Canadian Journal of Cardiology 28 (2012) 520–528

Society Position Statement

Transcatheter Aortic Valve Implantation: A Canadian Cardiovascular Society Position Statement

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ABSTRACT

Patients with severe symptomatic aortic stenosis have a poor prognosis with medical management alone, and balloon aortic valvuloplasty has failed to provide durable clinical benefit. Open surgical replacement of the aortic valve can improve symptoms and survival. Recently, transcatheter aortic valve implantation (TAVI) has been demonstrated to improve survival, quality of life, and functional status in nonoperable patients and to be a viable option for patients in whom the risk of open surgical morbidity or mortality is high. This Canadian Cardiovascular Society position statement represents the consensus of a representative group of cardiologists and cardiac surgeons as to the current, but

RÉSUMÉ

Les patients ayant une sténose aortique symptomatique sévère qui bénéficient seulement d'une prise en charge médicale ont un mauvais pronostic. De plus, la valvuloplastie aortique par ballonnet n'a pas procuré de bénéfice clinique durable. Le remplacement chirurgical de la valve aortique peut améliorer l'état symptomatique et la survie. Récemment, il a été démontré que l'implantation transcatheter de la valve aortique (ITVA) améliore la survie, la qualité de vie et l'état fonctionnel chez les patients inopérables et qu'elle est une option viable chez les patients ayant un risque élevé de morbidité ou de mortalité avec la chirurgie de remplacement. Cet énoncé de position

Introduction

Aortic stenosis (AS) may present at any age but is particularly common in the elderly. When symptoms develop, clinical deterioration occurs rapidly and survival may be measured in months to a few years. Surgical aortic valve replacement (SAVR) is accepted to prolong survival and improve symptoms on the basis of historical comparisons and long clinical experience. Consequently severe AS with symptoms or with left ventricular (LV) dysfunction is considered to be a class I indication for surgery[1]. Recently transcatheter aortic valve implantation (TAVI) or replacement (TAVR) has been shown to be a reproducible alternative to SAVR. For patients in whom the risk of conventional open heart surgery is prohibitive, TAVI outcomes may compare favourably, although experience and follow-up remains limited.

Received for publication March 20, 2012. Accepted April 19, 2012.

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The disclosure information of the authors and reviewers is available from the CCS on the following websites: www.ccs.ca and/or www.ccsguidelineprograms.ca.

This statement was developed following a thorough consideration of medical literature and the best available evidence and clinical experience. It represents the consensus of a Canadian panel comprised of multidisciplinary experts on this topic with a mandate to formulate disease-specific recommendations. These recommendations are aimed to provide a reasonable and practical approach to care for specialists and allied health professionals obliged with the duty of bestowing optimal care to patients and families, and can be subject to change as scientific knowledge and technology advance and as practice patterns evolve. The statement is not intended to be a substitute for physicians using their individual judgement in managing clinical care in consultation with the patient, with appropriate regard to all the individual circumstances of the patient, diagnostic and treatment options available and available resources. Adherence to these recommendations will not necessarily produce successful outcomes in every case.

0828-282X/$ – see front matter
http://dx.doi.org/10.1016/j.cjca.2012.04.015

evolving, role of this less-invasive new therapy. Specific recommendations are provided for selection of patients for TAVI vs surgical aortic valve replacement for native valves and for bioprostheses, approaches to patient evaluation for TAVI, appropriate constitution of multidisciplinary teams involved in performing TAVI, essential facilities that are needed to perform TAVI safely and effectively, and training/qualifications for TAVI operators. Cost considerations, complication rates, and the quality of the available evidence are also discussed. It is hoped that this consensus document will prove to be a useful resource for health professionals, institutions, departments, and decision-making bodies dealing with this important and rapidly evolving therapy.

de la Société canadienne de cardiologie (SCC) constitue le consensus d'un groupe représentatif de cardiologues et de chirurgiens cardiaques portant sur le rôle actuel de ce nouveau traitement moins invasif. Des recommandations spécifiques sont fournies en ce qui concerne la sélection des patients en vue d'une ITVA *vs* un remplacement valvulaire chirurgical pour les patients avec une valve native ou un bioprothèse, les approaches pour l'évaluation du patient en vue d'une ITVA, la constitution d'équipes multidisciplinaires pour la réalisation de l'ITVA, les installations essentielles à la réalisation sécuritaire et efficace de l'ITVA, et la formation et les qualifications des cardiologues et chirurgiens effectuant l'ITVA. Les considérations relatives au coût, les taux de complications et la qualité des données disponibles sont aussi discutés. Nous souhaitons que ce document de consensus soit utile aux professionnels de la santé, aux institutions, aux départements et aux organismes décisionnels impliqués dans cet important traitement qui évolue rapidement.

While promising, experience with TAVI remains limited and its role remains controversial. To provide guidance, the Canadian Cardiovascular Society (CCS) commissioned a position paper to make recommendations on the appropriate use of TAVI in the light of current evidence. A representative expert committee of cardiologists and cardiac surgeons was selected. The committee reviewed the current literature, developed a consensus, and made specific recommendations utilizing the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system which applies a structured method to weigh the quality of the evidence and to describe the strength of the conclusion or recommendation.[2] This article summarizes the evidence with an emphasis on the current status of this evolving field. The position statement was then reviewed by a secondary panel and the CCS Guidelines Committee which provided suggestions for revisions leading to this final document.

The TAVI procedure

There are currently 2 catheter-delivered valve systems in widespread clinical use to treat AS. The SAPIEN valves (Edwards Lifesciences Inc, Irvine, CA) utilize a bovine pericardial valve mounted on a balloon-expandable stent which is placed entirely within the native diseased valve. The CoreValve ReValving System (Medtronic Inc, Minneapolis, MN) utilizes a porcine pericardial valve mounted on a self-expanding stent which extends into the ascending aorta for stabilization. Both devices are now compatible with relatively low profile 7 mm external diameter delivery systems, theoretically allowing transfemoral transarterial access in the majority of patients with AS. Other newer valves are becoming available and offer various technical advantages designed to improve the ease and reliability of the procedure. Transcatheter valves can be implanted under local or general anaesthesia percutaneously through a femoral artery (transfemoral), or under general anaesthesia by surgical exposure of the left ventricle (transapical), axillary/subclavian artery, femoral artery, or ascending aorta.

Valve function

In vitro performance and durability of currently available transcatheter and surgical valves are comparable.[3,4] Early and mid-term clinical performance with regard to relief of AS is also comparable.[5,6] Paravalvular leaks are much more common with transcatheter valves. Most such leaks are mild although, while the clinical implications of such leaks are unclear, they are a marker of poorer late outcomes.[6] Severe leaks are infrequent but may result in heart failure requiring repeat intervention. Clinical durability of transcatheter valves beyond 5 years has been well documented, which is sufficiently long to provide adequate benefit for most current candidates. Longer term durability is unknown.

Registry Data

Building on early single-centre registries and pilot studies a number of recent large national and multinational registries (eg, Canadian, French, Italian, United Kingdom, Edwards SAPIEN Aortic Bioprosthesis Multi-Region Outcome Registry XT [SOURCE XT] and others) have evaluated outcomes using the SAPIEN and CoreValve devices in many thousands of patients.[7-11] Procedural success rates have ranged from 94% to 98% with procedural (30-day) risks of mortality from 4% to 11% and stroke from 2% to 5%. Survival at 1 year in these high-risk registries ranges from 76% to 85%, primarily depending on comorbidities. The registry data suggest that, as compared with SAVR, TAVI may be associated with a reduced risk of renal failure, myocardial injury, bleeding, morbidity, and a greater increase in ejection fraction. However more recently favourable and more objective data from 2 randomized trials (**P**lacement of **Aor**tic Tra**n**scathet**er** Valves [PARTNER] IA and IB) have become available and will be discussed in more detail later in this report.[4-6,12] It must be kept in mind that the patient population in which the use of TAVI has been evaluated in randomized trials against the alternatives of medical management and surgery to date represents a small subset of patients at high surgical risk (Fig. 1).

Who Should Undergo TAVI?

TAVI in nonoperable patients

The PARTNER trial (cohort B) is the only randomized trial evaluating TAVI in nonoperable patients.[12] Patients were refused surgery if the predicted risk of death or serious irreversible morbidity with surgery exceeded 50%. Patients were allocated to medical management or to TAVI utilizing the balloon-expandable SAPIEN valve (femoral artery access only, not transapical). The trial enrolled 358 patients with a mean age of

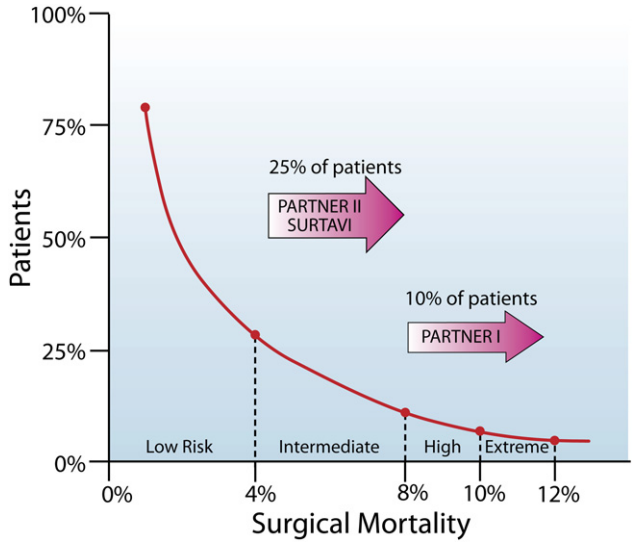

Figure 1. The spectrum of surgical risk. Transcatheter aortic valve implantation (TAVI) has been shown to be a viable alternative to surgery in patients who are at high or extreme risk with conventional surgery due to advanced age or comorbidities. These patients represent the highest risk; 5% to 10% of patients with severe aortic stenosis. TAVI has not yet been directly compared with surgery in the majority of patients who would be predicted to be at low or intermediate surgical risk. PARTNER, Placement of Aortic Transcatheter Valves; SURTAVI, Surgical Replacement and Transcatheter Aortic Valve Implantation.

83 years. The Society of Thoracic Surgeons (STS) predicted rate of procedural (30-day) mortality had patients undergone open surgery was 11%. The actual 30-day mortality was 5.0% with TAVI and 2.8% with medical treatment ($P = 0.41$). The primary end point, mortality after 1 year, was 30.7% with TAVI compared with 50.7% with medical treatment ($P < 0.0001$). This represents a significant 20% absolute reduction in 1-year mortality, with the number needed to treat (NNT) in order to prevent 1 death at 1 year equal to 5. TAVI was also associated with a marked and durable improvement in functional status and reduced hospitalization. Health economic analysis suggested that the quality of life benefits and costs of TAVI compared favourably with other commonly accepted therapies.[13-15] At 2-year follow-up survival and rehospitalization curves continued to diverge markedly showing further increases in benefit with TAVI over medical management.[5,6]

To date there are no randomized control trials examining the role of TAVI performed with alternative access techniques (transapical, transaortic, transaxillary). Although comparable outcomes have been achieved using each of these techniques, experience has been variable and additional studies are required.

TAVI in high-risk operable patients

The PARTNER IA study is the only randomized trial comparing SAVR and TAVI in high-risk patients with symptomatic severe AS.[4] Patients were eligible if their predicted risk of operative mortality was ≥ 15%. An STS score ≥ 10 was used as a guideline, representing the highest risk of 5% to 8% of the surgical population. The trial enrolled 699 patients and was powered to demonstrate the noninferiority of TAVI vs SAVR. The balloon-expandable SAPIEN valve was used with patients stratified to femoral or apical access based primarily on the adequacy of the femoral arteries.

The STS predicted risk of procedural mortality (within 30 days after a procedure) was 11.8%. Actual mortality 30 days after randomization was 3.4% with TAVI vs 6.5% with SAVR (intention to treat, $P = 0.07$). The primary end point, mortality 1 year after randomization, was 24.2% with TAVI (transfemoral and transapical combined) vs 26.8% with SAVR ($P = 0.44$, noninferiority $P = 0.001$).

In patients undergoing a transfemoral procedure the mortality rates at 30 days and at 1 year in the TAVI group were 3.3% and 22.2%, respectively, compared with 6.2% and 26.4% in the SAVR group ($P = 0.13$ for 30-day mortality, $P = 0.29$ for 1-year mortality, noninferiority $P = 0.002$). Patients randomized to surgery waited longer for surgery and more often refused surgery, thereby reducing the risk of mortality within 30 days of randomization. The "as treated" transfemoral aortic valve replacement (AVR) mortality was less than half that of SAVR (3.7% vs 8.2%) and this difference was significant ($P = 0.046$).[12] Quality of life was markedly improved.[15] Transapical patients did not fare as well, although to some degree this was a function of patient selection and learning curve.[4,13]

TAVI, as compared with SAVR, was associated with a lower rate of major bleeding (9.3% vs 19.5%, $P < 0.001$), a shorter intensive care stay (3 vs 5 days, $P < 0.001$), and shorter hospitalization (8 vs 12 days, $P < 0.001$). Rates of pacemaker implantation were similar (3.8% vs 3.6%). Major vascular complications were more frequent with TAVI (11% vs 3.2%, $P < 0.001$).

There was a trend to more major strokes (defined as strokes with sustained disability) with TAVI (3.8% vs 2.1% at 30 days, $P = 0.20$). Although this did not reach statistical significance, the rate of neurological events (transient ischemic attack [TIA], minor stroke, and major stroke combined) did (5.5% vs 2.4% at 30 days, $P = 0.04$). Nevertheless, the combined risk of death or major stroke was nonsignificantly lower with TAVI (6.9% vs 8.2% at 30 days, $P = 0.52$). After an early postprocedural phase the late risk of stroke after TAVI and SAVR was similar.[16] At 2-year follow-up there was no significant difference in the overall number of strokes with TAVI and SAVR.[6] However this early increase in neurological events has raised legitimate concerns and will require further study.[17]

TAVI in intermediate- and low-risk patients

As a result of a long experience and a large body of clinical data SAVR is commonly recognized as the standard of care for patients with symptomatic AS, despite the absence of randomized trials.[1] However rapid improvements in TAVI technology, improving outcomes in large registries, the randomized PARTNER trials, better outcomes in patients with lower STS risk scores, and preliminary results in lower risk patients with severe AS, suggest the potential for an expanded role for TAVI.[5] In some of such patients the risk of procedural mortality may be less important than the risk of morbidity with a particular procedure in a specific patient. Studies specifically comparing TAVI and surgery in patients at intermediate surgical risk (eg, STS ≥ 4% representing approximately the upper 20th percentile of operative risk) are currently under way (**Su**rgical **R**eplacement and **T**ranscatheter **A**ortic **V**alve **I**mplantation [SURTAVI] and PARTNER II). The TAVI decision tree is illustrated in Figure 2.

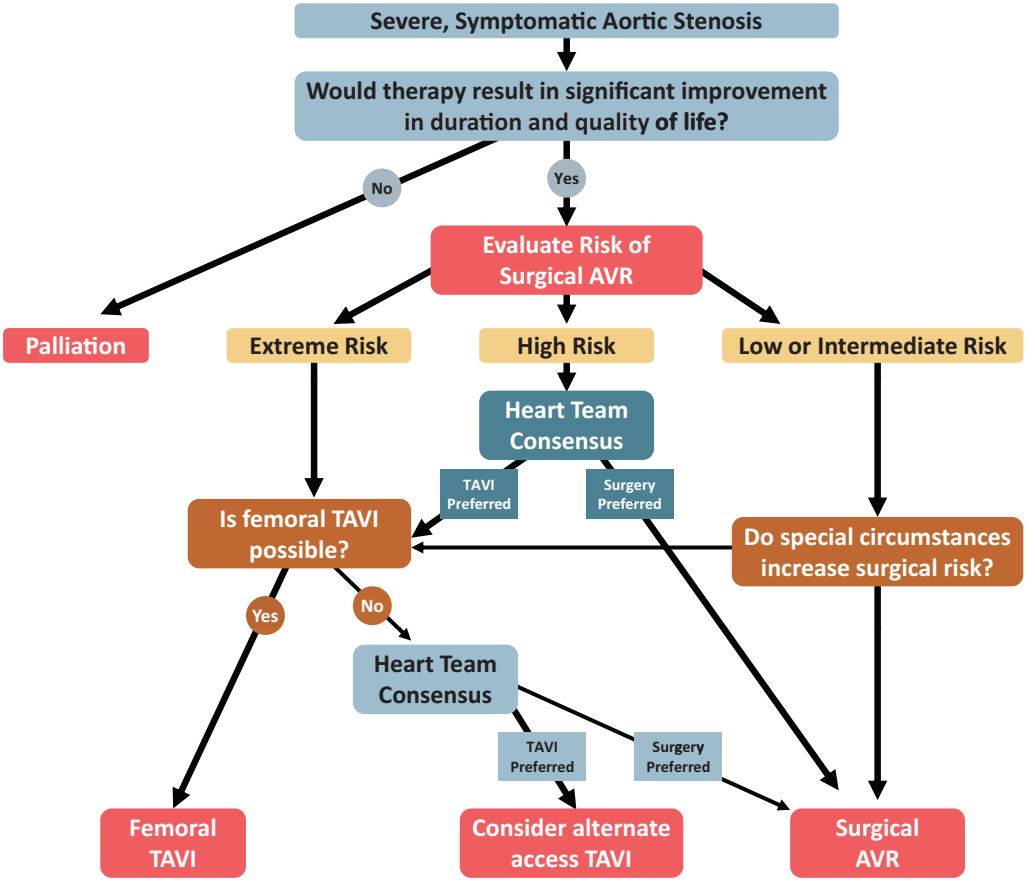

Figure 2. Clinical decision tree for patients with aortic stenosis. AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation.

RECOMMENDATION

For TAVI in patients with AS:

1. Transfemoral TAVI is recommended if:
   a. The risk of open heart surgery is prohibitive; and
   b. A significant improvement in duration or quality of life is likely; and
   c. Life expectancy with treatment is likely to exceed 1 to 2 years

   (Strong Recommendation, High-Quality Evidence).
2. Patients who are not candidates for open heart surgery or for TAVI using femoral artery access may be considered for other alternative access procedures (eg, transapical, transaxillary, or transaortic) (Conditional Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places a relatively high weight on the favourable outcomes in recent registry experience with alternative nontransfemoral access techniques, and less weight on early feasibility experience.

3. TAVI is a reasonable alternative to SAVR for patients at high risk ("high risk" can be defined as a risk of mortality of $\geq$ 8% or major morbidity of $>$ 50% within 30 days of surgery as predicted by an experienced cardiac surgeon or by the STS risk calculator) of mortality or major morbidity and:
   a. Duration and quality of life is likely to be significantly improved by treatment
   b. Life expectancy with treatment is likely to exceed 1 to 2 years with treatment
   c. There is a consensus amongst a multidisciplinary Heart Team including cardiologists and surgeons

   (Strong Recommendation, High-Quality Evidence).
4. SAVR is the treatment of choice for patients diagnosed with severe symptomatic AS considered at intermediate or low surgical risk (Strong Recommendation, Moderate-Quality Evidence).
5. TAVI may be offered to selected patients with severe symptomatic AS who would otherwise be considered intermediate to low risk of mortality where there is a consensus of the Heart Team that they are at significantly increased risk of either morbidity or mortality due to special circumstances (eg, frailty, very advanced age, patent bypass grafts, multivalve disease, etc) (Conditional Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places a relatively greater weight on quality of life and morbidity, and less weight on possible unknown differences in valve durability and patient mortality between transcatheter and surgically implanted aortic bioprostheses.

Valve-in-valve implants

Surgical and transcatheter biological valves fail eventually and reoperation can be associated with considerable risk. With surgical bioprostheses, the incidence of structural valve failure is 10% to 30% at 10 years and 20% to 50% at 15 years.[1,18] For modern biological valves surgically implanted in patients older than 60 years of age, at least 22% of patients will require reoperation by 15 years postoperatively.[19] The mortality of reoperative AVR, in patients deemed eligible for surgery, varies between 4% and 14%.[20] Early experience with implantation of transcatheter valves within failed surgical aortic valves has been very favourable, with high procedural success and low mortality,[21,22] however, experience remains limited and the duration of follow-up is short. Paravalvular leaks are infrequent due to effective sealing within the previously implanted valve ring. Hemodynamic function is excellent where the transcatheter valve has sufficient room to achieve full expansion, but may be suboptimal in smaller bioprostheses. A thorough understanding of the mechanism of failure, internal dimensions, and radiographic appearance of the failed bioprosthesis is required. Transcatheter valve durability in this setting is unknown.

RECOMMENDATION

For valve-in-valve implantation:

1. Surgical valve replacement is the treatment of choice for non-high risk patients with failure of bioprosthetic surgical valves (Strong Recommendation, Low-Quality Evidence).
2. Transcatheter valve-in-valve implants may be reasonable in patients with failed surgical bioprosthetic valves in whom there is a Heart Team consensus that:
   a. The risk of open heart surgery is prohibitive; and
   b. A significant improvement in duration or quality of life is likely; and
   c. Life expectancy with treatment is likely to exceed 1 to 2 years; and
   d. The dimensions and characteristics of the failed valve are understood and compatible with good transcatheter valve function

   (Conditional Recommendation, Low-Quality Evidence).
3. Transcatheter valve implants is reasonable in carefully selected patients with transcatheter valve failure (Conditional Recommendation, Low-Quality Evidence).

Evaluation for TAVI

Evaluation for TAVI follows the same basic principles as for SAVR. Ideally screening is done within a dedicated clinic environment with a consistent cohort of clinicians and nurses (Fig. 3). Preprocedure assessment, patient and family education, and patient tracking are labour intensive.

The standard initial assessment for TAVI includes transthoracic echocardiography (TTE), a chest X ray and screening blood work (with particular attention to hemoglobin, renal function, and hemostasis), coronary angiography, and aorto-ilio-femoral imaging using invasive and/or multislice computed tomographic (MSCT) angiography.[23] When possible, it is desirable for advanced imaging studies to be performed at the TAVI site, as there may be nuances with respect to how the multispecialty team performs and interprets the studies obtained for the TAVI procedure.

Assessment of aortic valve anatomy and function

TTE is the preferred tool to assess the severity of AS. Severe stenosis is defined as a peak aortic jet velocity ($>$ 4 m per second), a mean transvalvular gradient ($>$ 40 mm Hg), and/or an aortic valve area ($<$ 1.0 cm^2, indexed $<$ 0.6 cm^2/m^2).[1] In patients with severely reduced LV function and suspected AS but a low transaortic gradient a low-dose dobutamine stress TTE may be useful to determine the severity of AS as well as to assess the presence of contractile reserve.

Measurement of the aortic annulus

TAVI requires preprocedural noninvasive imaging of the aortic annulus to determine the ideal implant valve size. Echocardiography, and in particular, transesophageal echocardiography (TEE) has been widely used for aortic annulus measurements before TAVI.[24] MSCT and magnetic resonance imaging (MRI) angiography are increasingly used to determine the dimensions of the aortic annulus including the mean diameter, cross-sectional area, and perimeter of the aortic annulus.[25]

Assessment of LV anatomy and function

LV function is generally adequately assessed by TTE.[24] In patients with depressed LV systolic function TAVI compares favourably with SAVR with regard to postoperative improvement of LV function.[3] However, patients with severe systolic dysfunction, particularly in the presence of nonrevascularized coronary disease, severe mitral regurgitation, or poor contractile reserve are at higher risk for periprocedural hemodynamic instability.[26]

Assessment of coronary anatomy

Coronary angiography is performed before TAVI. Severe multivessel coronary disease may be a relative indication for SAVR combined with bypass.[27] TAVI preceded or followed by percutaneous revascularization may be weighed as an alternative, although many patients with modest coronary disease may do well without revascularization.[28] The presence of a patent bypass graft passing under, or adherent to, the sternum may represent a relative contraindication to repeat sternotomy.

Coronary obstruction may rarely ($<$ 1%) occur as a consequence of displacement of a native valve cusp over the left main or right coronary ostium during TAVI.[26] Bulky aortic leaflets, a narrow aortic root, and low lying ostia (annulus to ostial distance $\leq$ 12 mm) will increase the risk of coronary ostial occlusion. Therefore, the position of the coronary arteries relative to the aortic cusps and the extent and location of valve

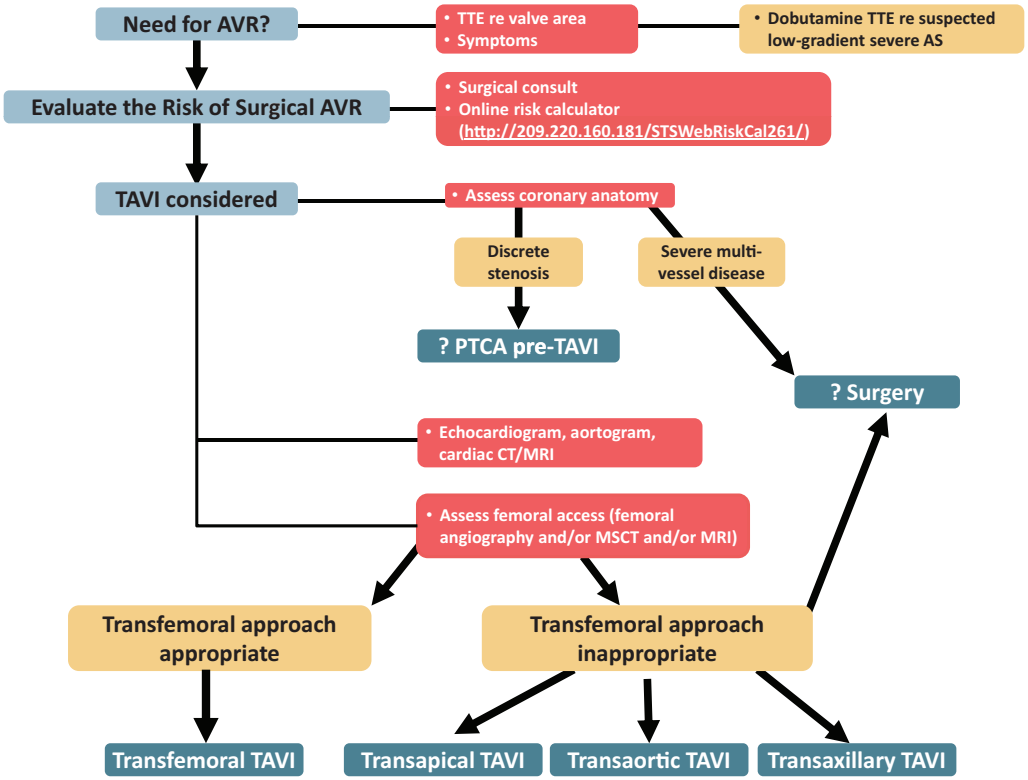

Figure 3. Evaluation of patients being considered for transcatheter aortic valve implantation (TAVI). AS, aortic stenosis; AVR, aortic valve replacement; CT, computed tomography; MRI, magnetic resonance imaging; MSCT, multislice computed tomography; PTCA, percutaneous transluminal coronary angioplasty; TTE, transthoracic echocardiography.

calcifications should be assessed by aortography and/or MSCT.[25]

Assessment of arterial access

The diameter, degree of calcification, and tortuosity of the arterial vasculature must be assessed by angiography and/or MSCT angiography. Both are valuable, however MSCT provides a more comprehensive evaluation.[25] Imaging should assess the entire path from the proposed access site (usually the common femoral artery) to the aortic valve. MRI and intravascular ultrasound may be helpful in patients with significant renal dysfunction. A dilated ascending aorta may be a contraindication to the implantation of some prostheses that rely on partial fixation in the ascending aorta, but not to prostheses that rely on annular fixation alone. Severe aortic tortuosity, aneurysms, and protruding atheroma or thrombus are relative, but not absolute, contraindications to transarterial access. A porcelain aorta is not a particular concern, so long as the aortic lumen, including the aortic root, is sufficiently large.

Current transarterial valve delivery systems measure approximately 7 mm in external diameter and can be accommodated by a relatively compliant artery with a diameter > 6 mm in diameter. However a larger arterial lumen may be necessary in the presence of diffuse atherosclerosis, calcification, particularly if circumferential on MSCT angiograph, or severe tortuosity. Although the femoral artery is the preferred means of access, when this is suboptimal transaxillary/subclavian, transaortic or transapical access may be preferable and should be evaluated, as should the vascular access options for cardiopulmonary support should this be necessary.

Functional assessment

Estimates of surgical risk and the possibility of benefit from TAVI may be augmented by various functional tests.[23,29] In symptomatic patients with severe AS, and especially in an older population, a standardized walk test (5-metre) is superior to New York Heart Association functional class to assess patient's functional impairment. Neurocognitive functions are commonly assessed with the use of various standardized objective measures (eg, Mini Mental State Examination, clock test) as is frailty.

Not all patients may experience significant clinical improvement after TAVI. Some patients, such as those with severe multisystem (particularly pulmonary) disease, malignancy, or dementia can deteriorate despite a successful procedure. In such cases, the selection process may be enhanced by enlisting the help of the experienced nurses, referring physicians, other specialists, social workers, and ethicists.

Surgical risk

Estimating surgical risk requires consideration of the patient's comorbidities, the complexity of the procedure, and the outcomes of the particular surgeon and program. In North America the STS has developed a predictive model for estimating surgical risk based on data from the majority of centres across the United States. Surgical risk can easily be

estimated with the aid of an on-line risk calculator (http://209.220.160.181/STSWebRiskCalc261). It is generally considered that an STS predicted risk of mortality exceeding 8% or a risk of major morbidity exceeding 50% is consistent with "high risk" (Fig. 1).

In Europe a similar predictive model, the logistic EuroSCORE, has primarily been utilized. While useful in low and intermediate risk patients this appears to routinely overestimate the likelihood of mortality in higher risk patients.[30] The newly introduced EuroSCORE II risk predictor will likely improve accuracy and can be found at http://euroscore.org/calculators.htm.

Such surgical risk scores are useful in low risk patients and when comparing large experiences. However these predictive models fall short when comorbidities are rare or nuanced as may be the case with hepatic disease, multivalve disease, ascending aortic calcification, frailty, and various degrees of pulmonary disease. For this reason risk assessment often comes down to the judgement of an experienced surgeon.

RECOMMENDATION

For evaluation of TAVI candidates:

1. Screening for TAVI should include all of the following:
   a. A comprehensive assessment of medical history
   b. A complete physical examination with special attention to signs of severe AS, lung disease, and peripheral artery disease; objective evaluation of neurocognitive function and frailty is encouraged; exercise testing or standardized walk tests may be helpful
   c. Electrocardiogram, chest X ray, complete blood count, electrolytes, creatinine, liver function; brain natriuretic peptide may be helpful
   d. TTE with an assessment of annulus diameter; low-dose dobutamine stress echocardiography may be helpful in patients with severely reduced LV function and a low transaortic gradient
   e. TEE to assess the annulus diameter is recommended, particularly in the absence of MSCT measurements
   f. Coronary angiography
   g. Aortography and ilio-femoral invasive angiography or MSCT angiography, preferably both
   h. Accurate measurement of aortic annulus size by TEE and/or MSCT or MRI is key for appropriate selection of prosthesis size

   (Strong Recommendation, Weak Evidence).

Program Principles

The multidisciplinary team

The Heart Team model has become increasingly accepted as optimal for TAVI evaluation as well as pre-, intra-, and postprocedural management. Ideally the TAVI team has a collaborative leadership involving an experienced interventional cardiologist and cardiovascular surgeon. Evaluation requires experienced cardiovascular imaging specialists, anaesthesiologists, and nursing staff. Procedural management may require additional interventionalists or surgeons depending on the route of access. A major component of assessment of the high risk patient includes a determination of the relative balance of risks and benefits for TAVI, conventional surgery, or conservative management with palliation.[23]

TAVI training

The TAVI operator should be an experienced interventional cardiologist or surgeon, ideally with a background in structural heart disease. It would appear reasonable to mandate that operators that are naïve to the techniques of TAVI undergo formal training, followed by proctored procedures with an experienced operator until the proctor and the new operator agree that the individual is competent to complete the procedure independently. It should be recognized that as the procedure becomes more widely available that the expectations for new programs and new operators should become more rigourous.

RECOMMENDATION

For TAVI programs:

1. The multidisciplinary heart team should include:
   a. Interventional cardiologists
   b. Cardiac surgeons
   c. Imaging specialist
   d. Cardiac anaesthetist
   e. Experienced nurses

   (Strong Recommendation, Low-Quality Evidence).
2. Primary operators should perform a minimum of 25 cases per year (Strong Recommendation, Low-Quality Evidence).
3. Training of a TAVI operator should include:
   a. Didactic theoretical sessions for 1 day, as a minimum
   b. Simulator training
   c. Observation of 2 to 5 TAVI cases, as a minimum
   d. Support for the initial 5 to 10 cases by a proctor, as a minimum
   e. New physicians in the field should have performed a12-month training in structural heart disease, as a minimum

   (Conditional Recommendation, Low-Quality Evidence).

The TAVI procedure room

Ideally TAVI is best performed in a specialized multipurpose procedural suite. The high risk nature of the procedure argues for the ready availability of anaesthesia and peripheral cardiopulmonary bypass. A relatively large room (800-900 square feet) is appropriate to accommodate anaesthesia, echocardiography, intra-aortic balloon pumps, and cardiopulmonary support.[31] Airflow exchange meeting surgical sterility standards and x-ray imaging meeting cardiac catheterization laboratory standards are recommended.

Procedural volume

Adequate institutional and individual operator case volumes are required for optimal outcomes and efficiency for both percutaneous catheterization and cardiac surgical procedures. This is particularly true for TAVI, a novel and high risk procedure that is currently used mainly in high-risk patients.[32] Un-

like most transcatheter procedures TAVI has very significant potential for severe adverse outcomes which require special expertise to manage and are largely avoidable with experience.[33] Outcomes are determined not only by operator experience but to a large extent by the multidisciplinary team which can efficiently evaluate, identify appropriate and inappropriate candidates, triage, and manage pre-, in-, and posthospital care.[23]

Manufacturers of currently available valves often specify minimum operator and institutional case volumes; typically in the range of 25 cases per year. However these numbers may not be sufficient to achieve optimal outcomes or efficiency. Minimum case numbers are likely higher as the number of primary operators increase, the number of valve types increase (eg, balloon-expandable vs self-expanding valves), the number of access routes increase (eg, percutaneous vs transapical access), and case complexity increases.

RECOMMENDATIONS

For facilities and institutions:

1. Institutions should perform a minimum of 25-50 cases per year (Strong Recommendation, Low-Quality Evidence).
2. TAVI should be performed in centres with:
   a. Established clinical excellence
   b. A large experience in high risk aortic valve surgery
   c. A commitment to a comprehensive valve program
   d. A strong, collaborative multidisciplinary Heart Team
   e. The ability to provide ongoing quality improvement
   f. The ability to participate in ongoing research
   (Strong Recommendation, Low-Quality Evidence).
3. TAVI programs should have ready access to:
   a. TTE and TEE
   b. MSCT
   c. A specially equipped cardiac catheterization lab or hybrid operating room
   d. Cardiac surgery
   e. Perfusion services
   f. A surgical recovery area
   g. An intensive care unit
   h. Renal replacement therapy
   i. Vascular surgery
   j. Peripheral vascular interventional expertise
   (Strong Recommendation, Moderate-Quality Evidence).

Postprocedural Management

Patients undergoing TAVI procedures are at risk for complications relating to the airway compromise, bleeding, congestive heart failure, neurologic events, and peripheral artery complications. Intensive care management is recommended overnight as a minimum.

Atrioventricular block is a particular concern and the need for a prophylactic temporary pacing, prolonged monitoring, and permanent pacemaker implantation depends on various clinical factors as well as the specific valve type. Electrocardiographic monitoring is recommended for at least 48 hours. Prophylaxis against valve-related thromboembolic complications is currently empiric. In general indefinite low-dose aspirin is recommended along with 1-3 months of a thienopyridine. However, evidence for this is lacking. For patients in whom there are indications for oral anticoagulants (such as atrial fibrillation) the need for adjunctive antiplatet agents is controversial and triple therapy should be avoided unless definite indications exist. Both transcatheter and surgical bioprosthetic valves share similar concerns with regard to the late risk of endocarditis. Consequently, adherence to standard guidelines for antibiotic prophylaxis are appropriate.[34]

In general, patients should follow up with their own doctor and with the Heart Team at 1 month, preferably with annual follow with a cardiovascular specialist. An echocardiogram should be performed before hospital discharge or at 1 month and, given current limited experience, preferably yearly.

TAVI Cost

Transcatheter valve systems are currently more costly than surgical valves. Consequently in a low risk patient SAVR may be less expensive. However in a high risk patient, faster recovery, shortened intensive care and hospital stay TAVI may be less expensive.[4] Economic analysis suggests that transfemoral TAVI can be performed with an incremental cost per life year, and quality adjusted life year, gained well within accepted values for commonly used cardiovascular technologies.[13-15] This appears to represent a good value in nonsurgical patients, although cost-effectiveness in surgical candidates remains to be determined. The procedure may become more cost-efficient in future as complications are reduced. Case costs may well fall with increased experience, optimal patient selection, and reduced complications as well as market influences.[35]

Conclusion

TAVI represents a new and proven therapy for patients with severe AS and should be considered as a viable option in patients in whom the risk of surgical valve replacement is high or prohibitive. Early experience suggests a potential role in lower risk patients and in patients with failed surgical valves, although this will require further evaluation.

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