.g., as retroperitoneal hematoma). Other perioperative complications to be anticipated by the anesthesiologist include cardiac tamponade, coronary artery ostia occlusion during device deployment, coronary artery embolization, and other complications associated with prosthetic valve maldeployment.

As a result of the lessons learned in the management of this first series of patients, anesthesiology involvement now routinely begins preoperatively, as all patients these days are seen in the anesthesia pre-assessment clinic for preoperative consultation and optimization. Whereas it remains difficult to decide when a patient, deemed by definition to be a nonsurgical candidate, is in fact a non-anesthetic candidate, our observation that there were no adverse events specifically related to anesthesia is somewhat reassuring. However, due to the number of observed and potential procedural and perioperative complications, all patients now receive invasive arterial and central venous pressure monitoring, in addition to the femo-

ral access secured by the cardiology team. Finally, the construction at our centre of a new operating theatre dedicated to advanced cardiac procedures has very recently allowed us to perform these procedures in the main operating room suite (with cardiopulmonary bypass pumps in close proximity/on standby), as opposed to (from an anesthesiologist's perspective), a remotely located cardiac catheterization laboratory. We believe that the comprehensive perioperative involvement of anesthesiology as part of a multidisciplinary team has significantly contributed to the improved outcomes achieved after the first series of patients.²¹

In summary, percutaneous replacement of the AV by a retrograde femoral approach is a new and exciting development in the treatment of aortic stenosis. Although it represents an intriguing alternative for those patients not considered candidates for conventional surgery, there are a number of significant concerns, as this case series demonstrates. Whereas the vast majority of these sick patients tolerated general anesthesia well, serious and, at times, spectacular complications, including major hemorrhage from vascular injury, arrhythmia and myocardial ischemia following rapid ventricular pacing, and prosthetic valve maldeployment, must be anticipated by the anesthesiologist and, where possible, managed in an expeditious fashion. To an extent, these complications may be part of a learning curve that accompanies any novel technique such as this.²¹ Future developments that may improve patient safety with this procedure include smaller profile catheters and sheaths that minimize trauma to the vascular access site, alternative methods of reducing left ventricular outflow during device placement that may be more cardioprotective, and the use of intracardiac echocardiography to possibly allow this procedure to be performed under local anesthesia.

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