About the Authors

Bryan Traynor, MD

Dr. Bryan Traynor, MB BCh graduated from Trinity College, Dublin, Ireland in 2015. He completed his general internal medicine (MRCPI 2017) and cardiology specialist training (CSCST 2024) through the RCPI in Ireland. Following his specialist training he undertook a 1-year subspecialty fellowship in interventional cardiology at the Mater Misericordiae University Hospital in Dublin. He then completed a further 2-year fellowship in complex coronary and structural heart disease intervention at St. Michael's Hospital, University of Toronto. He returned to Ireland as a consultant cardiologist at Cork University Hospital in August 2025.

Affiliations: Terrence Donnelly Heart Centre, St. Michael's Hospital, University of Toronto, Toronto, Ontario

Akshay Bagai, MD, MHS

Dr. Akshay Bagai is a practicing interventional cardiologist at St. Michael's Hospital and an Associate Professor in the Department of Medicine at the University of Toronto. Dr. Bagai received his MD and trained in Internal Medicine and Cardiology at the University of Toronto. He completed his training in Interventional Cardiology at St. Michael's Hospital. He obtained a Masters degree in Health Sciences from the Clinical Research Training Program at Duke University, USA. He returned to Toronto and joined the Division of Cardiology at St. Michael's Hospital in August 2013. His clinical and research interests are closely aligned and include complex, high risk, and total occlusion percutaneous coronary intervention, and transcatheter interventions for mitral and tricuspid valve disease.

Affiliations: Terrence Donnelly Heart Centre, St. Michael's Hospital, University of Toronto, Toronto, Ontario

doi.org/10.58931/cct.2025.126

Pushing the Envelope for Transcatheter Valve Interventions in Canada

Bryan Traynor, MD
Akshay Bagai, MD, MHS

Abstract

Transcatheter valve interventions (TVIs) have revolutionized the treatment of structural heart disease, by providing a less invasive option to surgical valve repair or replacement for patients. Canada has been at the forefront of adopting these therapies, yet significant challenges remain. These include expanding indications, training operators, optimizing access, and integrating these rapidly evolving procedures into a government-funded single-access healthcare system. This review explores the current landscape of TVIs in Canada. We discuss the necessity for centres of excellence, training pathways for operators, and the multidisciplinary infrastructure required to ensure equitable and high-quality care.

Background

The past two decades have witnessed a paradigm shift in the management of valvular heart disease, largely driven by transcatheter technologies that offer less invasive alternatives to surgical valve replacement or repair. Initially limited to high-risk surgical candidates, appropriate indications for many transcatheter valve interventions (TVIs) are now being expanded to include lower-risk populations, supported by robust clinical trial data and real-world evidence.[1,2] In Canada's government-funded healthcare system, the integration of novel interventions must balance clinical efficacy with cost-effectiveness, resource allocation, and accessibility. Unlike other jurisdictions with private healthcare components, Canada must navigate the implementation of TVIs within a system constrained by hospital budgets, procedural caps, and regional disparities. Moreover, provincial allocation of health budgets adds an additional constraint on adopting innovative technology. As indications for transcatheter therapies expand, success will necessitate not only technological advancements but also the development of specialized hospital programs, competent trained operators, and comprehensive post-procedural care. We explore the current state of TVIs across selected key disease states while highlighting the systemic requirements for sustainable program development into the future.

Transcatheter Aortic Valve Implantation (TAVI)

TAVI has transformed the management of valvular aortic stenosis (AS), particularly among elderly and high-risk patients. In Canada, TAVI has become widely adopted, with its indications expanding to low-risk populations. Continuous development of valve platforms, device iterations, and novel procedural techniques are enabling improvements in procedural success rates and lifetime management planning.

TAVI Indications

Although initially restricted to symptomatic severe AS patients who were at prohibitive or high surgical risk, TAVI is now also indicated for intermediate and low-risk patients, following landmark clinical trials.[1,2] TAVI using both the balloon-expandable SAPIEN-3 and self-expanding Evolut R/Pro prostheses has demonstrated non-inferior outcomes to surgical aortic valve replacement (SAVR) across all surgical risk subgroups, with outcomes sustained up to 5 years, and up to 10 years in low-risk populations.[1-7] While this update is reflected in the most recent 2020 American College of Cardiology (ACC)/ American Heart Association (AHA) Heart Valve Guidelines[8] and the 2021 European Society of cardiology (ESC/European [EACTS]) Guidelines,[9] the Canadian Cardiovascular Society's 2019 Position Statement on TAVI[10] has yet to be updated to include such patients. The Canadian Cardiovascular Society's National Quality Reports have demonstrated excellent outcomes, reinforcing the need for broader access.[10]

Current international guidelines and consensus support a heart team approach with shared decision-making. According to the European guidelines, SAVR is favoured in patients under the age of 75 and for those with high surgical risk, while the American guidelines recommend shared decision-making for those between 65 and 80 years. Surgery is also favoured in patients with complex anatomical features that are not suitable for TAVI, such as bicuspid valves with heavy calcification, low coronary heights, very small or large annuli, and inadequate vascular access.[8,9]

Current TAVI Devices

At present, three TAVI valve platforms are commercially available for use in Canada, while others are available through special access or as investigational devices being evaluated in clinical trials. These include the SAPIEN (Edwards Lifesciences), the Evolut (Medtronic, Minneapolis, MN) and the Navitor (Abbott Vascular, Abbott Park, IL) valves. Among high surgical risk patients with severe symptomatic AS, clinical trials have shown that the SAPIEN and Evolut platforms have demonstrated comparable clinical outcomes and mortality rates when directly compared.[11-13] Equivalent clinical outcomes have also been observed in meta analyses and real-world studies including data from Canadian registries.[14,15] Among patients with small aortic valve annular dimensions, both Evolut and SAPIEN devices have shown equivalent clinical outcomes; however, the Evolut valve has demonstrated superior hemodynamic performance with lower rates of bioprosthetic valve dysfunction and thrombosis.[12,16] These advantages may lead to improved long-term valve durability and outcomes for these patients. The Navitor valve has demonstrated excellent short-term outcomes among high-risk patients and has achieved significant improvements in outcomes compared with its predecessor, the PORTICO valve.[17,18] However, long-term and durability data for Navitor are still pending due to its recent introduction.

Access to TAVI

At present, 31 centres across Canada offer TAVI programs **(Figure 1)**. While TAVI is available in most provinces, limitations such as procedural volume caps and geographic disparities contribute to inequitable access, particularly in remote regions. Despite the rapid uptake and widespread use of the procedure, demand has outpaced capacity, resulting in growing wait times for TAVI.[19]

Western Canada
Mazankowski Alberta Heart Institute, Edmonton AB
Foothills Medical Centre, Calgary AB
Royal Jubilee Hospital, Victoria BC
St. Paul's Hospital, Vancouver BC
Vancouver General Hospital, Vancouver BC
Royal Columbian Hospital, New Westminster BC
Kelowna General Hospital, Kelowna BC
St. Boniface Hospital, Winnipeg MB
Regina General Hospital, Regina, SK
Royal University Hospital, Saskatoon SK
Ontario
Health Sciences North, Sudbury ON
Hamilton Health Sciences, Hamilton ON
London Health Sciences Centre, London ON
Kingston General Hospital, Kingston ON
Southlake Regional Health Centre, Newmarket ON
St. Michael's Hospital, Toronto ON
Sunnybrook Hospital, North York ON
Toronto General Hospital, Toronto ON
Trillium Health Partners, Mississauga ON
St. Mary's General Hospital, Kitchener ON
University of Ottawa Heart Institute, Ottawa ON
Quebec & Maritimes
Centre Hospitalier de l'University de Montreal (CHUM), Montreal QC
Hotel-Dieu De Sherbrooke (CHUS), Sherbrooke QC
Institut Universitaire De Cardiologie Et De Pneumologie de Quebec (IUCPQ), Quebec City QC
Hospital du Sacre-Coeur-de-Montreal, Montreal QC
Montreal Heart Institute, Montreal QC
McGill University Health Centre (Glen Site), Montreal QC
Jewish General Hospital, Montreal QC
Health Sciences Centre Eastern Health, St. John's NL
St. John Regional Hospital, Saint John NB
Queen Elizabeth II Health Sciences Centre, Halifax NS

Figure 1. Canadian TAVI centres: *courtesy of Bryan Traynor, MD*, and *Akshay Bagai, MD, MHS*

In response, innovative solutions to deal with this shortfall have included the development of a Canadian TAVI triage tool to help identify and prioritize patients based on clinical urgency.[20]

Challenges and Future Directions

Expansion of Indications for TAVI: Bicuspid aortic valve patients were excluded from the pivotal randomized controlled trials due to potential anatomical challenges such as asymmetric and higher leaflet calcification, fused raphe, larger annulus size, and associated aortopathy. Initial TAVI experiences in patients with bicuspid AS reported worse in-hospital outcomes including increased paravalvular leak, device malpositioning, permanent pacemaker implantation, aortic root injury, and stroke. However, with improvements in device technology, imaging modalities, and a better understanding of bicuspid aortic valve anatomy, outcomes for TAVI in patients with bicuspid aortic stenosis have improved.[21,22] Among patients with asymptomatic severe AS, the EARLY TAVR trial has demonstrated the short-term safety of TAVI compared with close follow-up (Recently FDA approved in the United States). However, active surveillance remains an important option, particularly for younger patients where concerns such as prosthetic valve degeneration and lifetime disease management are of greater importance.[23] Several ongoing clinical trials are assessing the benefit of TAVI for patients with moderate AS, including the PROGRESS (NCT04889872) and EXPAND TAVR II (NCT05149755) trials. In contrast, the TAVR UNLOAD trial failed to show a significant benefit for TAVI in moderate AS patients with reduced left ventricular systolic function.[24]

Lifetime Management: Increasing numbers of TAVI procedures are performed in younger, lower-risk patients as the evidence base has expanded. This shift has placed a greater emphasis on considering the long-term implications following TAVI. For example, optimizing valve durability, future coronary access, and future valve-in-valve TAVI planning have now become routine components of index TAVI procedure planning. Similar long-term considerations are also becoming increasingly important for patients receiving bioprosthetic SAVR procedures.

Canadian Health System Constraints: Funding limitations for TAVI programs remains a challenge with procedural caps limiting expansion. To address rising demand, more streamlined approval processes and dedicated funding strategies are required. This will become increasingly important as the burden of AS and expected need for TAVI procedures increases with a growing and aging population. Electrocardiogram-gated Cardiac CT angiography plays a vital role in TAVI procedure planning; however, limited access to timely CT imaging remains a key challenge for many TAVI programs, which limits expansion. Procedural complication rates associated with TAVI have declined dramatically in recent years, as improvements in device technologies, procedural techniques, and planning have been made.[25] As a result, some countries have removed the need for a mandatory on-site cardiovascular surgery department when performing TAVI.[26] This practice may become more acceptable as the need for TAVI continues to increase, particularly for patients deemed unfit for surgery. In a centralized health system with limited cardiovascular surgery sites, community hospitals without surgical back-up should be allowed to perform TAVI procedures in those who are not surgical bailout. Uncertainty remains regarding the universal need for coronary angiography prior to TAVI, as well as for the benefit of complete revascularization in patients with obstructive coronary artery disease.[27] Future studies including the ongoing COMPLETE TAVR trial (NCT04634240) aim to address these questions.

Aortic Insufficiency: Unlike AS, using TAVI for aortic insufficiency (AI) remains less established due to anatomical challenges. Most TAVI prostheses have been designed for calcified AS, while pure AI typically presents with larger associated annular dimensions and lack of calcification, making valve anchoring more challenging. However, dedicated devices such as the Trilogy system (JenaValve) and the J-Valve (Edwards Lifesciences) have shown promise in addressing these challenges and advancing transcatheter treatment options for severe AI.[28,29] Canadian experience with transcatheter treatment for AI remains limited to a small number of centres performing these procedures at low volumes. Additional data are needed to evaluate the transcatheter options for AI, particularly in patients at high surgical risk. Clinical trials have demonstrated the safety and effectiveness of the Trilogy system (JenaValve),[29] while enrolment has been completed for the ongoing J-Valve study (NCT06034028). Custom-designed transcatheter solutions for AI must be integrated into the

Canadian landscape through a controlled adoption strategy supported by national registries.

Transcatheter Mitral Valve Therapies

Mitral valve (MV) disease presents a complex challenge for transcatheter interventions, given its heterogeneous etiology. Mitral regurgitation (MR) is classified as primary or organic (PMR) and secondary or functional (FMR). PMR entails an intrinsic pathology of the leaflets and/or chordae tendineae. In contrast, FMR usually entails preserved leaflets and results from either ventricular remodelling/dysfunction (V-FMR) or from left atrial dilation (A-FMR), particularly among patients with atrial fibrillation (AF). The most common cause of primary MR is myxomatous degeneration of the MV leaflets, which leads to MV prolapse. Primary MR can also occur from leaflet perforation and cleft leaflets,

Name	City and Province
Mazankowski Alberta Heart Institute	Edmonton AB
Foothills Medical Centre	Calgary AB
Royal Columbian Hosptial	New Westminster BC
St. Paul's Hospital	Vancouver BC
Vancouver General Hospital	Vancouver BC
St. Boniface Hospital	Winnipeg MB
St. John Regional Hospital	Saint John NB
Queen Elizabeth II Health Sciences Centre	Halifax NS
St. Michael's Hospital	Toronto ON
Toronto General Hospital	Toronto ON
University of Ottawa Heart Institute	Ottawa ON
Southlake Regional Health Centre	Newmarket ON
Sunnybrook Hospital	North York ON
Trillium Health Partners	Mississauga ON
Hamilton Health Sciences	Hamilton ON
Kingston General Hospital	Kingston ON
London Health Sciences Centre	London ON
Montreal Heart Institute	Montreal QC
McGill University Health Centre (Glen Site)	Montreal QC
Institut Universitaire De Cardiologie Et De Pneumologie de Quebec (IUCPQ)	Quebec City QC
Centre Hospitalier de l'University de Montreal (CHUM)	Montreal QC
Hotel-Dieu De Sherbrooke (CHUS)	Sherbrooke QC
Royal University Hospital, Saskatoon	Saskatoon SK

Figure 2. Canadian M-TEER Centres; *courtesy of Bryan Traynor, MD, and Akshay Bagai, MD, MHS*

which are deep indentations that extend to the annulus. Additionally, rheumatic disease, certain medications, radiation exposure, and connective tissue diseases can cause restricted leaflet motion due to thickening of the leaflet edges and the subvalvular apparatus. An increasing cause of MR in the elderly population is mitral annular calcification. This degenerative process starts in the posterior annulus and extends into the base of the leaflets and subvalvular apparatus, affecting both annular and leaflet function. Thus, given the varied pathologies underlying primary MR, both surgical and transcatheter MV interventions require unique and varied techniques. These include MV repair techniques such as leaflet approximation, direct annuloplasty, indirect annuloplasty, and chordal repair, as well as MV replacement. At present, in Canada, the only commercially approved transcatheter technique is leaflet approximation with edge-to-edge repair.

Transcatheter Edge-to-Edge Repair

This technique emulates the surgical Alfieri edge-to-edge leaflet repair by approximating the free edges of the anterior and posterior leaflets using clips delivered percutaneously by catheters.[30] Currently, the procedure is performed under general anesthesia using fluoroscopy and transesophageal echocardiographic (TEE) guidance.

Transcatheter Mitral Edge-to -Edge Repair Indications

Surgical intervention remains the gold standard for treating severe primary MR, with repair recommended over replacement if feasible. To date, only the mitral transcatheter edge-to-edge repair (TEER) with the MitraClip device (Abbott, Santa Clara, CA) has been evaluated in a randomized clinical trial against surgical MV repair and/or replacement. In the EVEREST II trial, which included 154 degenerative MR patients, surgical treatment was more effective than transcatheter TEER with MitraClip for treating primary MR. However, many patients with degenerative MR have multiple comorbid conditions that place them at very high or prohibitive risk for surgery. In such a cohort of 127 degenerative MR patients

Name	City and Province
St. Paul's Hospital	Vancouver BC
Vancouver General Hospital	Vancouver BC
Queen Elizabeth II Health Sciences Centre	Halifax NS
St. Michael's Hospital	Toronto ON
Toronto General Hospital	Toronto ON
University of Ottawa Heart Institute	Ottawa ON
Southlake Regional Health Centre	Newmarket ON
Sunnybrook Hospital	North York ON
Trillium Health Partners	Mississauga ON
Hamilton Health Sciences	Hamilton ON
London Health Sciences Centre	London ON
Montreal Heart Institute	Montreal QC
McGill University Health Centre (Glen Site)	Montreal QC
Institut Universitaire De Cardiologie Et De Pneumologie de Quebec (IUCPQ)	Quebec City QC
Royal University Hospital	Saskatoon SK

Figure 3. Canadian T-TEER Centres; *courtesy of Bryan Traynor, MD Akshay Bagai, MD, MHS*

from the EVEREST II and REALISM (Real World Expanded Multicenter Study of the MitraClip System) studies, who were deemed at prohibitive surgical risk, treatment with the MitraClip device was associated with safety and good clinical outcomes. These included decreases in rehospitalization, functional improvements, and favourable ventricular remodelling.[31] Accordingly, the 2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease considered transcatheter TEER to be a reasonable treatment option for severely symptomatic patients (classified as New York Health Association [NYHA] III/IV) with primary severe MR who are at high or prohibitive surgical risk, provided that their MV anatomy is suitable for the repair procedure.[8]

Among patients with secondary or functional MR in the context of reduced left ventricular function, the 2020 Canadian Heart Failure Clinical Trial update recommends considering mitral TEER after patients have received maximally tolerated guideline-directed medical therapy (GDMT), including cardiac resynchronization therapy and revascularization where appropriate. This recommendation is supported by findings from the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial, which enrolled 614 patients after optimization of GDMT. The study showed that MitraClip therapy reduced secondary MR, and was associated with lower all-cause mortality at 2 years compared with GDMT alone.[32] Intervention with MitraClip has also been shown to reduce the risk of heart failure (HF)-related hospitalizations and significantly improve HF symptoms. These findings contrast with those of the Percutaneous Repair with the MitraClip device for Severe Functional/Secondary Mitral Regurgitation (MITRA-FR) trial, in which MitraClip intervention did not demonstrate a survival benefit.[33] The negative outcomes from the MITRA-FR trial have been attributed to factors such as more extensive LV dilation, less severe FMR, and the absence of forced optimization of medical GDMT prior to MitraClip therapy. More recently, the third randomized controlled trial conducted among this patient population, RESHAPE 2, showed that Mitra Clip therapy reduced the rate of first or recurrent hospitalization for HF or CV death at 24 months. Additionally, patients treated with MitraClip reported better health status at 12 months compared to those receiving GDMT alone.[34]

In Canada, the MitraClip device is being used for both degenerative and functional MR indications. A real-world observations study of 1,191 patients who underwent MitraClip across 11 Canadian centres found that MR etiology was degenerative in 41% of cases and functional in 59%. Among these patients, the rate of hospitalizations for HF dropped from 50.7% before to 10.3% within 1 year following M-TEER.[35] Although use of M-TEER is supported by data in patients with degenerative MR at high surgical risk, and in those with functional MR in the context of reduced LV function, mitral TEER use among patients with atrial functional MR (AFMR) requires additional studies. In such patients, the attribution of symptoms or a worse prognosis with AFMR is challenging. This is due to the frequent coexistence of comorbidities such as AF, heart failure with preserved ejection fraction, as well as other comorbidities such as hypertension and chronic kidney disease in these patients.

Current Mitral Edge-to-Edge Repair Devices

Two mitral TEER devices are now commercially available in Canada: the MitraClip (Abbott Vascular, Abbott Park, IL) and the PASCAL (Edwards Lifesciences). A pre-specified interim analysis from the CLASP IID trial, which included 180 patients, demonstrated that the PASCAL TEER system was non-inferior to the MitraClip TEER system in terms of both primary safety and efficacy endpoints.[36] In a recent real-world, multicenter study comparing the original PASCAL P10 device with the MitraClip NT device in the first 309 commercially-treated patients using propensity matching, both groups demonstrated high technical success. Notably, the PASCAL group achieved more effective MR reduction and lower mean mitral gradients. There were no differences in mortality or major adverse cardiac events, and both groups showed comparable improvements in NYHA functional class.[37] With two commercially available TEER devices of varying sizes, clinicians now have greater flexibility to tailor interventions to individual patient anatomy, optimizing MR reduction while balancing mitral gradients and procedure safety.

Access to Mitral Edge-to-Edge Repair

Access to mitral TEER remains limited, with 23 centres across Canada performing mitral TEER **(Figure 2)**. As the population of elderly patients with degenerative MR continues to grow, alongside the increasing number of HF patients

with functional MR, there a strong need for further expansion of the current mitral TEER programs, and to establish additional sites to meet the growing demand.

Challenges and Future Directions for Transcatheter Mitral Valve Interventions

Operator Expertise and Imaging Requirements: Transcatheter mitral interventions require advanced pre-procedural and intra-procedural TEE imaging, as well as procedural skills. In recent years, high-volume centres across Canada have begun formalizing training pathways for both cardiac imaging specialists and interventional cardiologists.

Transcatheter Mitral Valve Replacement (TMVR): Given the heterogeneity of MR etiologies, not all cases are suitable for mitral TEER (e.g., leaflet perforation, rheumatic, among others). Thus, TMVR provides treatment options for MV disease, both MR and MS, in patients at high surgical risk, or with anatomy not suitable for mitral TEER. TMVR also provides options for valve-in-valve or valve-in-ring procedures in patients with prior surgical MV replacement using a bioprosthesis or annuloplasty ring. Compared with TEER, TMVR provides complete or near-complete elimination of MR. Early feasibility studies across several TMVR platforms have shown promising results.[38,39] The transapical device, Tendyne (Abbott Vascular, Abbott Park, IL), has demonstrated efficacy in eliminating MR and improving patient outcomes.[40] Transseptal devices including the SAPIEN M3 (Edwards Lifesciences) and the Intrepid (Medtronic, Minneapolis, MN) are currently enrolling patients in clinical trials (NCT04153292, NCT03242642). While TMVR provides the advantage of being a solution that is "agnostic to the pathology", its broader application is limited by challenges with anatomic suitability, such as annular and predicted neo-left ventricular outflow tract dimensions.[41] At present, TMVR remains investigational in Canada and is available only at a small number of centres.

Transcatheter Tricuspid Valve Therapies

Tricuspid regurgitation (TR) is a common condition, affecting 4% of individuals over the age of 75.[42] TR also has several etiologies including primary valve disease, atrial functional mechanisms, ventricular function, or complications related to pacemaker/implantable cardioverter-defibrillator leads. Unlike MR, primary TR accounts for only a minority of cases, with most being functional or lead-related in origin. Traditionally, functional TR has been managed conservatively with diuretics due to the high surgical risk associated with surgical intervention.[43] However, the availability of transcatheter tricuspid therapies allows treatment of TR with reduced peri-procedural risk.

Transcatheter Edge-to-Edge Repair

Similar to mitral TEER, tricuspid TEER approximates the free edges of the valve leaflets (septal with either the anterior or posterior leaflet) using a clip delivered percutaneously via catheters. However, the tricuspid valve poses unique challenges including more complex heterogeneous anatomy, TEE imaging, and less predictable reductions in TR.

Tricuspid Edge-to-Edge Repair Indications

According to the 2020 AHA/ACC Valve Guidelines, the only class I indication for TR intervention is surgical repair among patients undergoing left-sided valve surgery. However, tricuspid TEER is likely to be included in the next version of the guidelines based upon the results of the TRILUMINATE trial. This study evaluated the safety and efficacy of tricuspid TEER in addition to medical therapy versus medical therapy alone in 572 patients with severe, symptomatic TR. At the 2-year follow-up, tricuspid TEER was shown to be safe, significantly reduced TR severity, and decreased the rate of heart failure hospitalizations, though it did not demonstrate a mortality benefit compared with medical therapy alone.[44] Thus, in general, tricuspid TEER should be considered for patients experiencing symptoms (fatigue, edema) attributable to severe TR despite optimal diuretic therapy, particularly when right ventricular function is preserved and pulmonary artery systolic pressure is <70mmHg and the valve anatomy is favourable for tricuspid TEER. However, patient selection for intervention in clinical practice is often more challenging. Many patients with TR also have multiple comorbidities (e.g., left side heart disease, renal insufficiency, AF, among others), which makes attribution of symptoms solely to the TR more challenging, and makes the response to TV intervention less predictable. In addition, the prognosis is frequently limited by their underlying comorbidities than by TR itself. Further research is needed to better identify which patients with TR

are most likely to benefit from transcatheter TR intervention.

Current Tricuspid Edge-to-Edge Repair Devices

At present, only Triclip (Abbott Vascular, Abbott Park, IL) is approved for tricuspid TEER in Canada. The PASCAL (Edwards Lifesciences) tricuspid TEER, which is available in Europe, but not yet approved in Canada, has also shown effective TR reduction and clinical improvements at 1 year, as reported in the PASTE registry of 1,059 patients.[45]

Access to Tricuspid Edge-to-Edge Repair

Access to tricuspid TEER is even further limited, with only 15 centres across Canada performing the procedure **(Figure 3)**. To date, adoption in Canada has been limited by procedural complexity, including the need for pre and peri-procedural imaging, and by a lack of funding in many regions. Recently, provincial funding for the Triclip device has expanded, with most, but not all, provinces funding Triclip. Further expansion of access will require investment in dedicated programs to develop the advanced imaging (i.e., 3-D intracardiac echocardiography) and procedural skills necessary to support safe and effective delivery of tricuspid TEER.

Challenges and Future Directions

Transcatheter Tricuspid Valve Replacement (TTVR): Although tricuspid TEER is generally safe and associated with low complication rates, its efficacy in TR reduction is limited by heterogeneity in valve morphology, intra-procedural imaging complexity, and operator experience. Orthotopic TTVR, where the replacement valve is placed in the tricuspid annulus, effectively eliminates TR and is not limited by valve morphology. Several devices using a variety of anchoring mechanisms are under development and have shown promise in early feasibility studies. Among these, only the EVOQUE valve (Edwards Lifesciences) has been recently approved by Health Canada and is available. In the TRISCEND II trial of 400 patients, TTVR with the EVOQUE device reduced TR to mild or less in 95.2% of patients and significantly improved quality of life at 1 year compared with medical therapy alone. Most adverse clinical events with TTVR were peri-procedural and included death from cardiovascular causes, severe bleeding, and conduction disorders leading to new pacemaker implantation.[46]

Given the complex nature of TR, and its severe clinical phenotypes, a one-size-fits-all approach is unlikely to succeed. Novel diagnostic tools that include artificial intelligence may offer future value by integrating multiple variables, analyzing large datasets, and harmonizing layers of knowledge to guide patient selection and procedural decision-making. Most importantly, these tools may help identify patients unlikely to benefit from transcatheter intervention. Additionally, the use of intracardiac echocardiography with image quality comparable to TEE may avoid the need for general anesthesia. Continuous improvements in current devices and new technologies will also expand treatment options and simplify procedural workflows.

Conclusion

TVIs are redefining structural heart disease management in Canada, with expanding indications across a range of valvular conditions. However, to fully integrate these therapies into the Canadian healthcare system, key barriers must be addressed, including limited access, procedural funding constraints, and gaps in operator training. By establishing centres of excellence, investing in multidisciplinary teams, and ensuring equitable distribution of resources, Canada can continue pushing the envelope for TVIs and improve outcomes for patients with valvular heart disease and remain at the global forefront of cardiovascular care.

Correspondence

Akshay Bagai, MD, MHS
Email: Akshay.Bagai@unityhealth.to

Financial Disclosures

B.T.: None declared
A.B.: Consulting/proctoring services for Abbott

References

1. Mack MJ, Leon MB, Thourani VH, Pibarot P, Hahn RT, Genereux P, et al. Transcatheter aortic-valve replacement in low-risk patients at five years. N Engl J Med. 2023;389(21):1949–1960. doi:10.1056/NEJMoa2307447
2. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18):1706–1715.

doi:10.1056/NEJMoa1816885
3. Makkar RR, Thourani VH, Mack MJ, Kodali SK, Kapadia S, Webb JG, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. N Engl J Med. 2020;382(9):799–809. doi:10.1056/NEJMoa1910555
4. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet. 2015;385(9986):2477–2484. doi:10.1016/S0140-6736(15)60308-7
5. Thyregod HGH, Jorgensen TH, Ihlemann N, Steinbruchel DA, Nissen H, Kjeldsen BJ, et al. Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial. Eur Heart J. 2024;45(13):1116–1124. doi:10.1093/eurheartj/ehae043
6. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376(14):1321–1331. doi:10.1056/NEJMoa1700456
7. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. 2014;370(19):1790–1798. doi:10.1056/NEJMoa1400590
8. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP, 3rd, Gentile F, et al. 2020 ACC/AHA Guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021;143(5):e72–e227. doi:10.1161/CIR.0000000000000923
9. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur J Cardiothorac Surg. 2021;60(4):727–800. doi:10.1093/ejcts/ezab389
10. Asgar AW, Ouzounian M, Adams C, Afilalo J, Fremes S, Lauck S, et al. 2019 Canadian Cardiovascular Society position statement for transcatheter aortic valve implantation. Can J Cardiol. 2019;35(11):1437–1448. doi:10.1016/j.cjca.2019.08.011
11. Thiele H, Kurz T, Feistritzer HJ, Stachel G, Hartung P, Eitel I, et al. Comparison of newer generation self-expandable vs. balloon-expandable valves in transcatheter aortic valve implantation: the randomized SOLVE-TAVI trial. Eur Heart J. 2020;41(20):1890–1899. doi:10.1093/eurheartj/ehaa036
12. Abdel-Wahab M, Mehilli J, Frerker C, Neumann FJ, Kurz T, Tolg R, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. JAMA. 2014;311(15):1503–1514. doi:10.1001/jama.2014.3316
13. Lanz J, Kim WK, Walther T, Burgdorf C, Mollmann H, Linke A, et al. Safety and efficacy of a self-expanding versus a balloon-expandable bioprosthesis for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: a randomised non-inferiority trial. Lancet. 2019;394(10209):1619–1628. doi:10.1016/S0140-6736(19)32220-2
14. Zhang XL, Wei ZH, Wang HW, Xu W, Wang Y, Xu B. Early and midterm outcomes of transcatheter aortic-valve replacement with balloon-expandable versus self-expanding valves: a meta-analysis. J Cardiol. 2022;80(3):204–210. doi:10.1016/j.jjcc.2022.04.011
15. Wijeysundera HC, Qiu F, Koh M, Prasad TJ, Cantor WJ, Cheema A, et al. Comparison of outcomes of balloon-expandable versus self-expandable transcatheter heart valves for severe aortic stenosis. Am J Cardiol. 2017;119(7):1094–1099. doi:10.1016/j.amjcard.2016.12.016
16. Herrmann HC, Mehran R, Blackman DJ, Bailey S, Mollmann H, Abdel-Wahab M, et al. Self-expanding or balloon-expandable TAVR in patients with a small aortic annulus. N Engl J Med. 2024;390(21):1959–1971. doi:10.1056/NEJMoa2312573
17. Sondergaard L, Walton AS, Worthley SG, Smith D, Chehab B, Manoharan G, et al. Thirty-day and one-year outcomes of the Navitor transcatheter heart valve in patients with aortic stenosis: the prospective, multicentre, global PORTICO NG Study. EuroIntervention. 2023;19(3):248–255. doi:10.4244/EIJ-D-22-01108
18. Aoun J, Zaid S, Goel S, Reardon MJ. A Comprehensive Evaluation of the NAVITOR Transcatheter Aortic Valve Replacement System. Heart Int. 2024;18(1):26–29. doi:10.17925/HI.2024.18.1.4
19. Albassam O, Henning KA, Qiu F, Cram P, Sheth TN, Ko DT, et al. Increasing wait-time mortality for severe aortic stenosis: a population-level study of the transition in practice from surgical aortic valve replacement to transcatheter aortic valve replacement. Circ Cardiovasc Interv. 2020;13(11):e009297. doi:10.1161/CIRCINTERVENTIONS.120.009297
20. Miranda RN, Qiu F, Manoragavan R, Austin PC, Naimark DMJ, Fremes SE, et al. Transcatheter aortic valve implantation wait-time management: derivation and validation of the Canadian TAVI triage tool (CAN3T). J Am Heart Assoc. 2024;13(5):e033768. doi:10.1161/JAHA.123.033768
21. Yoon SH, Kim WK, Dhoble A, Milhorini Pio S, Babaliaros V, Jilaihawi H, et al. Bicuspid aortic valve morphology and outcomes after transcatheter aortic valve replacement. J Am Coll Cardiol. 2020;76(9):1018–1030. doi:10.1016/j.jacc.2020.07.005
22. Williams MR, Jilaihawi H, Makkar R, O'Neill WW, Guyton R, Malaisrie SC, et al. The PARTNER 3 bicuspid registry for transcatheter aortic valve replacement in low-surgical-risk patients. JACC Cardiovasc Interv. 2022;15(5):523–532. doi:10.1016/j.jcin.2022.01.279
23. Genereux P, Schwartz A, Oldemeyer JB, Pibarot P, Cohen DJ, Blanke P, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217–227. doi:10.1056/NEJMoa2405880
24. Van Mieghem NM, Elmariah S, Spitzer E, Pibarot P, Nazif TM, Bax JJ, et al. Transcatheter Aortic valve replacement in patients with systolic heart failure and moderate aortic stenosis: TAVR UNLOAD. J Am Coll Cardiol. 2025;85(9):878–890. doi:10.1016/j.

jacc.2024.10.070
25. Harvey JE, 3rd, Kapadia SR, Cohen DJ, Kalra A, Irish W, Gunnarsson C, et al. Trends in complications among patients undergoing aortic valve replacement in the United States. J Am Heart Assoc. 2024;13(17):e031461. doi:10.1161/JAHA.123.031461
26. Eggebrecht H, Mehta RH, Haude M, Sack S, Mudra H, Hein R, et al. Transcatheter aortic valve implantation (TAVI) by centres with and without an on-site cardiac surgery programme: preliminary experience from the German TAVI registry. EuroIntervention. 2014;10(5):602–608. doi:10.4244/EIJV10I5A105
27. Tarantini G, Tang G, Nai Fovino L, Blackman D, Van Mieghem NM, Kim WK, et al. Management of coronary artery disease in patients undergoing transcatheter aortic valve implantation. A clinical consensus statement from the European Association of Percutaneous Cardiovascular Interventions in collaboration with the ESC Working Group on Cardiovascular Surgery. EuroIntervention. 2023;19(1):37–52. doi:10.4244/EIJ-D-22-00958
28. Hensey M, Murdoch DJ, Sathananthan J, Alenezi A, Sathananthan G, Moss R, et al. First-in-human experience of a new-generation transfemoral transcatheter aortic valve for the treatment of severe aortic regurgitation: the J-Valve transfemoral system. EuroIntervention. 2019;14(15):e1553–e1555. doi:10.4244/EIJ-D-18-00935
29. Vahl TP, Thourani VH, Makkar RR, Hamid N, Khalique OK, Daniels D, et al. Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study. Lancet. 2024;403(10435):1451–1459. doi:10.1016/S0140-6736(23)02806-4
30. Alfieri O, Maisano F, De Bonis M, Stefano PL, Torracca L, Oppizzi M, et al. The double-orifice technique in mitral valve repair: a simple solution for complex problems. J Thorac Cardiovasc Surg. 2001;122(4):674–681. doi:10.1067/mtc.2001.117277
31. Lim DS, Reynolds MR, Feldman T, Kar S, Herrmann HC, Wang A, et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation after transcatheter mitral valve repair. J Am Coll Cardiol. 2014;64(2):182–192. doi:10.1016/j.jacc.2013.10.021
32. Stone GW, Lindenfeld J, Abraham WT, Kar S, Lim DS, Mishell JM, et al. Transcatheter mitral-valve repair in patients with heart failure. N Engl J Med. 2018;379(24):2307–2318. doi:10.1056/NEJMoa1806640
33. Obadia JF, Messika-Zeitoun D, Leurent G, Iung B, Bonnet G, Piriou N, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. N Engl J Med. 2018;379(24):2297–2306. doi:10.1056/NEJMoa1805374
34. Anker SD, Friede T, von Bardeleben RS, Butler J, Khan MS, Diek M, et al. Transcatheter valve repair in heart failure with moderate to severe mitral regurgitation. N Engl J Med. 2024;391(19):1799–1809. doi:10.1056/NEJMoa2314328
35. Mehta SR, Asgar A, Boone R, Rodes-Cabau J, Cohen EA, Czarnecki A, et al. Efficacy and safety of transcatheter mitral valve edge-to-edge repair with a MitraClip device in real-world Canadian practice. CJC Open. 2025. https://doi.org/10.1016/j.cjco.2025.05.008
36. Zahr F, Smith RL, Gillam LD, Chadderdon S, Makkar R, von Bardeleben RS, et al. One-year outcomes from the CLASP IID randomized trial for degenerative mitral regurgitation. JACC Cardiovasc Interv. Published online October 26, 2023. doi:10.1016/j.jcin.2023.10.002
37. Mauri V, Sugiura A, Spieker M, Iliadis C, Horn P, Ozturk C, et al. Early outcomes of 2 mitral valve transcatheter leaflet approximation devices: a propensity score-matched multicenter comparison. JACC Cardiovasc Interv. 2022;15(24):2541–2551. doi:10.1016/j.jcin.2022.10.008
38. Zahr F, Song HK, Chadderdon S, Gada H, Mumtaz M, Byrne T, et al. 1-year outcomes following transfemoral transseptal transcatheter mitral valve replacement: Intrepid TMVR early feasibility study results. JACC Cardiovasc Interv. 2023;16(23):2868–2879. doi:10.1016/j.jcin.2023.10.001
39. Webb JG, Murdoch DJ, Boone RH, Moss R, Attinger-Toller A, Blanke P, et al. Percutaneous transcatheter mitral valve replacement: first-in-human experience with a new transseptal system. J Am Coll Cardiol. 2019;73(11):1239–1246. doi:10.1016/j.jacc.2018.12.065
40. Muller DWM, Sorajja P, Duncan A, Bethea B, Dahle G, Grayburn P, et al. 2-year outcomes of transcatheter mitral valve replacement in patients with severe symptomatic mitral regurgitation. J Am Coll Cardiol. 2021;78(19):1847–1859. doi:10.1016/j.jacc.2021.08.060
41. Scotti A, Coisne A, Granada JF. Screening for TMVR: a glimpse into the future technological needs and requirements. Can J Cardiol. 2023;39(5):590–592. doi:10.1016/j.cjca.2023.03.004
42. Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. J Am Coll Cardiol. 2004;43(3):405–409. doi:10.1016/j.jacc.2003.09.036
43. Ambrosino M, Sangoi M, Monzer N, Irving B, Fiorilli P, Khazan B, et al. Tricuspid regurgitation: a review of current interventional management. J Am Heart Assoc. 2024;13(6):e032999. doi:10.1161/JAHA.123.032999
44. Kar S, Makkar RR, Whisenant BK, Hamid N, Naik H, Tadros P, et al. Two-year outcomes of transcatheter edge-to-edge repair for severe tricuspid regurgitation: the TRILUMINATE pivotal randomized controlled trial. Circulation. 2025;151(23):1630–1638. doi:10.1161/CIRCULATIONAHA.125.074536
45. Wild MG, Stolz L, Rosch S, Rudolph F, Goebel B, Koll B, et al. transcatheter valve repair for tricuspid regurgitation: 1-year results from a large European real-world registry. J Am Coll Cardiol. 2025;85(3):220–231. doi:10.1016/j.jacc.2024.10.068
46. Hahn RT, Makkar R, Thourani VH, Makar M, Sharma RP, Haeffele C, et al. Transcatheter valve replacement in severe tricuspid regurgitation. N Engl J Med. 2025;392(2):115–126. doi:10.1056/NEJMoa2401918