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CANADIAN CARDIOVASCULAR SOCIETY TOOLKIT: TRANSCATHETER AORTIC VALVE IMPLANTATION

2019



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THE CANADIAN CARDIOVASCULAR SOCIETY (CCS) TAVI TOOLKIT OVERVIEW

The TAVI toolkit has been developed in an effort to:

- Complement the CCS TAVI Quality Indicators (QIs);
- Improve the data quality of the CCS TAVI Quality Report by providing guidance, resources, and practice-ready strategies;
- Strengthen collaboration and on-going commitment to the CCS TAVI Quality Report initiative;
- Share resources and capitalize on local initiatives to accelerate national quality improvement; and
- Support clinicians and programs to optimize care.

This module introduces the framework used to develop a suite of individual modules built to augment the CCS TAVI Quality Indicators.





HEART TEAM TREATMENT RECOMMENDATION MODULE

CONTENTS

Module Overview.....	1
1. CCS Quality Indicator Definition	2
2. Opportunities and Challenges	4
3. Practical Tips and Best Practices.....	5
4. Questions and Answers.....	9
5. Resources	10
List of Tables.....	18
List of Figures	18
Sources.....	18

MODULE OVERVIEW

In the TAVI Toolkit Heart Team Treatment Recommendation module, users are provided with:

- Objective and key considerations for documenting Heart Team Treatment Recommendation;
- Benefits and challenges of using a Heart Team decision-making approach;
- Practical tips to promote Heart Team decision making; and
- Helpful resources to support implementation.

Following review of this module, users will have strategies and tools to support the documentation of a Heart Team approach to treatment for this **structural indicator**.

I. CCS QUALITY INDICATOR DEFINITION

Documentation of Heart Team Treatment Recommendation aims to promote a multi-disciplinary decision-making process to support quality of care.

Table I. Heart Team Treatment Recommendation (CCS Quality Indicator)¹

HEART TEAM TREATMENT RECOMMENDATION	
Description	Documented consensus treatment recommendation made by Heart Team at multidisciplinary meeting to review patients. The Heart Team should meet minimum requirements of an interventional cardiologist and cardiac surgeon but should ideally be composed of the patient's treating physician, geriatrician or internist, cardiac imaging specialist and TAVI nurse coordinator. This multi-disciplinary team should convene as a group on a regular basis to review and interpret clinical data to arrive at a consensus on the optimal treatment strategy for each patient.
Numerator	Number of TAVI patients who have a documented treatment recommendation from a heart team (minimum of interventional cardiologist and cardiac surgeon) meeting at a center during the given observation period.
Denominator	Total number of patients referred for TAVI at a center in a given observation period.
Method of Calculation	This structure indicator would be confirmed annually by the participating sites (i.e., Does a multidisciplinary team that includes at minimum a cardiologist and cardiac surgeon meet regularly to discuss a consensus treatment recommendations for patients referred for TAVI?)
Sources of Data	Institutional clinical data Hospital records (patient charts)

The Heart Team approach is widely endorsed in international guidelines as a strong recommendation. The primary purpose is to leverage multi-disciplinary expertise to guide the management of patients with complex severe valvular heart disease. A strong, collaborative Heart Team is widely accepted as a requisite component of TAVI programs.

At a minimum, the Heart Team is comprised of an interventional cardiologist and cardiac surgeons who share expertise in the management of complex structural heart disease. The additional contributions of imaging specialists (CT radiology and echocardiology) and nursing, as well as anaesthesiology, heart function specialists, and geriatric cardiology can augment the multi-disciplinary expertise.

A Heart Team approach is well suited to conduct the complex evaluation of patients with heart valve disease. The approach relies on their collective understanding of the risks and benefits of different treatment options to determine if TAVI is indicated, technically feasible, and reasonable. The Heart Team can present treatment options to patients and their family to foster shared decision-making.

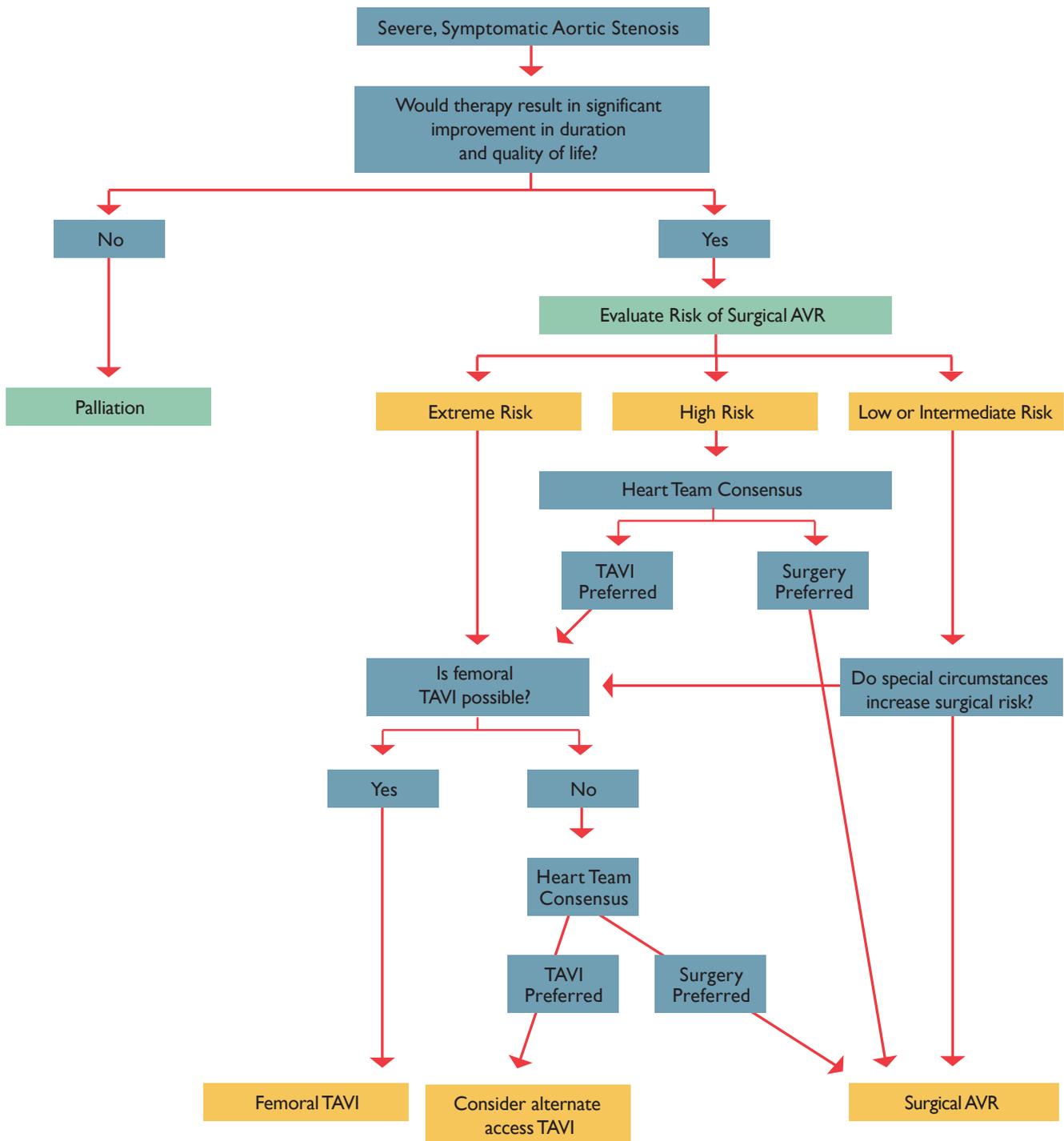


Figure 1. CCS Position Statement: Clinical decision trees for patients with AS²

2. OPPORTUNITIES AND CHALLENGES

Opportunities

TAVI owes much of its success to the Heart Team given the integral role they play in this (among other) complex cardiac management programs. This has been attributed to the multi-disciplinary approach the Team takes which prioritizes the interests of clinicians and patients, as well as the advancement of transcatheter heart valve innovation. Patient selection remains a significant challenge, especially as evidence continues to evolve. The goal is for the multidisciplinary team to move away from a system of fragmented care and offer a balanced and complementary approach to guide the management of patients with complex heart valve disease.

The expertise of cardiology and cardiac surgery provides complementary input to build a consensus treatment recommendation for each patient and contribute to individualized procedure planning. In addition, the input of imaging specialists, anaesthesiologists, nurses, geriatric medical specialists and other engaged experts can augment the quality of case selection and the anticipation of procedural and post-procedural needs.

The role of the TAVI nurse coordinator is pivotal to coordinate the complex aspects of patients' assessment and procedure planning, facilitates effective and streamlined multi-disciplinary collaboration, and serves as a central point of contact for patients and their family. Centres can capitalize on the availability and interest of diverse stakeholders by including them in the multidisciplinary assessment, the treatment recommendation meetings, and the in-hospital care. This "large Heart Team" concept can be an effective approach to implement coordinated and comprehensive strategies along patients' journey of care from referral to follow-up.

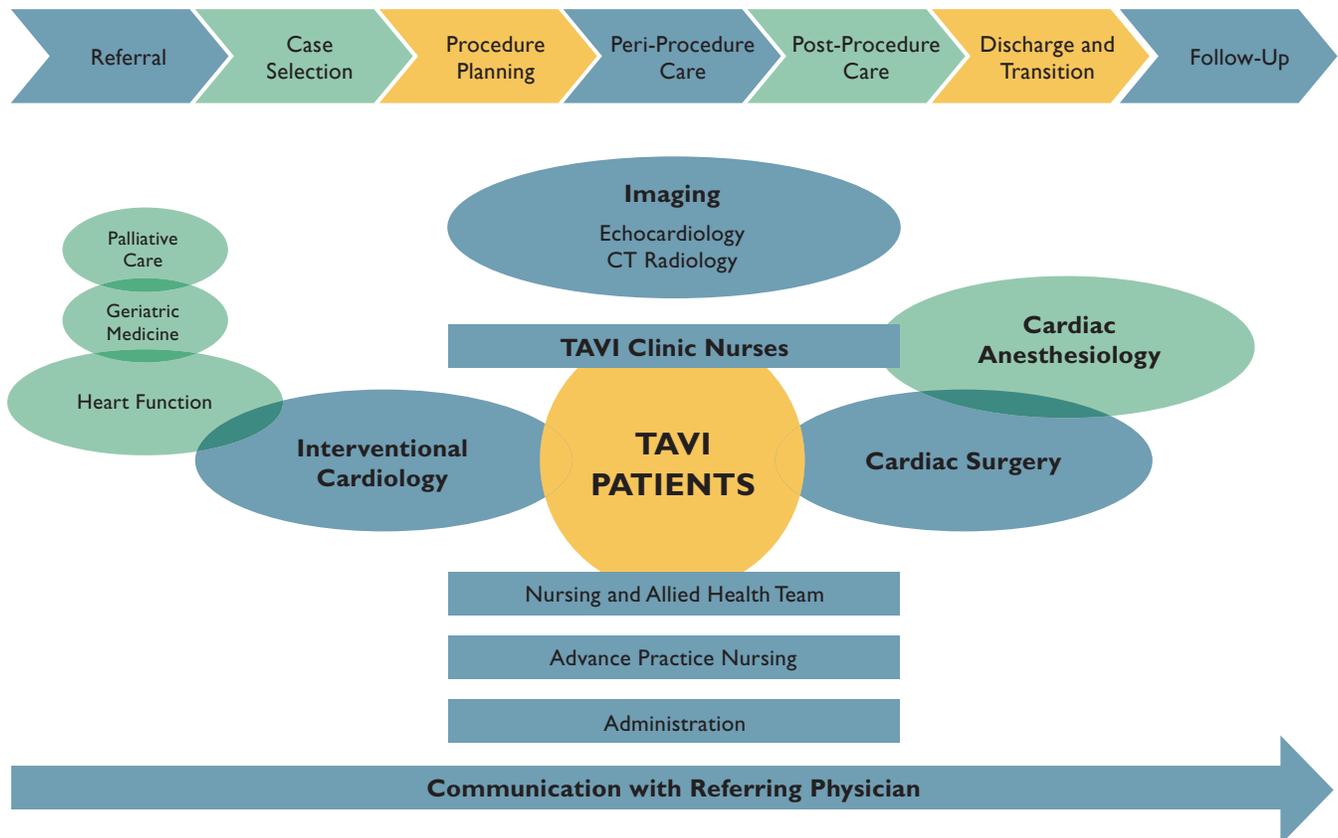


Figure 2. Conceptualization of a "Large" Heart Team approach to care of TAVI patients

Challenges

Canadian centres have reported the following challenges in promoting a Heart Team approach:

- There is no clear consensus on the definition, desired goals, means of implementation, and metrics to assess success and unintended consequences of a Heart Team approach. There is a need to study the hypothesized benefits, understand how the Heart Team improves care, and identify the structural and operational factors that are central to its success. Metrics are required to measure the timeliness and appropriateness of recommendations and outcomes.
- A Heart Team approach requires time and collaboration between stakeholders across disciplines who may not routinely meet. Finding a suitable time to discuss patients and ensuring the key stakeholders are present can be challenging. Overcoming these logistical barriers can be perceived as excessively difficult in spite of the support of the Team.
- There can be uneven buy-in from different disciplines about the value-add of the process. There are few studies reporting evidence about the value of a Heart Team approach.
- If a program is built on a traditional model of referrals to individual cardiologists or surgeons rather than the endorsement and operationalization of a centrally coordinated program, the timing and impact of a Heart Team meeting can be problematic.
- The documentation of the Heart Team's recommendation is not standardized. It is unclear how the process can help improve TAVI programs and multi-disciplinary communication.

3. PRACTICAL TIPS AND BEST PRACTICES

Using Documentation of Heart Team Recommendations to Improve Communication

The development of a program-endorsed form that serves as a template for recording individual treatment recommendations and provides a preliminary procedure plan that can be a helpful clinical tool.

Data elements that can be helpful include:

- Basic patient demographics, including urgency (e.g., elective out-patient vs. urgent in-patient);
- Treatment recommendations, including reasons patient may not be accepted for TAVI;
- Procedure planning, including planned procedural approach, pre-procedure requirements, etc.;
- Record of Heart Team members present for discussion.

See [Resources](#) for examples of forms used in Canadian centers to document Heart Team Recommendations. These forms can be adapted to meet local needs.

Using Documentation of Heart Team Recommendation to Support Shared Decision-Making

As TAVI quality indicators evolve, it will become increasingly important to support patients' treatment recommendation. Helping patients opt for SAVR or TAVI, or on-going medical management when treatment may not be recommended or would be futile, requires a concerted approach by the Team. To this end, the Heart Team becomes a vehicle to facilitate joint decision-making.

Shared decision-making is a process by which clinicians and patients work together to select treatment based on clinical evidence and the patient's informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences. Shared decision-making improves decision quality and patient satisfaction and, in some cases, results in more cost-effective care.

Resources for Clinicians:

The translation of clinical practice guidelines is an important step to facilitate the uptake of evidence in clinical care. International guidelines continue to evolve rapidly to keep pace with clinical trials, new procedural approaches and devices, and a large volume of emerging evidence. In 2016, an international panel of experts considered the evidence of three linked rapid systematic reviews; it produced an interactive set of recommendations for clinicians to consider when making a treatment recommendation.

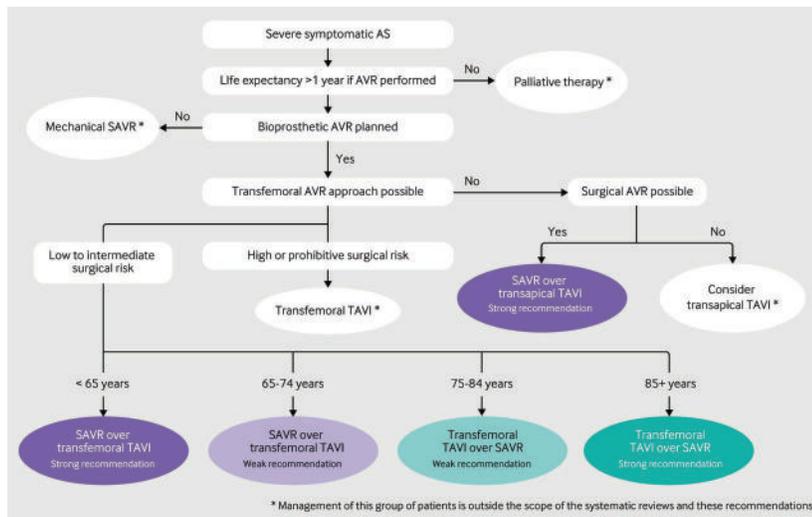


Figure 3. Flowchart for management of severe aortic stenosis³

See [Resources](#) for further details.

Resources for Patients:

Decision aids are a part of a shared decision-making process. These tools help people take an active role in decision-making by making explicit the decision that needs to be made, providing information about the options and outcomes, and by clarifying personal values. They are used and presented by clinicians and are a means of helping people make informed choices about healthcare that take into account their personal values and preferences. They are designed to complement, rather than replace, counseling from a health practitioner.

The goals are:

- To inform people about the available options, from an evidence-based perspective
- To encourage active engagement with the decision-making process
- To help people think through what is important to them, so that they can make choices that reflect their own values and preferences

The ACC CardioSmart Decision Aids hub recently expanded to include two new free, downloadable [TAVI Decision Aid Tools](#) that help patients understand what AS is and what treatments are available.

The first tool guides patients with intermediate or high surgical risk through the treatment options available for severe AS and helps them choose between TAVI and surgery. The second tool is dedicated to patients with prohibitive surgical risk/patients who are inoperable to help them evaluate the proper treatment and choose between TAVI and symptoms management/palliative approach. See Resources for further details on this ACC resource.

Incorporating the Measurement of Frailty in the Heart Team Treatment Recommendations

Careful case selection remains an important component of TAVI program quality. In addition to the pivotal question about whether TAVR is anatomically and clinically feasible, there is strong evidence to support the consideration of patients' frailty when making individual treatment recommendations and determining patients' likelihood to derive benefit.

Frailty is different than aging; it is not captured in surgical risk scores and helps explain the heterogeneity of older adults. Frailty is a complex health state, often defined as an age-related, multi-system syndrome that increases health vulnerabilities and risks of adverse events (e.g., significant decline, functional impairment, death) when exposed to stressors (e.g., hospitalization, illness), compared to patients who are the same age.

Frailty may be associated with increased risk of major adverse events including in-hospital complications, longer length of stay, increased hospital readmission, worsening quality of life, falls, functional dependence, disability, and death. The predictive value of frailty was highlighted in early clinical trials and continues to play a role in international administrative registries and on-going studies. The cycle of frailty in cardiovascular disease is well documented:

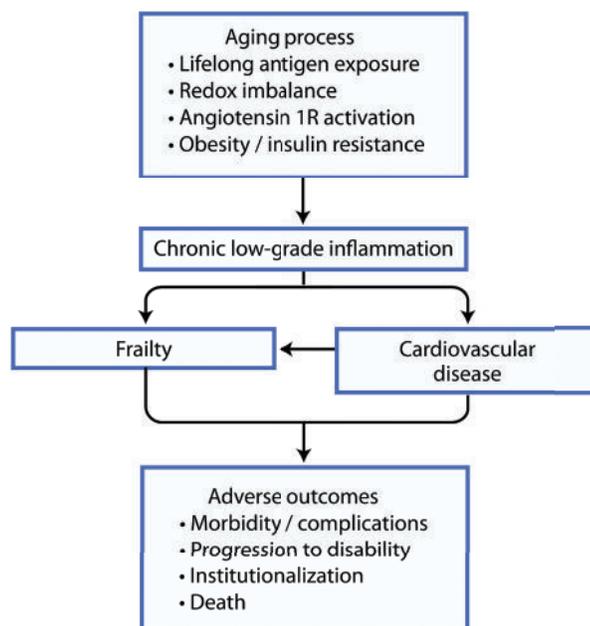


Figure 4. Cycle of frailty and cardiovascular disease⁴

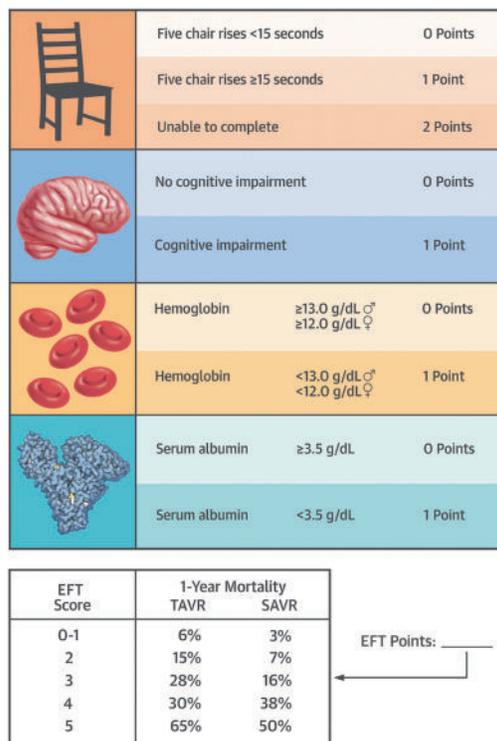
Measuring frailty in clinical practice can be challenging to measure consistently and rigorously, and its value is often questioned. Upward of 20 frailty assessment tools have been developed, leading to significant confusion and variability in clinical care and research. The absence of consensus surrounding frailty assessment tools, the unstandardized measurements employed in research and clinical care, and the lack of validation in the TAVI population have been significant barriers to the seamless integration of frailty measurement in practice.

The recent publication of the Essential Frailty Toolset (EFT)⁵ gives clinicians a pragmatic and reliable tool to measure frailty in TAVI programs. The EFT is a simple assessment of four easily available indicators:

1. Chair rises [Lower extremity strength]: The capacity to perform five sequential chair rises with arms folded on chest. The timer starts when the patient is sitting on a flat chair and instructed to begin to stand; it is stopped when the patient stands at the completion of the last stand.
2. Cognitive status [Short term memory and orientation]: The score obtained on the Mini-Cog™ measurement of three-word registration and clock drawing; alternatively, the following questions can be asked: (1) What day of the month is it? (2) What day of the week is it? (3) What hospital are you in? and (4) What floor are you on?
3. Hemoglobin
4. Albumin

The four indicators generate a score that is associated with a predictive risk of 1-year mortality for TAVI and SAVR. The EFT is quick to perform, does not require specialized equipment, and has high inter-observer reliability; it is available as a free smart phone application and does not require a license.

CENTRAL ILLUSTRATION: Essential Frailty Toolset in Older Adults Undergoing Aortic Valve Replacement



Afilalo, J. et al. *J Am Coll Cardiol.* 2017;70(6):689-700.

Figure 5. Essential Frailty Toolset components and score⁵

If measured, information about frailty should be shared with the Heart Team at the time of treatment recommendation. See **Resources** for an example of documentation of frailty using the Essential Frailty Toolset.

4. QUESTIONS AND ANSWERS

Does documenting a Heart Team approach mean that both interventional cardiologists and cardiac surgeons must participate in each procedure?

The intent of this structural quality indicator is to promote the participation of both specialists in treatment recommendations. This joint expertise is essential for case selection and procedure planning. The configuration and expertise of implanting medical teams varies across centres and is not captured in this quality indicator.

There is no evidence that a Heart Team approach makes a difference for outcomes in the era of contemporary TAVI. Why should we continue to promote it?

There is widespread endorsement of the rationale for team-based care of complex patients in the rapidly evolving clinical context of transcatheter heart valve therapies. In spite of low levels of evidence, the recommendation for programs to maintain a Heart Team approach remains highly recommended in Canadian and international guidelines.

To comply with the CCS Quality Indicator, do people need to meet in-person to discuss patients, or can the discussion happen in other ways (e.g., telephone, e-mail, remote meetings)?

The spirit of the quality indicator is to favour in-person, focused recommendations that employ multi-modality imaging and promote multi-disciplinary input.

How should results of tests concerning frailty or shared decision-making be used by the Heart Team?

Ideally, the Heart Team conducts a comprehensive assessment inclusive of anatomical and functional (e.g., frailty) criteria, and patient perspective. The TAVI nurse coordinator is well suited to present findings related to the assessment of frailty and report on conversations with patients to highlight their goals of care.

Resource #2: Shared Decision-Making

Example #1: The following shared decision-making resource is published as a free, open access [manuscript](#). The resource outlines the following statement:

“Severe aortic stenosis affects approximately 3 in 100 people over the age of 75 years. Patients typically experience symptoms of heart failure and reduced quality of life. Without aortic valve replacement, life expectancy is typically 50% at two years, with escalation of heart failure and reduced quality of life. These recommendations are for patients with symptoms and severe aortic stenosis: patients without symptoms or with milder disease are not considered here”.³ (i5085)

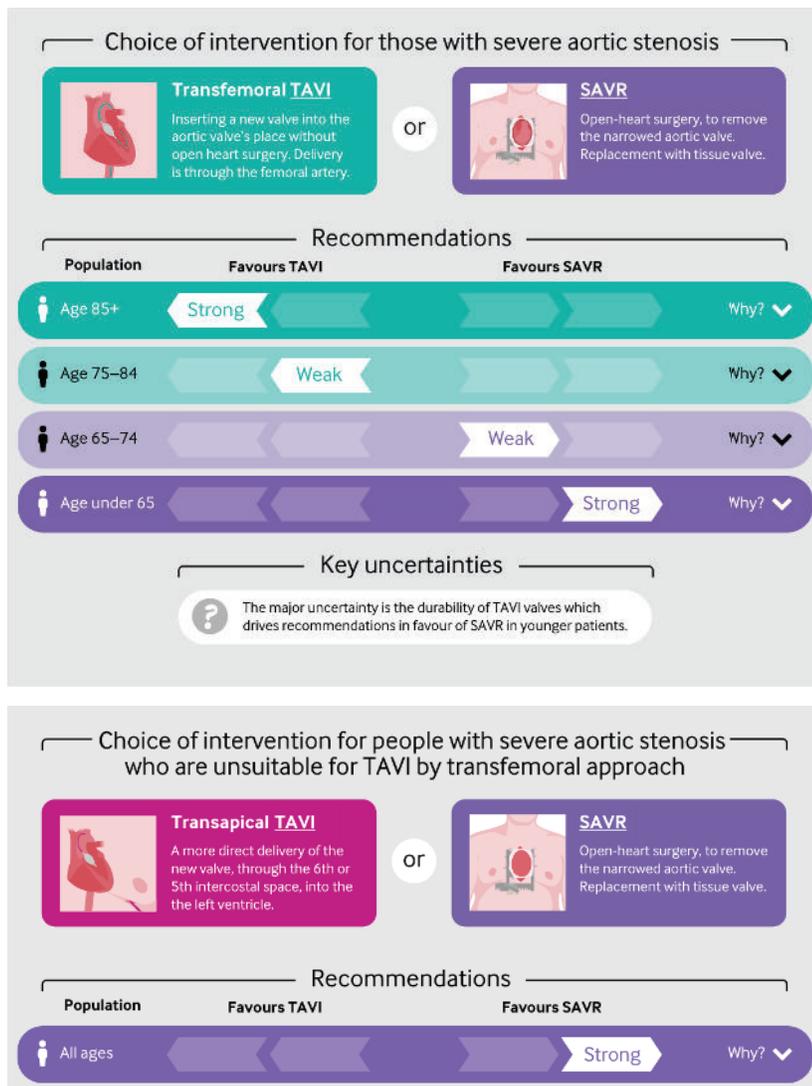


Figure 7. Key considerations for patients with symptoms and severe AS³

PRACTICAL ISSUES

	TAVI	SAVR
PROCEDURE	<ul style="list-style-type: none"> Conscious sedation Catheter-based procedure Under 2 hours Bovine or porcine valve and attached to a flexible, metallic mesh frame 	<ul style="list-style-type: none"> General anesthesia Major surgery About 3-5 hours Valve replacement uses bovine or porcine tissue The heart may be stopped and supported by a machine
RECOVERY	<ul style="list-style-type: none"> Consider who will help with activities during recovery Avoid strenuous activity Rehabilitation may help recovery Some patients report poor sleep Typically 2-5 days in hospital About 1 month to recover Pain from insertion site resolves within a few weeks Data on emotional well-being after TAVI is scant 	<ul style="list-style-type: none"> Typically 5-10 days in hospital About 2-3 months to recover About 1 in 4 report pain in the sternum after 1 year, with 1 in 10 with more serious pain Some report mood swings, anxiety, though may also have been present before surgery
ADVERSE EFFECTS	<ul style="list-style-type: none"> Endocarditis (about 1% per year) Repeat procedure if unsuccessful Some symptoms of heart failure can remain after procedure Cognitive decline might occur after valve replacement, but how often is not clear See summary of findings Long-term effects of TAVI are less well known than surgery 	<ul style="list-style-type: none"> See summary of findings
WORK & EDUCATION	<ul style="list-style-type: none"> Time until return to work depends on speed of recovery May be 2-6 weeks 	<ul style="list-style-type: none"> May be 6-8 weeks
TRAVEL & DRIVING	<ul style="list-style-type: none"> Driving may be limited during recovery 	<ul style="list-style-type: none"> Driving is limited for 6 weeks until the sternal bone heals
MEDICATION	<ul style="list-style-type: none"> Antiplatelet or anticoagulation medication after procedure, as needed Pain medication after procedure, as needed 	
VISITS	<ul style="list-style-type: none"> Post operative visits are typically within 1-2 months, and then yearly to check that the valve is working 	

Figure 8. Practical considerations that may influence a patient's choice of procedure³

Resources #3: Decision Aids

The ACC/CardioSmart has published two decision aids that reflect current evidence. Both brochures call on patients to consider:

- Their goals for treating AS;
- Their concerns related to treatment options;
- Additional questions for their clinician?

1. ACC/CardioSmart decision aid for severe AS treatment options (TAVR vs. Symptom Management)

Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. This booklet is specifically for individuals who cannot have open-heart surgery. You, your family, and your clinicians can begin to discuss which treatment option is best for you”.⁷ The content focuses on:

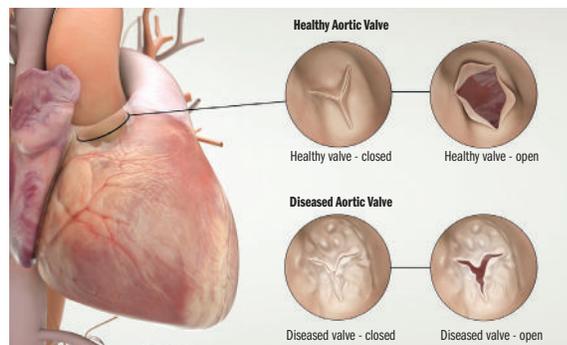
- (1) Understanding AS;
- (2) Treatment options (TAVR vs. symptom management);
- (3) Benefits;
- (4) Risks; and
- (5) Introduction to palliative care.

2. ACC/CardioSmart decision aid for treatment options for severe aortic stenosis for patients deciding between TAVR and surgery

Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. You, your family, and your clinicians can begin to discuss which treatment option is best for you”.⁸ The following are illustrations of this brochure:

UNDERSTANDING AS

Aortic Stenosis (AS) is tightening of the aortic valve in the heart. This can get worse over time. AS makes it harder for the heart to do its job.



SYMPTOMS OF SEVERE AS INCLUDE:

- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. **Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.**

Figure 9. Understanding AS⁸

TREATMENT OPTIONS

TAVR

Transcatheter Aortic Valve Replacement
transcatheter procedure

WHAT:

TAVR is a procedure where a new valve is placed in the heart through a small tube (called a “catheter”) typically in the leg.

HOW:

This procedure involves a small incision where a catheter is inserted to access the heart to replace the valve.

WHO:

This method is an option for both patients who are and those that are not candidates for open-heart surgery.

HOSPITAL STAY:

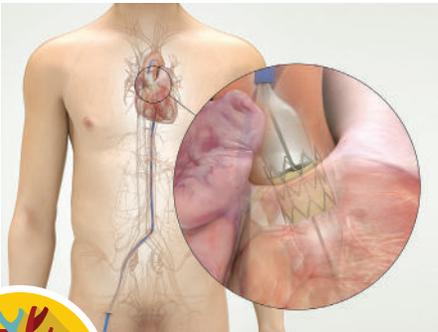
On average, 2-3 days

RECOVERY TIME:

On average, 1-2 weeks

VALVE TYPE:

A bioprosthetic valve is used



SAVR

Surgical Aortic Valve Replacement
open-heart surgery

WHAT:

SAVR is open-heart surgery where a new valve is placed in the heart directly, replacing the old valve.

HOW:

This surgery usually involves an incision along the breastbone to access the heart to replace the valve.

WHO:

Those without other severe health problems are good candidates for open-heart surgery.

HOSPITAL STAY:

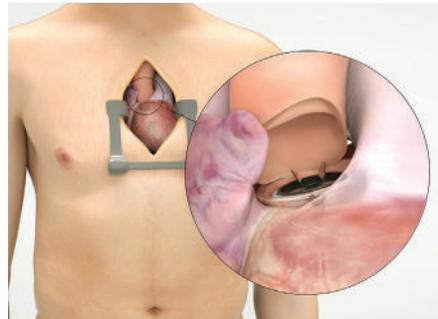
On average, 1 week

RECOVERY TIME:

On average, 6-8 weeks

VALVE TYPE:

A bioprosthetic valve or mechanical valve is used



Every patient is different, and we cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we do about TAVR valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if it ever needs to be replaced.

Figure 10. TAVR and SAVR overview⁸

THE RISKS & BENEFITS OF YOUR OPTIONS

TAVR vs. SAVR: Which is the best decision for me?*

*Leon et al. (2016). New England Journal of Medicine; Reardon et al. (2017). New England Journal of Medicine

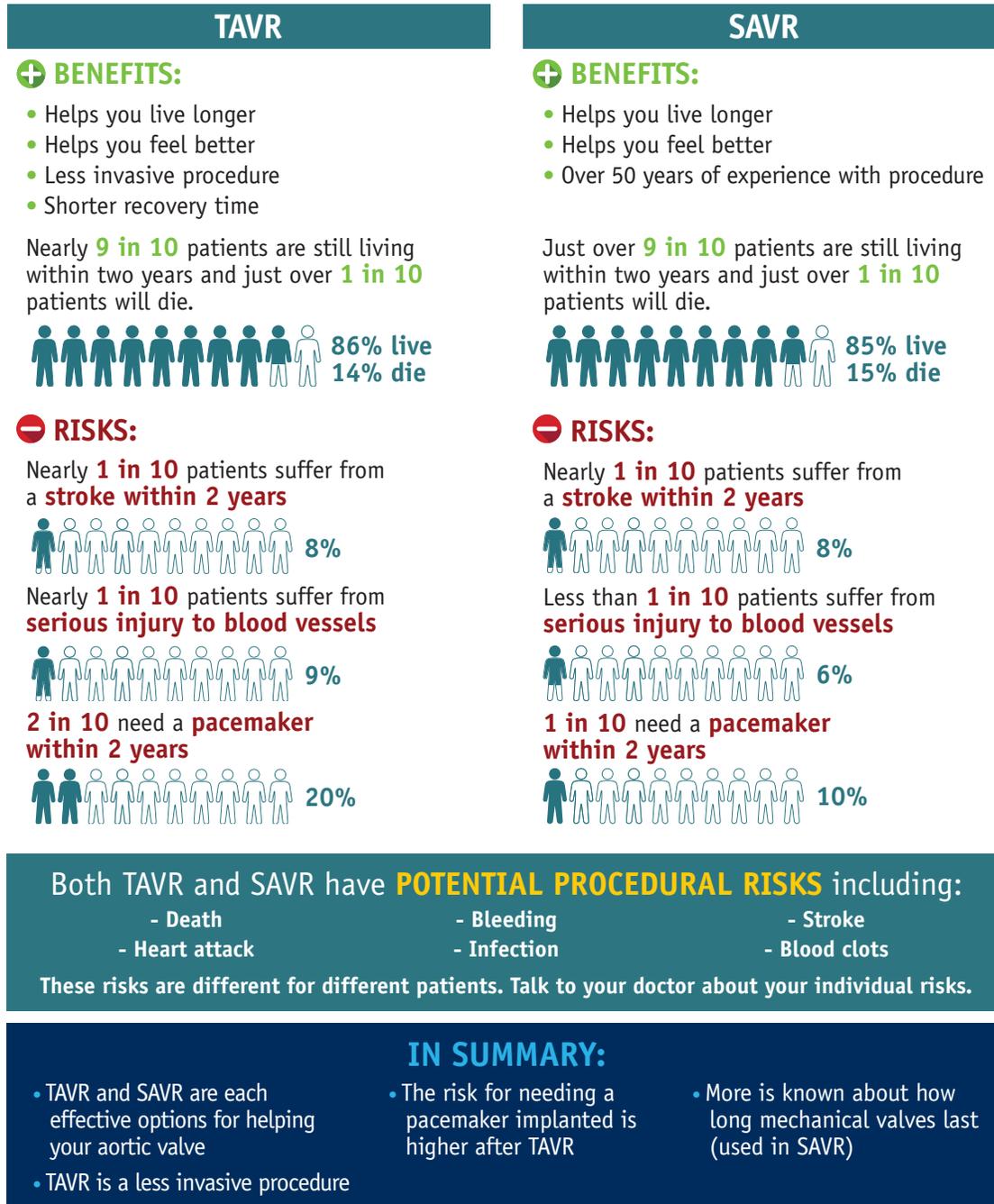


Figure II. Risks and Benefits of TAVR and SAVR⁸

TREATMENT SCENARIO 1



- **JANE IS AN 80-YEAR-OLD WOMAN WITH SEVERE AS.**
- She also has moderate lung disease and diabetes.
- She has shortness of breath when she walks across a room.
- Her clinician thinks it might be related to her aortic valve. Jane talked to her clinician to better understand the risks and benefits involved with her options.

Option 1: Choose TAVR

- ▶ TAVR is less invasive.
- ▶ The recovery time is shorter.
- ▶ Jane can expect similar results.



After talking to her clinician, Jane decided the **TAVR procedure** was the best option for her. She is concerned her other illnesses will make recovering from open-heart surgery more difficult.

Option 2: Choose SAVR

- ▶ TAVR is a newer procedure, while SAVR has been around for a long time.
- ▶ Jane knows people who have had open-heart surgery.

Figure 12. TAVR vs. SAVR case study⁸

Resource #4: Clinical documentation to support TAVI case selection using EFT



Date:	Patient Information:	
Essential Frailty Toolset (EFT)		
Measure	Score	EFT Points
Chair Rises	13 Sec.	0
Cognition: Items	2	0
Cognition: Clock	Normal	
Albumin	3.0 g/dL	1
Hemoglobin	12.1g/dL	0
EFT Score	1/5 (Predicted 1-yr mortality: 6% - All access)	
Other Frailty Indicators		
Measure	Score	Rating
ADLs	5/6	✓
IADLs	4/8	✗
5-Metre Gait	6 Sec.	✓
Overall Nursing Recommendation		
Comments:	✓	



Patient photograph guidelines:

- Patient is told ahead of time that photograph is routine practice (include in patient education resources)
- Patient is encouraged to pretend it is a "family photo" (i.e., not a "passport photo")
- Bulky clothes removed
- Without mobility aid if possible
- Photograph is taken in same setting with consistent approach

Figure 13. Sample clinical documentation to support TAVI case selection using EFT (Centre for Heart Valve Innovation, St. Paul's Hospital, Vancouver General Hospital)⁹

LIST OF TABLES

1. Table 1. Heart Team Treatment Recommendation (CCS Quality Indicator) ¹	2
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LIST OF FIGURES

1. Figure 1. Clinical decision trees for patients with AS ²	3
2. Figure 2. Conceptualization of a “Large” Heart Team approach to care of TAVI patients	4
3. Figure 3. Flowchart for management of severe AS ³	6
4. Figure 4. Cycle of frailty and cardiovascular disease ⁴	7
5. Figure 5. Essential Frailty Toolset components and score ⁵	8
6. Figure 6. Sample documentation of Heart Team treatment recommendations for procedure planning ⁶	10
7. Figure 7. Key considerations for patients with symptoms and severe AS ³	11
8. Figure 8. Practical considerations that may influence a patient’s choice of procedure ³	12
9. Figure 9. Understanding AS ⁸	13
10. Figure 10. TAVR and SAVR overview ⁸	14
11. Figure 11. Risks and Benefits of TAVR and SAVR ⁸	15
12. Figure 12. TAVR vs. SAVR case study ⁸	16
13. Figure 13. Sample clinical documentation to support TAVI case selection using EFT ⁹	17

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