



Centre universitaire de santé McGill
McGill University Health Centre

**Technology Assessment Unit of the McGill
University Health Centre (MUHC)**

Aortic valve bypass (apicoaortic conduit) in adult degenerative aortic stenosis

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PRINCIPAL MESSAGES

Aortic valve bypass (AVB, apicoaortic conduit) is a procedure for the relief of severe calcific aortic stenosis in patients at high risk of complications from surgical valve replacement. The documented clinical experience with this procedure is not yet substantial.

An alternative, transcatheter aortic valve implantation (TAVI), is relatively well-documented, and is being carried out at the MUHC.

The available evidence suggests that AVB is associated with a higher perioperative mortality than TAVI. It is not associated with the need for new pacemaker implantation. In other respects, including costs, the two procedures appear to be fairly comparable.

It is recommended that AVB should be available at the MUHC for those cases in which there is agreement that it is likely to have a better outcome than TAVI. When either procedure is feasible there is as yet no reason to use AVB in preference to the TAVI procedure.

At the MUHC the choice between these two procedures should be made by the existing joint committee.

LIST OF ABBREVIATIONS

AS	aortic valve stenosis
AV	aortic valve
AVB	aortic valve bypass
CABG	coronary artery bypass graft
CHF	congestive heart failure
CPB	cardiac pulmonary bypass
LVAD	left ventricular assist device
MUHC	McGill University Health Centre
NYHA	New York Heart Association
TA	transapical
TAVI	transcatheter aortic valve implantation
TF	transfemoral

EXECUTIVE SUMMARY

Background

Aortic valve bypass (AVB; apicoaortic conduit) involves the surgical implantation of a valved conduit between the apex of the left ventricle and the aorta, with the objective of relieving obstruction of the left ventricular outflow tract. It has a 40-year history of use in patients with congenital obstructions and idiopathic hypertrophic sub-aortic stenosis and more recently has been adopted for the relief of symptomatic degenerative aortic valve stenosis (AS) in patients who are poor candidates for surgical aortic valve replacement. These patients are also eligible for consideration for transcatheter aortic valve implantation (TAVI). This review was undertaken to determine the health benefits and risks of AVB in adults, and to compare the experience and costs with recent MUHC experience and published results for TAVI.

Method

We conducted a systematic review of the literature for aortic valve bypass in patients with degenerative aortic stenosis, and reviewed recent randomized controlled trial and registry publications for the latest experience with TAVI.

Results

Literature review

There was one systematic review and no randomized controlled trials. Twenty-three reports of retrospective or prospective case series were identified, describing around 185 adult patients with AVB implantation for degenerative AS, along with 37 case reports.

Effectiveness

For all studies that reported mortality (106 patients), perioperative mortality was 12.3% (the 11% in the most recent study). Five percent of the survivors were reported as needing subsequent surgery for complications of the procedure or implant dehiscence or malfunction. Follow-up in these series was generally short, around 2 years, and mortality to the end of follow-up was 37.7%. Survivors were reported as having symptomatic and functional improvement. There were no reports of patients needing new insertion of a pacemaker.

Costs

The estimated cost per procedure for AVB was approximately \$28,400 with the costs of the equipment accounting for 63% of the total.

Recent experience with TAVI

In a recent randomized trial of TAVI versus best medical management in patients considered at high risk or ineligible for surgery, 1.1% of patients considered ineligible for surgery who were randomized to TAVI died within 24 hours of TAVI and 11 (5%) died in the first 30 days after the procedure. One-year survival after TAVI was superior to standard medical management (30.7% mortality versus 50.7%). The rate of pacemaker insertion in the first 30 days of follow-up was lower than that in the group receiving standard medical management (3.4% vs 5.0%). In recent TAVI registry studies the procedural success rate was >95%, and the 30-day mortality rate was 8-12.7%. Major access site complications were reported in 1.9-19.5% of patients and 4.9-39.3% of patients required a permanent pacemaker.

The estimated cost per procedure for TAVI at the MUHC was approximately \$26,100.

Conclusions

There is evidence that the AVB procedure is capable of substantially relieving the symptoms, and almost certainly increasing the life expectancy, of patients with severe calcific aortic stenosis. (It is possible that the proposed new procedure for introduction of the apical cannula may further improve outcomes). However, data on which to base prediction of outcomes is insubstantial.

The TAVI procedure is currently being successfully carried out at the MUHC. The short-term outcomes of the procedure are better documented.

It is possible that some cases may be identified for whom the AVB procedure is preferable to TAVI. But apart from such cases there is no evidence that AVB would be preferable to TAVI when both are feasible. The reported periprocedural mortality and overall mortality of AVB appears to be higher than TAVI, and the rate of pacemaker insertion is lower. AVB and TAVI do not appear to differ substantially in other parameters, including cost.

Recommendations

- **It is recommended that the choice of intervention for patients with severe calcific aortic stenosis (surgical aortic valve replacement, TAVI, AVB) continue to be made by the existing joint committee.**

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- **The department of cardiovascular surgery should be authorised to obtain the necessary expendable equipment for AVB and to use this procedure when there is agreement that it is likely to have a better outcome than TAVI.**
 - **A detailed case registry should be maintained and reviewed in one year at the latest.**
 - **For those cases in which both procedures appear feasible there is no reason to replace the better documented TAVI procedure by AVB at this time.**

SOMMAIRE

Contexte

Le pontage de la valve aortique (PVA; tubulure apico-aortique) implique l'implantation chirurgicale d'une tubulure avec valve entre l'apex du ventricule gauche et l'aorte dans le but de palier à une obstruction de l'éjection ventriculaire gauche. Cette approche est utilisée depuis plus de 40 ans chez les patients présentant des obstructions congénitales et des sténoses idiopathiques hypertrophiques sous-aortiques et plus récemment, a été adoptée pour soulager les patients avec une sténose symptomatique et dégénérative de la valve aortique (VA) et qui sont de mauvais candidats pour le remplacement chirurgicale de la valve aortique. Ces patients sont aussi éligibles pour l'implantation par cathétérisme d'une valve aortique (ICVA). Cette revue fut réalisée pour déterminer les bénéfices pour la santé et les risques du PVA chez l'adulte et pour comparer les expériences et les coûts de cette technologie avec l'expérience récente du CUSM avec l'ICVA et les résultats qui ont été publiés.

Méthodologie

Une revue systématique de la littérature fut menée sur le pontage de la valve aortique chez les patients avec une sténose aortique dégénérative, de même qu'une revue des études randomisées et des publications portant sur l'expérience la plus récente avec l'ICVA.

Résultats:

Revue de littérature

Une revue systématique fut identifiée et aucune étude randomisée ne fut trouvée. Vingt-trois études rétrospectives ou prospectives de séries de cas furent identifiées impliquant environ 185 patients ayant subi un PVA pour une sténose aortique dégénérative, de même que 37 études de cas.

Efficacité clinique

Selon les études rapportant des décès (106 patients), le décès peropératoire était de 12,3% (11% chez l'étude la plus récente). Cinq pourcent des survivants ont nécessité une seconde chirurgie pour complications, déhiscence ou dysfonction. Le suivi mentionné dans ces séries était généralement court, environ 2 ans, et la mortalité à la fin de ce suivi était de 37,7%. Les survivants présentaient une amélioration

fonctionnelle et symptomatique. Aucun rapport ne mentionnait le besoin de l'implantation d'un stimulateur cardiaque.

Coûts

Le coût estimé d'une procédure PVA était d'environ 28 400 \$, incluant le coût de l'équipement qui représentait 63% du coût total.

Expérience récente avec l'ICVA

Dans une étude randomisée récente comparant l'ICVA et le meilleur management médical des patients à haut risque ou non-éligibles pour la chirurgie, 1,1% des patients non-éligibles pour la chirurgie et choisis de façon randomisée pour l'ICVA sont décédés en deçà de 24 hres après cette procédure et 11 patients (5%), en deçà de 30 jours. Le taux de survie à un an après l'ICVA était supérieur à celui d'un management médical standard (30,7% de décès vs 50,7%). Durant les premiers 30 jours de suivi, le taux d'implantation d'un stimulateur cardiaque était plus faible que chez les patients sous management médical standard (3,4% vs 5,0%). Selon des études récentes sur l'ICVA, le taux de succès de cette procédure était > 95% et le taux de décès après 30 jours était de 8-12,7%. Des complications majeures au site d'accès furent rapportées chez 1,9 à 19,5% des patients et 4,9 à 39,3% des patients ont requis un stimulateur cardiaque.

Le coût estimé d'une procédure d'ICVA au CUSM était d'environ 26 100 \$.

Conclusions

Il existe des preuves selon lesquelles la procédure PVA peut soulager de façon substantielle les symptômes des patients avec une sténose aortique calcifiée sévère, et peut presque certainement augmenter leur espérance de vie. (Il est possible que la nouvelle technique proposée pour l'introduction de la canule apicale puisse améliorer un peu plus les résultats de cette technologie). Cependant, les données supportant cette prédiction sont peu fiables.

La procédure ICVA est couramment utilisée au CUSM et les résultats à court terme sont mieux documentés.

Il est possible que l'on puisse identifier certains patients chez qui le PVA est plus indiqué que l'ICVA. Mais à l'exception de ces quelques cas, il n'y a aucune évidence que le PVA est mieux indiqué que l'ICVA lorsque les deux procédures sont réalisables. Les décès du PVA lors de la procédure et les décès totaux semblent supérieurs à ceux de l'ICVA et le taux d'implantation d'un stimulateur cardiaque est plus faible. Le PVA et l'ICVA ne semblent pas différer substantiellement au niveau d'autres paramètres, incluant le coût.

Recommandations

- **Il est recommandé que le choix de l'intervention pour traiter les patients avec une sténose aortique calcifiée sévère (chirurgie de remplacement valvulaire aortique, PVA, ICVA) demeure la prérogative du comité conjoint actuel.**
- **Le département de chirurgie cardiovasculaire devrait être autorisé à faire l'acquisition des fournitures jetables requises pour le PVA et à utiliser cette procédure lorsqu'il y a consensus à l'effet que les résultats seraient meilleurs qu'avec l'ICVA.**
- **Un registre détaillé devrait être complété et revu après un an, au plus tard.**
- **Concernant les cas où les deux procédures peuvent être considérées, il n'y a aucune raison pour remplacer en ce moment la procédure ICVA, mieux documentée, par la procédure PVA.**

Aortic valve bypass (apicoaortic conduit) in adult degenerative aortic stenosis

1. BACKGROUND

Calcific aortic valve stenosis (AS) is a common disease of the elderly. In advanced forms it is associated with severe morbidity and high mortality¹. While the majority of cases are correctable by surgical aortic valve replacement, there remain a number of patients who, for reasons of age and co-morbidity, are considered too frail to undergo this procedure¹, who have had previous coronary artery bypass graft (CABG) surgery or have extensive calcification of the aorta (“porcelain aorta”), both of which put them at high risk of complications. However, in 2002, transcatheter aortic valve implantation (TAVI) became available for such patients, and this procedure is now carried out at the MUHC.

Over the past several decades, a small number of patients with AS have been treated surgically with aortic valve bypass (AVB), which was originally developed to treat people with congenital aortic stenosis not amenable to other forms of surgery (See Appendix 2). The procedure consists of the insertion of a valved duct into the apex of the left ventricle to convey blood into the ascending or descending aorta, thereby providing an additional outlet for blood and relieving pressure overload on the left ventricle. The current report is produced at the request of Mr G Stoopler (Administrative Director, Surgical Mission, MUHC) to evaluate an application by the Department of Cardiovascular Surgery (Dr Benoit De Varennes) to carry out this procedure, using a newly developed device for the implantation of the conduit into the left ventricular apex (Correx, Inc).

2. OBJECTIVES

- To estimate the health benefits and risks of aortic valve bypass in adults with degenerative aortic stenosis who are considered ineligible for surgical aortic valve replacement due to high operative risk.
- To compare the estimated health outcomes of AVB with the outcomes that might be expected from the alternative procedure, TAVI, which is currently offered to such patients at the MUHC.
- To compare the costs of the two procedures, from the point of view of the MUHC
- To develop recommendations to guide MUHC policy on this issue.

3. METHODS

3.1. Systematic review of the literature

We searched the following databases for systematic reviews: Cochrane Reviews (to November 15, 2010), Centre for Reviews and Dissemination (CRD; to November 15, 2010; encompasses Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), and Health Technology Assessment (HTA) Database).

We searched the following databases for clinical trials, observational studies, and case reports: PubMed (1947-present; October 31, 2010), EMBASE (1980-2010 Week 42), ISI Web of Science (Science Citation Index, 1899-present; Conference Proceedings Citation Index, 1990-present; October 31, 2010).

Searches involved combinations of the following textwords: apico-aortic (and spelling variations), apical aortic (and spelling variations), “aortic valve bypass” (and variations), “porcelain aorta” with “aortic stenosis”. A detailed search strategy is given by database in Appendix 1. Search terms were in English, but there was no other language restriction in the initial search.

In addition we searched the Cardiothoracic Surgery Network (ctsnet.org) for additional relevant material, explored ‘Related’ links on PubMed as indicated, scanned the citation lists of retrieved papers, and queried experts.

3.2. Meta-analysis

Since the initial scoping search indicated that there were little or no data based on controlled trials, no formal meta-analysis was planned. Perioperative mortality, rates of reoperation, and death during follow-up were summarized across the studies.

3.3. Cost analysis

We calculated costs from the point of view of the MUHC for the AVB procedure and post procedure hospitalization. We excluded costs of the standard workup for aortic stenosis, follow-up visits, treating complications and physician fees. The average resource use was estimated by Dr. de Varennes. The unit costs of operating room, recovery room, ICU and hospitalization were the average costs at MUHC in 2009, estimated by the Department of Finance, MUHC.

4. LITERATURE REVIEW: EFFECTIVENESS

4.1. Health technology assessment reports/Systematic reviews

We identified one systematic review, Elmistekawy et al, 2010², and no health technology assessments.

The authors of the systematic review examined the use of aortic valve bypass (apicoaortic conduit) in severe aortic stenosis. They did not find any randomized controlled trials, but found 11 uncontrolled observational retrospective studies in adult patients operated on for aortic stenosis of any etiology, and 21 individual case reports. They concluded that:

Apico-Aortic Conduit has been used safely as a surgical alternative option for patients with left ventricular outflow tract obstruction or severe calcified aortic valve stenosis. It is a valuable technique especially in the subset of high-risk patients with multiple co-morbidities, ineligible for TAVI, and/or at risk of a sternal re-entry for stenotic aortic valve surgery or with a porcelain aorta.²

The review did not include a detailed discussion of adverse events and did not assess costs.

4.2. Randomized controlled trials

We did not identify any RCTs that compared AVB with other therapies.

4.3. Nonrandomized studies and case reports

The systematic search retrieved 212 articles of interest, of which 98 were retained after title/abstract screen (excluding those concerned with an exclusively pediatric population or a procedure other than AVB), and 23 after full-text review.

All 23 articles described non-randomized studies (prospective cohort, retrospective chart review, and case series)³⁻²⁵. Two described an adult population but did not include any adults with degenerative AS^{16, 19}. Of two studies that described surgical procedures in both adults and children, one did not present outcomes for adults separately¹⁰, while another did not present outcomes for AVB separately²⁵. The remaining 19 studies are summarized in Table 3. Where multiple reports updated the same series (eg, Gammie 2006⁶, Gammie 2008⁴, White 2007⁵, and Vliek 2010³), the most recent update that provided the needed information was used. The imaging study by White et al⁵ contains minimal clinical details and indicates that these patients were described elsewhere⁶. One study of 18 adults indicated that 4 had calcific aortic stenosis, but did not ascribe outcomes to these 4¹⁷, however since all patients were adults undergoing AVB, they were included in the summary, to a total of 185 patients.

In addition, we identified 37 individual case reports that included reports of unusual surgical approaches and adverse events; these are summarized in Table 4²⁶⁻⁶².

Five nonrandomized studies or case reports were excluded because they were in a language other than English, French, or German, and the English-language abstract did not include clinical details. These included a Russian-language case series of 16 patients⁶³.

The literature on this method covers nearly 40 years of practice, with evolution of techniques as outcomes were observed. In earlier series, patients generally had

complex outflow tract obstruction of congenital origin or associated with idiopathic hypertrophic subaortic stenosis and a history of previous cardiac surgery, while in later reports, patients tended to be elderly with symptomatic AS, porcelain aorta and/or previous CABG, and/or multiple comorbidities (lung pathology, diabetes). As this latter group is our population of interest, we have focused our attention on the later reports. The largest series of patients with acquired AS were those described by Gammie^{3, 4, 6} and Brown⁸. Together, Gammie and Brown report having performed the procedure in >130 patients⁸, but overall outcomes and complication rates have not been reported for all these.

4.4. Clinical outcomes

4.4.1. Indications for aortic valve bypass

At the time of all but the most recent of these reports the TAVI procedure was not available and the alternative options to AVB were surgical valve replacement or medical treatment. Indications for aortic valve bypass described in these case series and case reports were symptomatic AS with porcelain aorta/extensive calcification of aorta, previous coronary artery bypass graft (CABG) surgery with patent grafts, previous sternotomy, previous radiotherapy to the mediastinum. The procedure is contraindicated for patients with aortic valve insufficiency or small left ventricular volume.

4.4.2. Perioperative mortality

In the 106 adult patients described in the case series where mortality was reported, 13 (12.3%) died during the procedure or immediately postoperatively. In the most recent report, by Vliek et al³ (47 patients with a mean follow-up of 21.7±17 months), the average mortality was 11% (5/47 patients), four of whom died early in the series. In the largest series (a description of surgical method by Brown, 2007⁸, 56 patients), perioperative mortality was not reported.

Fatal complications during surgery included inability to oxygenate the patient in the operating room due to severe lung disease, inability to wean the patient from cardiopulmonary bypass (CPG), cardiac arrest during the procedure, tearing of the cardiac apex with haemorrhage during stent placement, coagulopathy (both bleeding diathesis and thrombosis were recorded), and intraoperative gastrointestinal hemorrhage (Table 3). Fatal complications in the immediate postoperative period were recurrence of respiratory insufficiency, myocardial infarction, coagulopathy, and sepsis. A patient receiving post-discharge anticoagulation for emboli presented in cardiac arrest and was found to have an International Normalized Ratio (INR) of 11 and a massive lateral chest wall hematoma⁴. A case report described fatal thrombus at the aortic root with occlusion of coronary artery ostia and CABG insertions⁴², in a patient with a complicated postoperative course requiring left ventricular assist device (LVAD) implantation.

4.4.3. Significant early complications/reoperations

In the above reports there is little systematic reporting of complications. In the 171 survivors described in the case series, 9 (5.3%) were reoperated on shortly after the procedure, principally for control of bleeding due to dehiscence or bleeding diathesis (Table 3). The rate of perioperative stroke for all patients was 2.2%, which likely represents underreporting.

Four recent case reports described thrombus formation in the ascending aorta^{31, 35, 42, 52}, one of which proved fatal⁴². In response to that report, Gammie and Brown, 2010⁶⁴, indicated that they had not observed any thrombus formation in their series of >100 patients, in the absence of anticoagulation other than aspirin.

4.4.4. Late mortality/ late complications

Mean follow-up in the later case series (those that described the procedure on patients with degenerative AS) was usually around 2 years, with up to 5 years follow-up for some patients (Table 3). Mean follow-up in younger patients could be significantly longer, up to 25 years in some cases⁶⁵.

Twenty seven of 93 surviving (29%) patients in studies reporting mortality died during follow-up, the majority for unrelated or undetermined reasons. Five patients randomized to medical management in the PARTNER trial (TAVI versus best medical management)⁶⁶ were described as undergoing aortic valve bypass plus aortic valve replacement, and four died. No other details were provided.

Other significant complications included dehiscence of the conduit from the apex, resulting in pseudoaneurysm or hemorrhage. Dehiscence could present with sudden death, renewed congestive heart failure (CHF) or anginal symptoms, or be observed upon follow-up imaging. Dehiscence/disruption has been related to early operative technique with direct implantation of the conduit or inadequate reinforcement, uncontrolled hypertension, infection, myocardial infarction or trauma (Table 3, Table 4).

Calcification or thrombosis of the implanted valve, or valvular insufficiency leading to the need for replacement, has been described in patients with longer follow-up. In one early series in 20 pediatric/young adult patients the rate of conduit survival was 80±9% at 3 years and 53±11% at 7 years⁶⁷.

4.4.5. Functional and hemodynamic improvement

Most patients who survived to follow-up experienced a sustained functional improvement, with improvement from NYHA Class III or IV to NYHA Class I or II (Table 3). The majority, who had received a bioprosthetic valve, did not require ongoing anticoagulation, although the lack of need for anticoagulation has been questioned^{31, 42, 68}.

Hemodynamic measurements showed a clinically significant reduction in AV gradient and peak AV flow-rates between pre-procedure and pre-discharge measurements,

which was maintained into follow-up (Table 3). The follow-up hemodynamic studies described in Vliek et al³ suggest that AVB arrests the progression of AS, with there being no change in aortic valve area between pre-operative and follow-up imaging. Stroke volume increased, and the partitioning of flow between the native valve and the conduit was, on average, unchanged from immediately after surgery to follow-up. However, follow-up was short: the mean follow-up was <2 years and only 21 of their cohort of 47 patients had 6-month echocardiography results.

4.5. Meta-analysis

Given the lack of comparator data, and the small and highly selected group of patients, no meta-analysis was conducted. Summary results were calculated as described above: interoperative/perioperative mortality, 12.3%, reoperation, 5.3%, stroke, 2.2%, and death during follow-up 29%.

4.6. Costs

The costs considered are those incurred by the MUHC. They include direct costs of supplies, expendable equipment and salaries (excluding MD salaries which are not paid by the MUHC) but do not include costs of complications. The cost of the TAVI procedure at the MUHC has been the object of a recent TAU report (Report 45)⁶⁹ in which the costs of pre-operative evaluation and special tests were estimated to average \$3,714 per TAVI procedure. We assumed that the preoperative evaluation for AVB and TAVI would be identical. As in the TAVI report⁶⁹, for this cost analysis we excluded the costs of complications, and of costs of effects on health care use (eg, emergency room visits for angina and CHF) for which there was insufficient data.

The estimated cost per procedure for AVB was approximately \$28,400 (see Table 1). For a projected 10 patients undergoing the procedure, the total cost would be \$284,000.

Table 1 Estimated cost of the aortic valve bypass procedure

Item	Unit cost (\$)	Resource use (average)	Average cost (\$)
Preoperative evaluation			3,714.00
Anesthesia (Technician fees)	35 /hour	3.5 hours	122.50
Operating room	836/hour	3.5 hours	2,926.00
ICU (Nursing)	466/day	2 days	932.00
Hospitalization after procedures	333/day	8 days	2664.00
Equipment (shunt, disposables, etc.)	--	--	18,000.00
Sum	--	--	28,358.50

4.7. Alternate therapy: TAVI

At the present time neither TAVI nor AVB would be carried out in patients considered eligible for surgical valve replacement. There have been no direct comparisons of AVB and TAVI. For the purposes of comparison with AVB it is desirable to attempt to summarize the results that may be expected from the TAVI procedure.

4.7.1. RCT and recent registry studies of TAVI

Randomized controlled trial

A recent randomized controlled trial⁶⁶ compared TAVI with best standard care (valvuloplasty and medical management) in patients who were considered high-risk or ineligible for surgical valve replacement. Randomization was stratified, and results have been reported for patients who were considered ineligible, ie, had a predicted probability of 50% or more of death within 30 days or serious permanent disability by the Society of Thoracic Surgeons (STS) risk score. In the 179 patients randomized to TAVI (Edwards SAPIEN valve), 6 did not receive a heart valve, 2 (1.1%) died within 24 hours of the procedure, 3 (1.7%) had a major stroke, and 1 (0.6%) had a valve embolization. In the 30 days after the procedure, a total of 11 (5%) died. The 1-year death rate of those randomized to TAVI was 30.7%, compared to 50.7% in those randomized to best standard care (hazard ratio 0.55, 95% CI 0.40 to 0.74; $P < 0.001$). The rate of death from any cause or repeat hospitalization and the rate of cardiac symptoms were also significantly lower in those who had undergone TAVI. TAVI was associated with a higher rate of major strokes (5.0% versus 1.1%), major vascular complications (16.2% versus 1.1%), and major bleeding (16.8% versus 3.9%) at 30 days post-procedure. In both groups a high proportion of patients had pacemakers at baseline (23% TAVI and 19.5% control). The percentage of patients requiring a new pacemaker did not differ significantly at 30 days (3.4% TAVI vs 5% control) or at one year (4.5% TAVI vs 7.8% control).

Registries

Recent publications have reported results from Canadian and European registries of patients who have undergone TAVI^{2, 70-73}. These are presented in Table 5. The mean age was around 81 years, the procedural success rate >95%, and the 30-day mortality rate was 8-12.7%. Major access site complications were reported in 1.9-19.5% of patients, although definitions varied across reports, and 4.9-39.3% of patients required a permanent pacemaker, which may reflect the characteristics of the valves used, and local practice in pacemaker implantation⁷¹. In a recent review of these and other data, the overall best estimate of permanent pacemaker need was 14.2%, 5.4% in studies involving the Edwards valve and 20.8% in studies involving the CoreValve prosthesis⁷⁴.

The Canadian experience included 345 procedures in 339 patients between January 2005 and June 2009, using the Edwards valve (or variations), implanted by the transfemoral (TF) or transapical (TA) route. Procedures were performed on patients

considered at high risk or ineligible for surgical valve replacement, who were evaluated for TAVI by a multidisciplinary team. The success rate was 93.3%, the procedural death rate 1.7%, and the 30-day mortality rate 10.4%. Major access site complications occurred in 13% of patients, an equal rate in the TF and TA approaches. At 30 days, the rates of MI were 1.2%, stroke 2.3 % (3.0% by the TA and 1.7% by the TF route), sepsis 2.9%, need for permanent pacemaker 4.9% (3.6% by the TA route and 6.2% by the TF route), and need for hemodialysis 2.6%. At a median follow-up of 8 months, mortality was 22.1%. Subgroup analyses of those patients who were considered ineligible for surgical valve replacement due to frailty (as agreed on by 2 cardiac surgeons) or porcelain aorta, showed no differences between those with and those without these risk factors for procedural and 30-day mortality. Patients with frailty more frequently developed acute renal failure requiring dialysis, and those with porcelain aorta more frequently had valve malposition requiring implantation of a second valve.

4.8. Budget impact

The indications determining the selection of cases for AVB and TAVI are at present virtually identical, and the criteria which would determine the use of AVB in preference to TAVI remain to be defined. However, the estimated cost of the two procedures is comparable (AVB \$28,400, TAVI \$26,100⁶⁹, per case). In the TAVI report submitted on November 25, 2009, it was predicted that the annual TAVI rate would be approximately 30 per year, but it was recommended that use of this procedure should only follow on a review of all cases carried out in the following year. If it is assumed that the 10 AVB procedures will be carried out in patients who would otherwise have undergone TAVI the budget impact would be negligible (\$2,300 per case). However, if the 10 TAVI cases are to be carried out in patients who would otherwise have not been operated on the budget impact would be \$284,000.

5. DISCUSSION

It is possible, but not yet certain, that some cases will be identified for whom AVB would be preferable to TAVI. Since all TAVI procedures are at this time currently reviewed by a joint committee including surgeons and cardiologists, it is presumably this committee that would identify such cases.

Apart from the above, it is necessary to consider whether AVB should replace TAVI in patients in whom both procedures appear to be indicated. Comparison of the two procedures cannot be precise on the basis of presently available data. An approximate comparison is shown in Table 2 below.

Table 2 Summary of evidence, outcomes, and costs for AVB and TAVI

	AVB	TAVI	
Quality of evidence	Retrospective reports, case series	RCT ⁶⁶	Registries*
Number of procedures	~185	179	~3000
Periprocedural/perioperative mortality	12.3% [†]	1.1%	1.5-1.8%
30-day mortality	Not available	5% [◄]	8.0-12.7%
Stroke rate (30-day)	3.8% [◆]	6.7%	1.9-3.6%
Pacemaker implantation (30-day)	None reported	3.4%	4.9-39.3% [▲]
Available follow-up period	~2 years	1 year	8 months [‡]
Mortality to end of follow-up	37.7%	30.7%	22.1% [‡]
Cost per procedure	\$28,400	\$26,100	

* For details, see Table 5.

[†] Includes deaths resulting from the procedure, as well as intraoperative mortality.

[◄] ITT; in those who underwent TAVI, mortality was 6.4%.

[◆] Perioperative/in-hospital stroke rate.

[▲] Rate of pacemaker implantation was three-fold higher in the German registry (Zahn, 2010)⁷¹ than any other.

[‡] Results from Canadian registry (Rodés-Cabeau, 2010)⁷⁰; other registries did not report later follow-up.

The limitations of the above data must be noted. The evidence-base for AVB in patients with degenerative AS is small and consists of uncontrolled studies and case reports. The evidence-base for TAVI is more substantial, with RCT and moderate-sized registry studies. As would be expected, the perioperative mortality for AVB is substantially higher than the periprocedural mortality for TAVI, but 30 day mortalities cannot be compared. Mortality to the end of follow-up is higher, although not all studies for AVB reported mortality, and the figure is calculated for those studies that did. Furthermore, long-term mortality in such patients is probably largely determined by comorbidities and will be highly dependent on case selection. Both procedures have the potential to relieve symptoms and improve quality of life, although follow-up has been short. Based upon a cost-per-procedure calculation, the cost of the two procedures is comparable.

6. CONCLUSIONS

- There is evidence that the AVB procedure is capable of substantially relieving the symptoms, and almost certainly increasing the life expectancy, of patients with severe calcific aortic stenosis. (It is even possible that the proposed new procedure for introduction of the apical cannula may further improve

outcomes). However, data on which to base prediction of outcomes is insubstantial.

- The TAVI procedure is currently being successfully carried out at the MUHC. The short-term outcomes of the procedure are better documented.
- It is possible that some cases may be identified for whom the AVB procedure is preferable to TAVI. Apart from such cases there is as yet no evidence that AVB should be used in preference to TAVI when both are feasible. The reported periprocedural mortality of AVB appears to be higher than TAVI (approximately 12% versus 2%), and the need for pacemaker insertion lower (AVB 0. TAVI 3.4% [RCT], 14.2% [summary of all available evidence]) they do not appear to differ substantially in any other parameter, including cost.

7. RECOMMENDATIONS

- **It is recommended that the choice of intervention for patients with severe calcific aortic stenosis (surgical aortic valve replacement, TAVI, AVB) continue to be made by the existing joint committee.**
- **The department of cardiovascular surgery should be authorised to obtain the necessary expendable equipment for AVB and to use this procedure when there is agreement that it is likely to have a better outcome than TAVI.**
- **A detailed case registry should be maintained and reviewed in one year at the latest.**
- **For those cases in which both procedures appear feasible there is no reason to replace the better documented TAVI procedure by AVB at this time.**

TABLES

Table 3 Case series of aortic valve bypass (apicoaortic conduit) for aortic stenosis in adults

Follow-up time, late morbidity/mortality, and final status is provided in the second half of this table, beginning on page 14.

Reference	Date of surgery	Adults [†]	Age/ Preop status	Without CPB (%); Beating heart	Perioperative deaths (%) [†]	Causes of perioperative mortality (adult)
Vliek, 2010 ³ , Gammie, 2008 ⁴ , White, 2007 ⁵ ▼, Gammie, 2006 ⁶	2003-2009	47	81.6±8.8 y 80% NYHA III, IV. AVA 0.63±0.16 cm ² AVG 46±14 mmHg	28 (60%); Not stated.	5 (11%)	- advanced pulmonary fibrosis, could not be oxygenated in operating room - exsanguination from intraoperative lower gastrointestinal hemorrhage - friable ventricle with torn sutures; intraoperative hemorrhagic diathesis; multisystem organ failure - post discharge: over-anticoagulated for emboli, cardiac arrest, massive lateral chest wall hematoma - not described
Ogawa, 2009 ⁷	Not stated	3	60-79 y. NYHA III, IV. AVA 0.41-0.6 cm ² AVG (peak) 66-164 mmHg.	0; 0	0	
Brofferio, 2009 ²³ ◀	Not stated	4	74±9 y AVG (peak) 75±17 mmHg	Not described.	0	
Brown, 2007 ⁸	Not stated	56	75±11 y	"Can usually be done without CPB"	Not described.	

Reference	Date of surgery	Adults [†]	Age/ Preop status	Without CPB (%); Beating heart	Perioperative deaths (%) [†]	Causes of perioperative mortality (adult)
Lockowandt, 2006 ⁹	2002-2005	13	75±8.7 y 100% NYHA III, IV. AVA 0.63±0.15 cm ² AVG 52±7 mmHg	9 (69%); Not stated	1 (8%)	- MI, postop day 3
Ruhl, 2006 ²⁴ ◀	Not stated	5	72.5±4 y. Previous CABG with patent grafts AVA 0.8±0.2 cm ²	Not described	0	
Takemura, 2006 ¹¹ [abstract, Japanese]	2001-2005	7	81 y (74-87 y) 6/7 NYHA III, IV	1	0	
Crestanello, 2004 ¹²	1995-2003	13	71±4 y (35-86 y) 85% NYHA III, IV AVA 0.65±0.0.2 cm ² AVG 42±4 mmHg	0; 5/13 (38.5%)	3 (24%)	- unable to wean from CPB - perioperative massive intravascular thrombosis after protamine administration - HIT, thrombosis of iliac and femoral veins, phlegmasia ceruleans dolens, thrombectomy, sepsis, respiratory failure and multiple strokes
Vassiliades, 2003 ¹³	Not stated	3	75-83 y All NYHA IV AVA 0.43 cm ² AVG 66 mmHg	3; 3	0	
Kerut, 2001 ¹⁴ ◀	Not stated	4	Not stated; operations were for porcelain aorta.	Not stated	0	
Cooley, 2000 ¹⁵	Not given	4	75-82 y AVG 60-73 mmHg	0	2 (50%)	- 82 y M pre-existing symptomatic pulmonary congestion; post-operative, HIT, exploratory

Reference	Date of surgery	Adults [†]	Age/ Preop status	Without CPB (%); Beating heart	Perioperative deaths (%) [†]	Causes of perioperative mortality (adult)
						thoracotomy for hemostasis, respiratory insufficiency - 75 y F with severe CHF, dilated left ventricle, multiple comorbidities, suffered cardiac arrest at end of procedure
Sweeney, 1986 ¹⁷	1975-1984	18♦ (38)	20-77 y	2; 2	Not stated [All 4/20 (20%)]	
Brown, 1984 ¹⁸	1976-1983	4 (23)	19-80	0, 0	1/4 (25%) [All 5/23 (22%)]	- 80 y M, friable ventricle with tearing during surgery; intraoperative hemorrhagic diathesis; multisystem organ failure
Norman, 1980 ⁷⁵ , Nihill, 1978 ²⁰ , Cooley, 1978 ²¹ ,	1975-1979	4 (27) ⁷⁵	39-66 y (4-72 y) AVG 40-100 mmHg	0; 0 Conduit grafted to abdominal aorta	1/4 (25%) [All 3/27 (11%)]	- 49 y M, ventricular failure on day 2.

AS, aortic stenosis; AV, aortic valve; AVA, aortic valve area; AVB, aortic valve bypass; AVG, aortic valve gradient, mean unless otherwise stated; AVR, aortic valve replacement; CABG, coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CPB, cardiac pulmonary bypass; CRD, chronic renal failure; CT, computed tomography; DM, diabetes mellitus; ESRD, end stage renal disease; F, female; HIT, heparin-induced thrombocytopenia; IHSS, idiopathic hypertrophic subaortic stenosis; LV, left ventricle; LVAD, left ventricular assistive device; LVOT, left ventricular outflow tract; LVH, left ventricular hypertrophy; M, male; mmHg, mm mercury; MI, myocardial infarction; mo, months; NYHA, New York Heart Association; MVA, motor vehicle accident; y, year.

[†] Figure given in brackets for older series is total number, adults and children, congenital AS and acquired AS, in series

[‡] Methodology paper describing technique.

◀ Imaging study; minimal clinical details supplied.

▼ Imaging study, minimal clinical details. Internal evidence suggests patients are ones whose clinical outcomes were described in Gammie, 2006.

♦ Four patients are described as having AS and severe aortic calcification, but individual outcomes are not identified.

Table 3 (continued) Case series of aortic valve bypass (apicoaortic conduit) for aortic stenosis in adults

Reference	Follow-up	Reoperation/ Other major complication	Late mortality	Status at last follow-up
Vliek, 2010 ³ , Gammie, 2008 ⁴ , White, 2007 ⁵ ▼, Gammie, 2006 ⁶	mean 21.7±17 mo; 4.7 mo – 5.5 y ³ .	Reop: 4/47, bleeding ³ 9 reoperations in 6/31 patients ⁴ : 2 bleeding, 2 pseudoaneurysm, 4 evacuation hemothorax; 1, infection Other: 3/47, stroke ³	12/31: 3 respiratory failure, 2 failure to thrive, 1 cancer, 6 undetermined ⁴ .	No conduit obstruction ³ . AVA unchanged. Mean AVG 17±7 mmHg. No clinical evidence of conduit infection; no late reoperation; no heart block requiring pacemaker; renal function well-preserved ⁴ .
Ogawa, 2009 ⁷	8-10 mo	None	None	“Well”
Brofferio, 2009 ²³ ◀	206±139 days	Not stated	None	AVG 32±4 mmHg.
Brown, 2007 ⁸ †	Not stated	Not stated	Not stated	AVG 8.8±3.3 mmHg.
Lockowandt, 2006 ⁹	6-33 mo	Reop: 3: 2, bleeding, 1, infection with dehiscence. Other: 2.	4: 2 MI (1 with partial dehiscence of implant and hemorrhage), 2 pneumonia.	9 surviving, all NYHA I, II. No known thromboembolic events.
Ruhl, 2006 ²⁴ ◀	8 days to 10 months	Not stated.	Not stated.	Imaging study, using ECG-triggered MRI
Takemura, 2006 ¹¹ [abstract, Japanese]	22 mos	Not stated.	1: obstructive ileus 4 months post operation.	1 patient in shock pre-operatively had hypoxic encephalopathy. 2 patients NYHA I, II, 2 NYHA III.
Crestanello, 2004 ¹²	2.1±0.8 y	Reop: 2, bleeding Other: 1, stroke; 1, reintubation for respiratory infection	4: 2, heart failure, 1, ischemic cardiomyopathy, 1, cancer	6, all NYHA I, II. No conduit obstruction, thromboembolic complications.
Vassiliades, 2003 ¹³	Up to 6.2 mos	None	1, pulmonary embolism	2, well, NHYA II, II-III.

Reference	Follow-up	Reoperation/ Other major complication	Late mortality	Status at last follow-up
Kerut, 2001 ¹⁴ ◄	Not stated	Not stated	Not stated	Not stated
Cooley, 2000 ¹⁵	Not stated	1, bleeding	None	“Well”
Sweeney, 1986 ¹⁷ ♦	5-year	1 adult: removal of disrupted conduit (non-fatal, late)	4: 2 AVB-related, disruption, 2 unrelated.	14/18 adults surviving. 6/7 patients aged 65-77, well.
Brown, 1984 ¹⁸	[All mean 44.6 mos]	[All Reop: 4 Other: 5]	No adult deaths.	
Nihill, 1978 ²⁰ , Cooley, 1978 ²¹ , Norman, 1976 ⁷⁵	Up to 4 y	Not described.	None.	LV gradient 0-60 mmHg.

AS, aortic stenosis; AV, aortic valve; AVA, aortic valve area; AVB, aortic valve bypass; AVR, aortic valve replacement; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CRD, chronic renal failure; CT, computed tomography; DM, diabetes mellitus; ESRD, end stage renal disease; F, female; FTT, failure to thrive; LV, left ventricle; LVAD, left ventricular assistive device; LVOT, left ventricular outflow tract; LVH, left ventricular hypertrophy; M, male; mmHg, mm mercury; NYHA, New York Heart Association; MVA, motor vehicle accident.

† Figure given in brackets for older series is total number, adults and children, congenital AS and acquired AS, in series

‡ Methodology paper describing technique.

◄ Imaging study; minimal clinical details supplied.

▼ Imaging study, minimal clinical details. Internal evidence suggests patients are ones whose clinical outcomes were described in Gammie, 2006.

♦ Four patients are described as having AS and severe aortic calcification, but individual outcomes are not identified.

Table 4 Case reports of aortic valve bypass (apicoaortic conduit) for aortic stenosis in adults

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
Campbell, 2010 ²⁶	69 y F. LVH, ESRD. Calcific AS, porcelain aorta. AVA 0.6 cm ² . AVG (mean) 60 mmMg.	No details; surgery had been 2 mos prior.	Eventual removal of AVB.	2 mos post surgery, severe hypotension during dialysis from inducible mid-LV obstruction from hyperkinetic ventricle occluding conduit. Patient eventually underwent aortic valve and ascending aorta replacement.
Ghoreishi, 2010 ²⁷	77 y M. Paroxysmal nocturnal hematuria. AVA 0.8 cm ² . AVG (peak) 56 mmMg.	Yes; yes.	Discharged home day 9.	None reported.
Hattori, 2010a ²⁸	82 y F. "Severe" AS.	No details.	Patient survived surgery; report included post-operative imaging.	None reported.
Hattori, 2010b ²⁹	70 y M. DM, CRF. Porcelain aorta from ascending to abdominal. AVA 0.8 cm ² . AVG (mean) 42 mmMg.	No; yes. Apico-biaxillary conduit implanted.	MRI 56% forward flow at ascending aorta, 44% flow at conduit.	None reported.
Jaarsma, 2010 ³⁰	55 y F. Porcelain aorta. "Severe" AS	Not stated.	MRI study showing retrograde flow proximal to the aortic anastomosis.	None reported.
Kotani, 2010 ³¹	71 y F. Porcelain aorta. NYHA IV. AVA 0.44 cm ² . AVG (peak) 98 mmMg.	No; no.	At one year, patient NYHA I, without stroke.	On warfarin post-surgery. CT at 18 days showed thrombus in distal aortic arch. MRI Flow rates 0.91 l/min (29%) and stagnation in distal aortic arch. CT at 6 months thrombus much reduced. Flow now 0.22 l/min (6%).

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
Shimizu, 2010 ³²	80 y F. Porcelain aorta from ascending to abdominal. AVA 0.6 cm ² . AVG 74 mmMg.	No; no. Circulatory arrest with deep hypothermia. Anastomosis to brachycephalic artery.	No gradient at 2 mo follow-up.	None reported.
Shontz, 2010 ³³	76 y F. DM, CRF, prior CVA. Porcelain aorta. AVA 0.9 cm ² . AVG 37 mmMg.	Yes; rapid LV pacing for coring and placement of LV apex plug.	AVG 15 mmMg. Patient discharged.	None reported.
Slietaly, 2010 ³⁴	77 y F. History of Hodgkin lymphoma, radiotherapy, chemotherapy, complete occlusion of SVC. "Severe" AS. Porcelain aorta.	No; not stated.	Death	Postoperatively, permanent 3° heart block; pacemaker implanted. At 18 months, symptomatic aortic valve regurgitation and LV overload; AVR performed; postoperative atrial fibrillation. Postop day 7, cardiac arrest, resuscitation, isolated thrombus left main coronary artery, removed with angioplasty, patient died 2 days later, multiorgan failure.
Takahashi, 2010 ³⁵	86 y F. Liver cirrhosis (chronic HCV). Porcelain aorta. AVA. AVG (peak) 50 mmHg.	No; induced vfib, deep hypothermia.	AVG 20 mmHg. No thromboembolic events.	CT at 14 days identified thrombus formation in descending aorta. Anticoagulation increased INR 2.5-3; thrombus resolved without thromboembolic events.
Dimitrikakis, 2009 ³⁶	49 y M. History CAGB, coarctation repair. NYHA III. AVA 0.8 cm ² . AVG (peak) 75 mmMg.	No; not described.	Good conduit function postoperatively.	Readmitted at 6 weeks with uncontrolled hypertension (systolic bp 300 mmHg, patient had stopped medication), dehiscence of AAC from LV, associated pseudoaneurysm, left hemothorax, left lung collapse. No evidence infection at redo AVB. Well with good blood pressure control at 1 year.
Herrman et al, 2009 ³⁷	16 y F. Congenital anomalies. Calcific AS, porcelain aorta,	No; no.	AVG 19 mmHg prior to discharge.	None reported.

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
	MS. AVG 67 mmHg.			
Sabada, 2009 ³⁸	65 y F. Previous AVR with patient-prosthesis mismatch. AVA 0.55 cm ² . AVG (mean) 39 mmHg.	No; not described.	Exercise tolerance improved.	None reported.
Shin, 2009 ³⁹	74 y F. AVA 0.29 cm ² . AVG (mean) 64 mmHg.	No; induced vfib.	AVG 19 mmHg pre-discharge. At 8 mo follow-up, no heart failure, embolic events.	Mild stroke, recovery without neurological deficit. Mural thrombosis adjacent to aortic anastomosis on imaging.
Hirnle, 2009 ⁴⁰ [from abstract; Polish original]	73 y M. Porcelain aorta. AVG (peak) 95 mmHg.	Yes	AVG (peak) 33 mmHg.	None reported.
Hirota, 2009 ⁴¹	79 y M. CRF. Previous aortic-femoral graft. Porcelain aorta, calcified annulus.	No; yes. Hand-sewn cuff to implant.	Peak flow velocity decreased 4.1 to 2.5 m/s.	None reported.
Parsa, 2009 ⁴²	82 y M. CABG. AVR. Porcelain aorta. HYHA IV. AVA 0.37 cm ² .	No; not described.	Death	Postoperative arrhythmia, LV function reduced, placement of LVAD. Improved, LVAD explanted, anticoagulation stopped. ~3 days postoperative, large thrombus in aortic root, heparin restarted, multiple comorbidities precluded further surgery, multisystem organ failure, death. On autopsy, occlusion of native and grafted coronary ostia with MI.
Zimrin, 2008 ⁴³	87 y M. CABG. CHF. AVA 0.3 cm ² . AVG (peak) 80 mmHg.	Yes; yes.	Able to carry out ADL.	None reported.

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
Doi, 2007 ⁴⁴	78 y F. CABG. AVG 52 mmHg.	No; yes. Friable apex; conduit sutured directly to myocardium.	Recovery from second surgery.	Subepicardial aneurysm on postoperative CT near anastomosis. Patient underwent second surgery for repair.
Fujii, 2007 ⁴⁵	75 y M. CABG. Severely calcified aortic annulus. NYHA III. AVG (peak) 130 mmHg.	No; no.	At 6 months, NYHA Class II.	None described.
Nishimura, 2007 ⁴⁶	74 y F, CABG. Porcelain aorta. AVA 0.7 cm ² . AVG (peak) 80 mmHg.	No; no, vfib.	AVG 23 mmHg.	None reported.
Pulitani, 2007 ⁴⁷	59 y M, CABG. "Severe" AS, porcelain aorta.	Not stated.	Patient survived surgery; report included post-operative imaging.	None reported.
Strecker, 2007 ⁴⁸	58 y M. Relapsing prosthetic endocarditis with annular abscess, 2 previous AV replacements. Intraoperative decision to implant AVB due to perivalvular leakage, inability to implant new valve. LVOT closed; conduit anastomosed to ascending aorta	No; no.	Conduit functioning at 2 months.	None reported.
Chiu, 2006 ⁴⁹	76 y M. COPD, CAD. Porcelain aorta.	No; not described.	Conduit patent on postoperative MRI.	None reported.
Miyatake, 2006 ⁵⁰	69 y F. LVH. History of mediastinal radiation therapy.	No; no, vfib.	AVG 33 mmHg. No anastomotic stenosis at	None reported.

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
	Porcelain aorta. HYHA III. AVA 0.37 cm ² . AVG 120 mmHg.		8 months.	
Takeda, 2006 ⁵²	72 y F. DM, CRF with hemodialysis. Porcelain aorta. AVG 58 mmHg.	No; induced bradycardia.	CHF symptoms resolved, cardiac output preserved.	CT at 1 month showed thrombus in aortic arch; anticoagulation started, no thromboembolic events.
Paule, 2005 ⁵³	71 y M. History CABG, MI. AVG 70 mmHg.	No; no.	To death at 6 years postoperative, from GI cancer.	LV insufficiency due to atrial flutter, 5 years postoperative.
Schmid, 2006 ⁵¹	49 y M. CABG. Porcelain aorta.	No; no.	Recovered.	None reported.
Skrabal, 2004 ⁵⁴	58 y M. 3 previous AVR, ongoing hemolysis.	Not described.	Hemoglobin stable.	None reported.
Janelle, 2003 ⁵⁵	41 y M. History Hodgkin lymphoma with mantle radiation. Porcelain aorta. Frozen mediastinum. AVA 0.7 cm ² . AVG 50 mmHg.	No; not described.	Discharged at postoperative day 18.	Postoperative cardiac arrest from bradyarrhythmia of unknown origin; resuscitation successful.
Takemura, 2003 ⁵⁶ [abstract, Japanese]	83 y F. AV block, respiratory insufficiency, ARF. AVG 100 mmHg.	No; not described.	Discharged stable.	Required dialysis for 2 weeks postoperatively.
Schreiber, 2002 ⁵⁷	73 y F. CAD. Porcelain aorta. AVG 50 mmHg.	No.	"Improved"	None reported.
Salas, 1989 ⁵⁸	51 y M. Hyperlipoproteinemia, type IIa. AVG 130 mmHg.	Yes; yes. Conduit implanted into supraceliac aorta.	Death.	Repeated episodes of ventricular fibrillation, septicemia; death 25 days postoperative.
Tanaka, 1987 ⁵⁹	53 y M. Werner's syndrome. Porcelain aorta.	No; yes.	Asymptomatic.	None reported.

Reference	Age, Indication for AVB, Preop status	Without CPB; Beating heart	Outcome	Adverse Events
	“Large” AV gradient. Aortic regurgitation Grade III.			
Minami, 1983 ⁶⁰	46 y F. Aortitis syndrome, stenotic descending aorta, extensive calcification.	No; no. Many sutures required around LV implant to stem bleeding.	Death.	Sudden death 22 days postoperative; autopsy showed cardiac tamponade, massive pericardial coagula.
Berry, 1981 ⁶¹ [abstract]	70 y F. Calcific AS, porcelain aorta.	Apico-abdominal aortic bypass.	Death.	8 months postoperative, gastric erosion with fatal GI hemorrhage.
Ugori, 1979 ⁶²	33 y M. History of AVB for severe AS, small annulus. History of MVA with steering wheel injury to chest.	Not described; prior to presentation. Fabric graft had been anastomosed directly to myocardium.	Recovery.	Pseudoaneurysm of LV and disruption of conduit. Aneurysm resected and conduit revised. Patient recovered uneventfully.

AS, aortic stenosis; AV, aortic valve; AVA, aortic valve area; AVB, aortic valve bypass; AVR, aortic valve replacement; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CRD, chronic renal failure; CT, computed tomography; DM, diabetes mellitus; ESRD, end stage renal disease; F, female; LV, left ventricle; LVAD, left ventricular assistive device; LVOT, left ventricular outflow tract; LVH, left ventricular hypertrophy; M, male; mmHg, mm mercury; NYHA, New York Heart Association; MVA, motor vehicle accident.

Table 5 Transcatheter aortic valve implantation (TAVI), summary of recent registry reports

	Canadian ⁷⁰ N=339♦ TF; TA	German ⁷¹ N=697 PC; SY	French ⁷⁶ N=244 PC; TA	European ⁷² N=1038 TF; TA	Evaluation registry ⁷³ N=646
Number (% of total)	168 (49); 177 (51)	666 (96); 31 (4)	173 (71); 71 (29)	463 (45); 575 (55)	646
Age (years)	83±8; 80±8	81.4±6.3	82.3±7.3	81.7±6.7; 80.7±7.0	81±7
Surgical risk score	9.0±5.8;10.5±6.9 (STS)	20.5±13.2 (EuroScore)	25.6±11.4 (EuroScore)	25.7±14.5; 29.1±16.3 (EuroScore)	23.1±13.8 (EuroScore)
Date	Jan 2005 – June 2009	Jan 2009 – Dec 2009	Feb 2009 – June 2009	Nov 2007 – Jan 2009	Apr 2007 – Apr 2008
Procedural outcomes					
Procedural success, %	90.5; 96.1	98.4	98.3	95.2; 92.7	97
Procedural death, %	1.8; 1.7	7.5 [▲] ; 22.6 [▲]		Not reported	1.5
Major access site complications, %	13.0; 13.1	19.5 (groin)	7.3	10.6; 2.4	1.9
Stroke, %	0.6; 0.6	combined, below		combined, below	0.6
30-day outcomes					
30 day mortality, %	9.5; 11.3	12.4	12.7	6.3; 10.3	8.0
Myocardial infarction, %	0.6; 1.7	0.3	1.2		0.6
Stroke, %	3.0; 1.7	2.8	3.6	2.4; 2.6	1.9
Sepsis, %	3.0; 2.8			8.0	
Need for hemodialysis, %	1.8; 3.4		1.6	1.3; 7.1	
Pacemaker implantation, %	3.6; 6.2	39.3	11.8	6.7; 7.3	9.3
Late outcomes					
Mortality (mean follow-up)	11.5% (8 mos)				

PC, percutaneous – consists of transfemoral, subclavian and transbrachial approaches; TA, transapical; TF, transfemoral; SY, surgical – consists of transapical and transaortic approaches

- ◆ 345 procedures in 339 patients. Procedural outcomes are reported by number of procedures.
- ▲ In-hospital death, includes procedural and other causes.

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APPENDICES

Appendix 1 Detailed description of search terms

EMBASE

apicoaortic.tw OR apico-aortic.tw OR apico aortic.tw OR apical-aortic.tw OR apical aortic.tw

OR aortic valve bypass.tw

OR aortic stenosis.tw AND conduit.tw

OR porcelain aorta.tw AND stenosis.tw

filter by human

Note: Although “apico aortic conduit” mapped to a subject heading, the results were not related to this topic

PubMed

apicoaortic OR apico-aortic OR "apico aortic" OR apical-aortic OR "apical aortic"

OR "aortic valve bypass"

OR "Aortic Valve Stenosis[MeSH]" AND conduit

OR "Aortic Valve Stenosis{MeSH}" AND "porcelain aorta"

filter by human

ISI Web of Knowledge

apicoaortic OR "apico-aortic" OR "apico aortic" OR "apical aortic" OR "apical-aortic"

OR "aortic valve bypass" OR "aortic-valve bypass"

OR ("aortic stenosis" OR "aortic valve stenosis") AND Topic=("porcelain aorta") NOT Title=(transcatheter OR TAVI OR "valve implantation")

Appendix 2 Historical note

The AVB procedure was first described by Alexis Carrel in 1910. Recognising the difficulty of correcting the various forms of left ventricular outflow obstruction he proposed that a valved bypass could be established between the left ventricle and

the descending aorta⁷⁷. In 1955 Sarnoff and colleagues perfected a comparable procedure which they carried out in several dogs, with long-term survival and normal cardiac function, all without the aid of cardiac bypass⁷⁸. Cooley (1975) reported that the procedure was first carried out in man, but not formally described, by Templeton⁷⁹. Since one of his Templeton's patients survived for 13 years the procedure must have been carried out in 1962 or earlier. It has subsequently been used for outflow tract obstruction due to congenital abnormalities⁷⁹, idiopathic hypertrophic subaortic stenosis¹⁶ and calcific aortic valve stenosis¹⁵. The latter application is the subject of this report.