



TAVR in Medium and Low Surgical Risk Population

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What is Risk?

- Possibility of danger/injury/loss
 - Person or thing that creates a hazard
 - Chance of financial loss
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Challenge in surgery: Difficult to forecast exact probabilities & all possible outcomes for any individual patient.

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Mitigating Risk:

- Avoidance (Decline surgery)
- Modification
 - Alter timing of procedure
 - Modify patient comorbidities – Prehabilitation, Nutrition, DM/HgbA1c, etc

➤ *Risk exposure vs Anticipated value of the procedure*





What is Risk: PROM (Predicted Risk of Mortality)

Definitions

Operative Mortality: Death occurring within 30 days of surgical procedure or any time during index hospitalization (not discharged within 30 days of surgery), [or Discharge to Hospice - July 2020]

Reoperation: Reoperations include return to OR (RTOR) for Bleed, RTOR Other Cardiac, RTOR Graft Occlusion, Reintervention for Myocardial Ischemia, Aortic Reintervention, and RTOR for Valve Dysfunction.

Prolonged Ventilation: > 24 hours of ventilation from the time of exiting the OR (includes ventilation time if reintubated after surgery)

Renal Failure: Those without pre-existing renal failure (Creat \geq 4 mg/dl or currently on dialysis) that develop renal failure according to RIFLE criteria - increase creat $3 \times$ > baseline, or creat \geq 4 mg/dl with at least 0.5 mg/dl rise, or require dialysis.

Stroke: Any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain in which the symptoms did NOT resolve within 24 hours.

Deep Sternal Wound Infection: DSWI includes deep sternal wound or mediastinitis within 30 days of surgery or any time during index hospitalization

Readmission: Any patient returning to the hospital as an inpatient (observation status is excluded) within 30 days of discharge from surgical stay

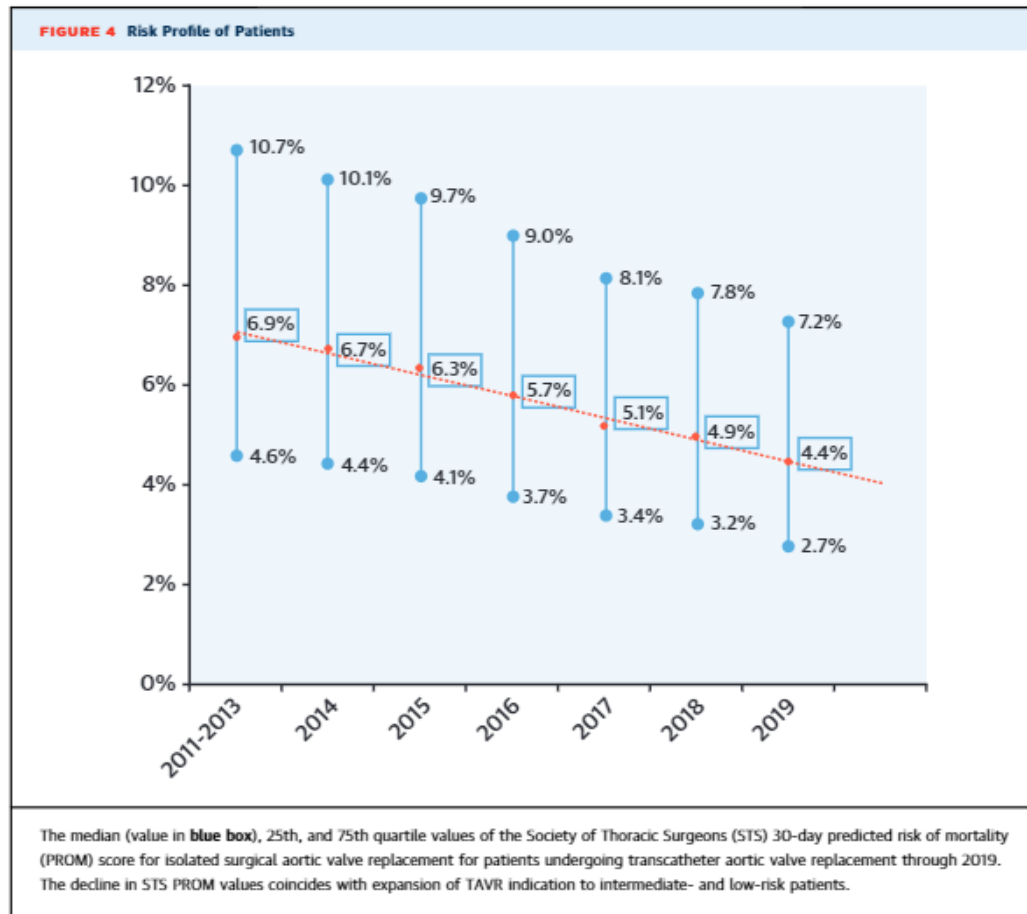
Surgical LOS: Days spent in hospital after surgical date, calculated from end of OR time

ICU LOS: Hours spent in ICU after surgical procedure, calculated from end of OR time

< 6 Hour Ventilation: Patients with early extubation, calculated from end of OR time



What is Risk: PROM (Predicted Risk of Mortality)



STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement.
Am Coll Cardiol 2020;76:2492-516

Risk Assessment



	High Risk (1 criterion)	Prohibitive Risk (1 criterion)
STS PROM	> 8%	> 50% Risk of Death / Major Morbidity at 1 Year
Frailty	≥ 2 Indices (Mod-Severe)	
Major Organ System Compromise*	≤ 2 Organ Systems	≥ 3 Organ Systems
Procedure-specific Impediment†	Possible	Severe

* **Examples of major organ system compromise:** Cardiac- severe LV systolic or diastolic dysfunction or RV dysfunction, fixed\ PHTN; CKD stage 3 or worse; pulmonary dysfunction with FEV1 <50% or DLCO₂ <50% of predicted; CNS dysfunction –Crohan’s disease, ulcerative colitis, nutritional impirment, or serum albumin <3.0; cancer –active malignancy; and liver-any history or cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

† **Examples:** tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage.

Nishimura RA et al. JACC. 2014. doi: 10.1016/j.jacc.2014.02.537.



Complexities of Measuring Risk



While some patients may have low STS scores, certain conditions may preclude them from being suitable candidates for surgery, ie *Decline Surgery*

For example:

- Extensively calcified (porcelain) aorta
- Chest wall deformity
- Oxygen-dependent respiratory insufficiency
- Frailty

Leon M et al. New England Journal of Medicine 2010 October 21;363(17):1597-1607.



Example: Porcelain aorta in TAVR candidate



Frailty: An Important Parameter in Assessing Operative Risk



Prevalence of frailty increases with aging;
old does not necessarily equal frail

Elderly patients achieve measurable benefit from cardiac surgery, particularly in terms of Quality of life

Increased survival

Prevention of adverse cardiovascular events

➤ The “Eyeball Test”



Same age: 90
&
STS PROM = 12%

One passes the
“eyeball test,”
one does not



Frailty: An Important Parameter in Assessing Operative Risk



Cardiac Surgery Consult: What is your opinion? Do you say ...

Prevalence of frailty increases with aging:

Old does ≠ frail



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Frailty: An Important Parameter in Assessing Operative Risk

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➤ The “Eyeball Test”



Frailty: An Important Parameter in Assessing Operative Risk

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

	Five chair rises <15 seconds	0 Points
	Five chair rises ≥15 seconds	1 Point
	Unable to complete	2 Points
	No cognitive impairment	0 Points
	Cognitive impairment	1 Point
	Hemoglobin ≥13.0 g/dL ♂ ≥12.0 g/dL ♀	0 Points
	Hemoglobin <13.0 g/dL ♂ <12.0 g/dL ♀	1 Point
	Serum albumin ≥3.5 g/dL	0 Points
	Serum albumin <3.5 g/dL	1 Point

EFT Score	1-Year Mortality	
	TAVR	SAVR
0-1	6%	3%
2	15%	7%
3	28%	16%
4	30%	38%
5	65%	50%

EFT Points: _____

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

The EFT is scored 0 (least frail) to 5 (most frail) based on the following 4 items: pre-procedural anemia, hypoalbuminemia, lower-extremity muscle weakness defined as a time of ≥15 s or inability to complete five sit-to-stand repetitions without using arms, and cognitive impairment defined as a score of <24 on the Mini-Mental State Examination (which is highly unlikely if the patient is able to correctly recall 3 out of 3 words after a distractive task and may obviate the need for further cognitive testing). EFT = Essential Frailty Toolset; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

PARTNER II Trial Frailty Index Assessment:

- 5m Walk test
- Grip Strength
- Serum Albumin
- Katz ADL

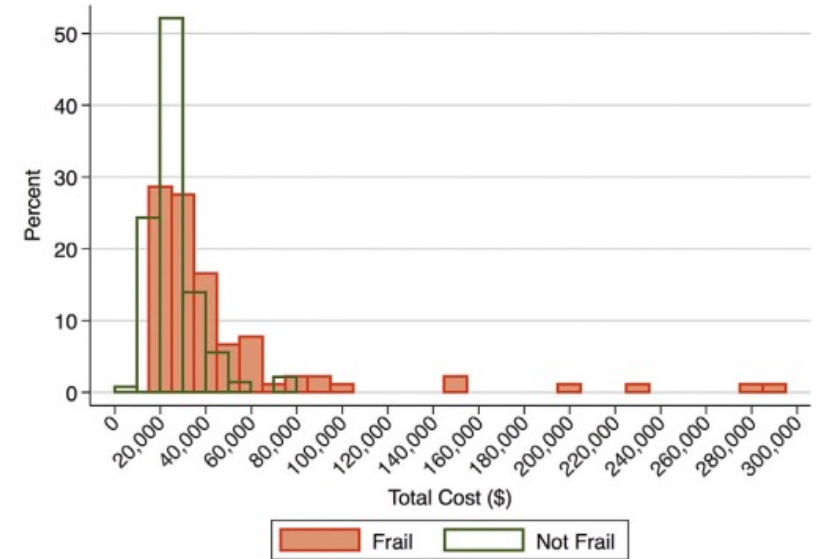


Figure 1. Hospitalization cost by frailty status.

Canadian Journal of Cardiology 33 (2017) 1020–1026

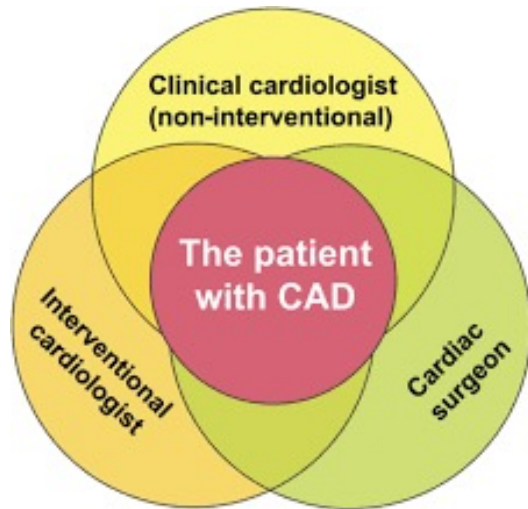
Clinical Research Cost of Cardiac Surgery in Frail Compared With Nonfrail Older Adults



Development of the “Heart Team”

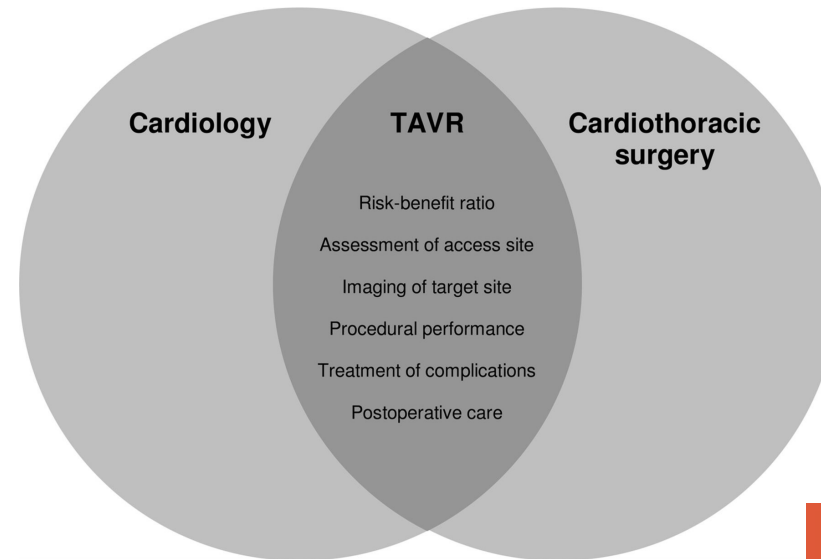
Heart Team has emerged as a class 1 indication:

2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery Guidelines for Coronary Revascularization



2012 ACC/AHA Guidelines for Coronary Artery Bypass Grafting

The development of a **TAVR Heart Team** and blending the disciplines of cardiology and cardio-thoracic surgery will enhance optimal patient selection, procedural performance and outcome.



European Heart Journal

David R. Holmes, Jr et al. *Eur Heart J* 2014;35:66-68

Co-published in The Annals of Thoracic Surgery, European Journal of Cardio-Thoracic Surgery, and European Heart Journal. Copyright © 2013 by The Society of Thoracic Surgeons; published with permission by the European Association for Cardio-Thoracic Surgery and the European Society of Cardiology.



CENTRAL ILLUSTRATION Mortality Associated With Untreated Aortic Stenosis

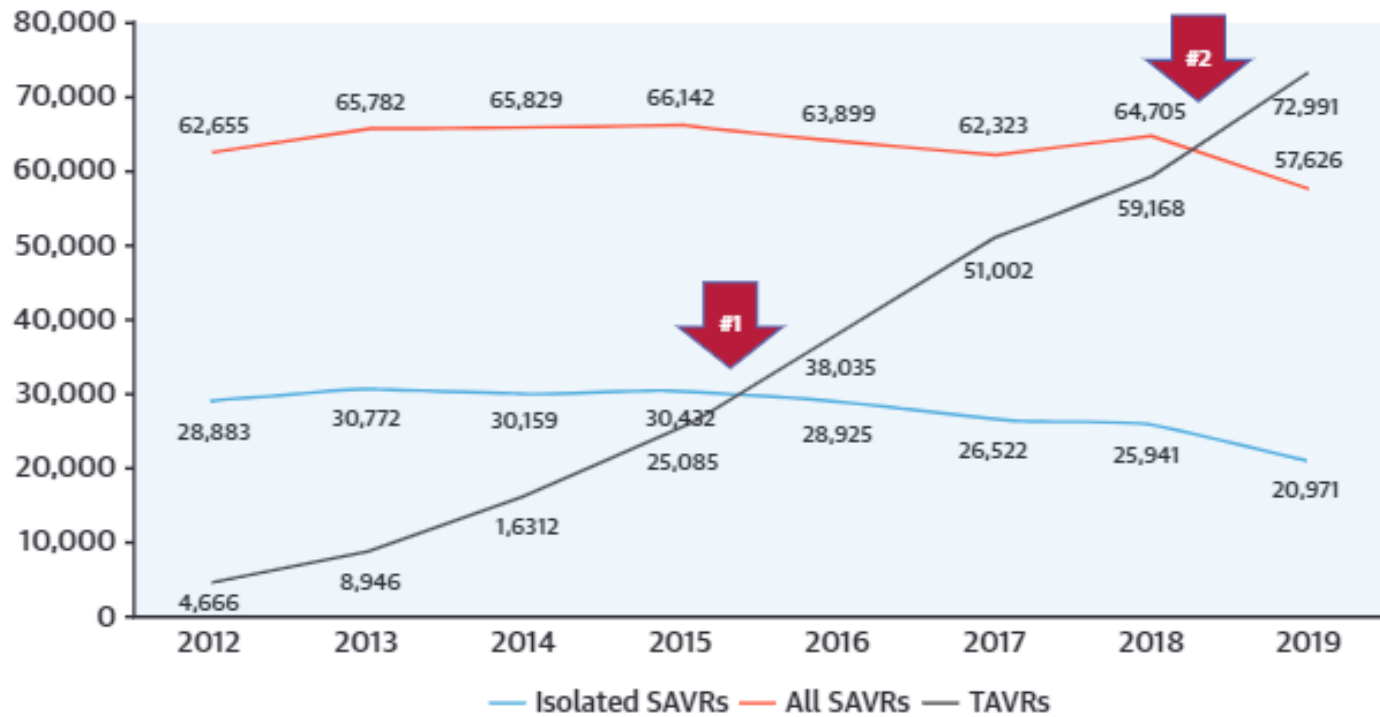
595,120 Patients With AS Assessment	AS Severity		4-Year Treatment Rates With AVR	4-Year Mortality Without AVR
	ACC/AHA Dx	Intermediate Dx		
No AS 524,342 (88.1%)	61,293 (86.6%)	9,485 (13.4%)		
AS Dx 70,778 (11.9%)	Mild AS 34,614 (48.9%)		1.0%	25.0%
	Mild-to-Moderate AS 5,796 (8.2%)		4.2%	29.7%
	Moderate AS 14,550 (20.6%)		11.4%	33.5%
	Moderate-to-Severe AS 3,689 (5.2%)		36.7%	45.7%
	Severe AS 12,129 (17.1%)		60.7%	44.9%

Généreux P, et al. J Am Coll Cardiol. 2023;■(■):■-■.

A total of 595,120 patients with documented AS assessment per echocardiogram were included in our study. Among them, 70,778 (11.9%) patients were diagnosed with some degree of AS, from whom 61,293 (86.6%) were classified as mild, moderate, or severe, and 9,485 (13.4%) were identified with "intermediate" severity (mild-to-moderate or moderate-to-severe AS). Treatment rates up to 4 years were low, with mortality increasing with AS severity increment. ACC = American College of Cardiology; AHA = American Heart Association; AS = aortic stenosis; AVR = aortic valve replacement; Dx = diagnosis.



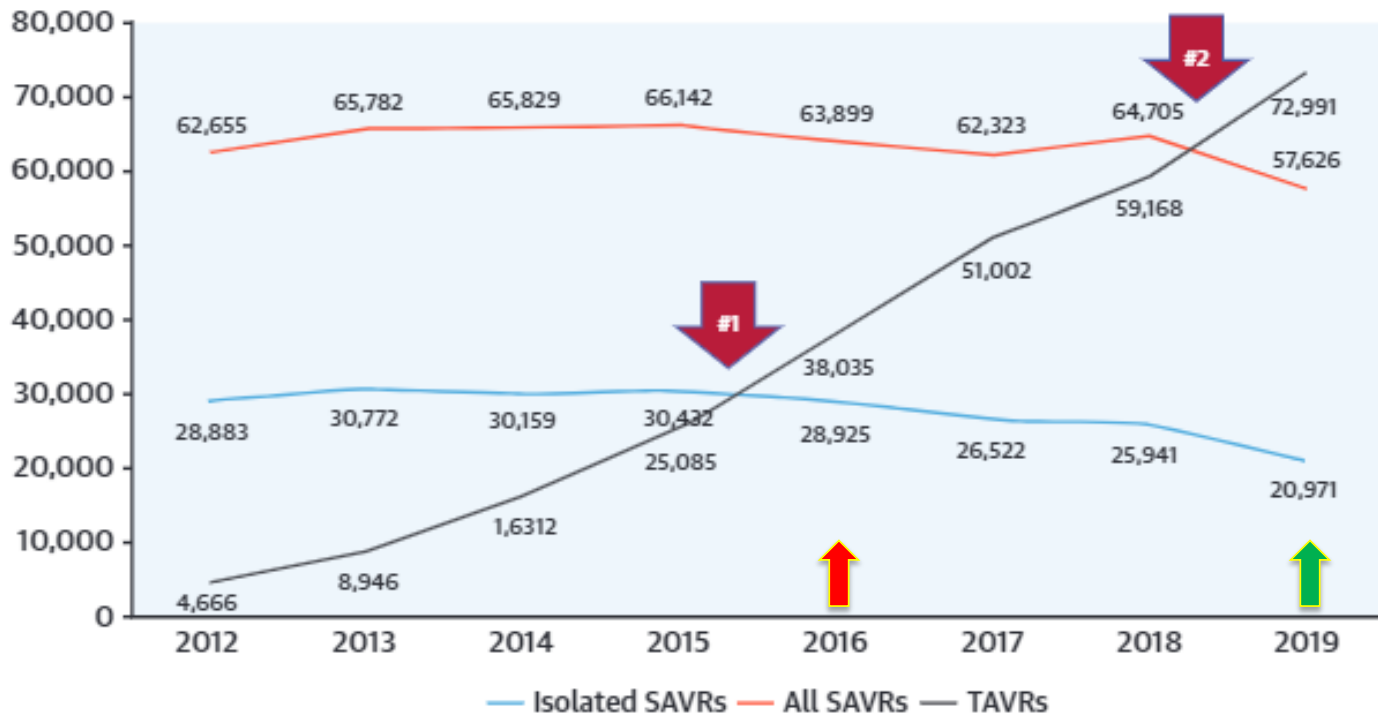
FIGURE 2 Annual Volumes of TAVR and SAVR



The volume of isolated surgical aortic valve replacement (SAVR) (**blue line**), all forms of SAVR (SAVR + coronary artery bypass grafting, Bentall procedures, and SAVR plus other surgical procedures, **red line**), and transcatheter aortic valve replacement (TAVR) (**gray line**) are shown from 2012 until 2018. The 2 **red arrows** denote transition points: **Arrow #1**—the volume of TAVR first exceeded isolated SAVR between 2015 and 2016 with the beginning of a decline in isolated SAVR volume that in 2019 was 9,801 fewer cases than the peak in 2013. TAVR in intermediate-risk patients was approved in 2016. **Arrow #2**—the volume of TAVR exceeded all forms of SAVR between 2018 and 2019 with a 1-year decline in 2019 from 2018 of 7,079 for all types of SAVR cases. TAVR for low-risk patients was approved in 2019. Source of SAVR data is the Society of Thoracic Surgeons National Database. AVR = aortic valve replacement.



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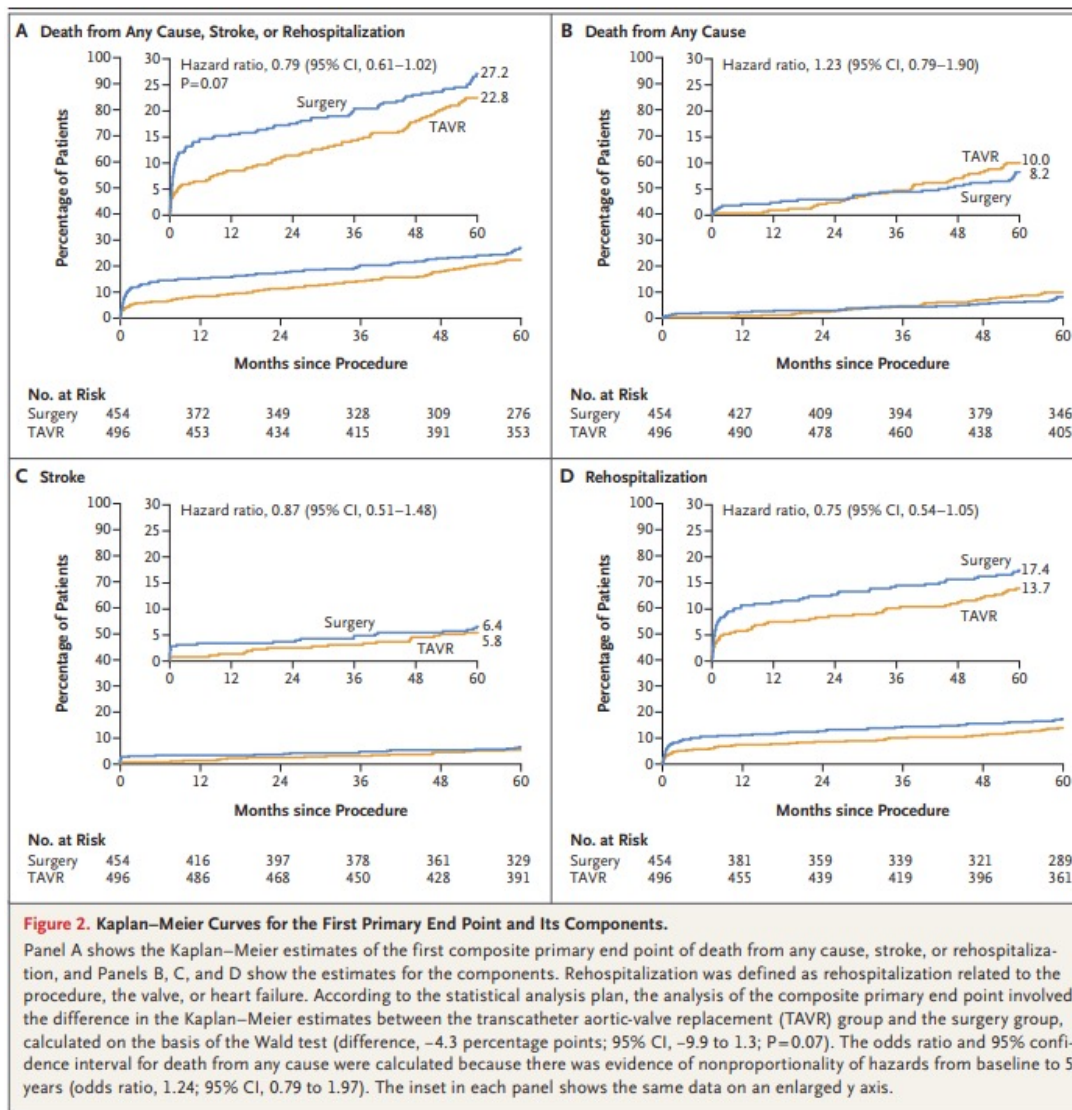


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Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

M.J. Mack, M.B. Leon, V.H. Thourani, P. Pibarot, R.T. Hahn, P. Genereux, S.K. Kodali, S.R. Kapadia, D.J. Cohen, S.J. Pocock, M. Lu, R. White, M. Szerlip, J. Ternacle, S.C. Malaisrie, H.C. Herrmann, W.Y. Szeto, M.J. Russo, V. Babaliaros, C.R. Smith, P. Blanke, J.G. Webb, and R. Makkar, for the PARTNER 3 Investigators*



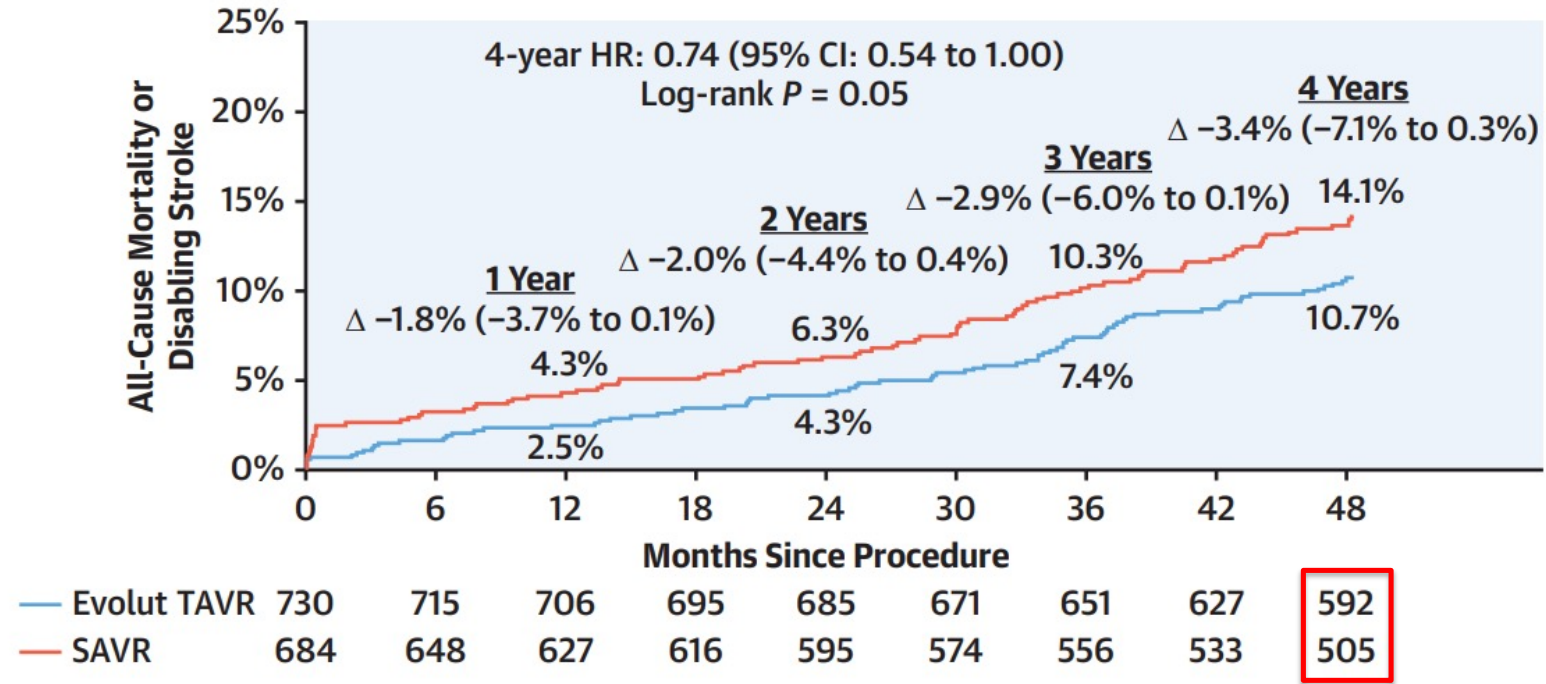
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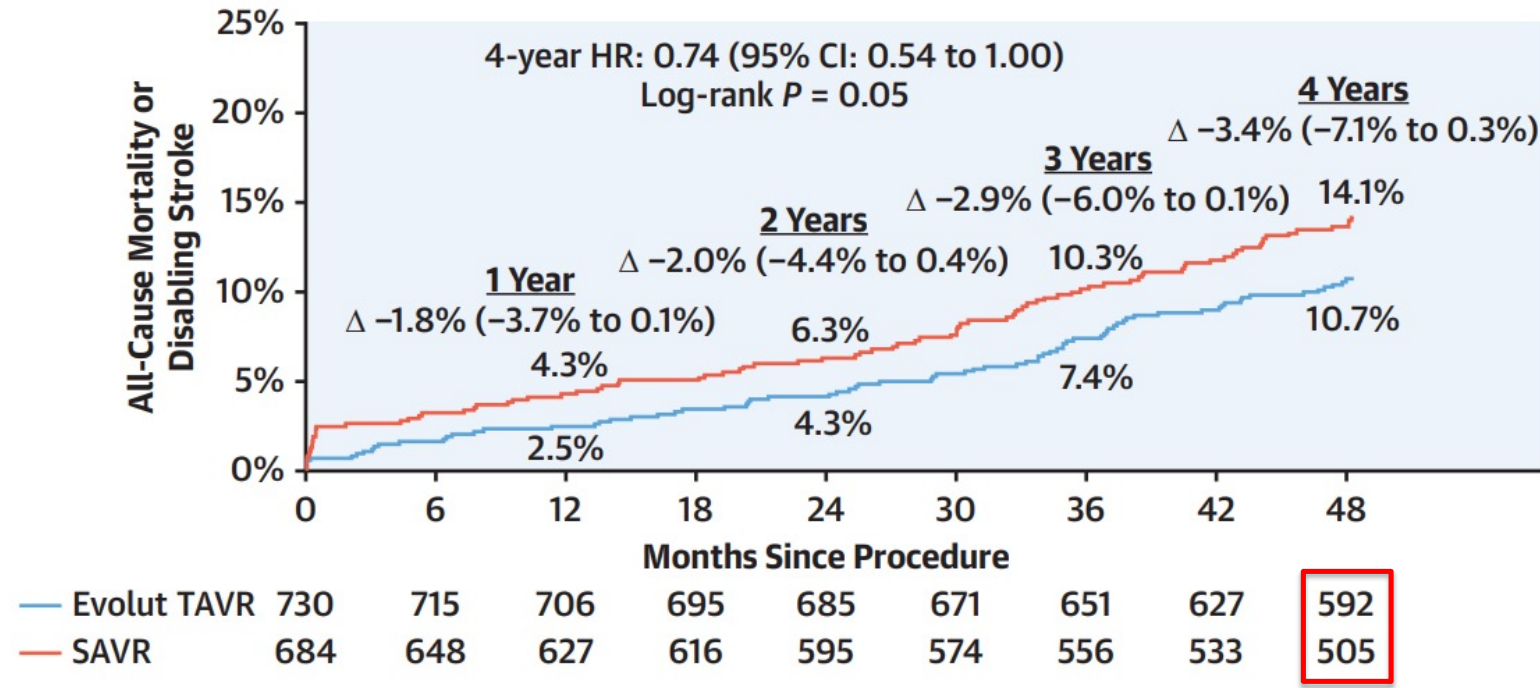
FIGURE 1 Primary Endpoint of All-Cause Mortality or Disabling Stroke Through 4 Years



Kaplan-Meier estimates for all-cause mortality or disabling stroke through 4 years. At 4 years, there was a 26% relative reduction in the hazard ($P = 0.05$) for death or disabling stroke with transcatheter (TAVR) compared with surgical (SAVR) aortic valve replacement, and the curves continued to separate over time. Deltas represent the difference in Kaplan-Meier rates (95% CI) for TAVR vs SAVR.



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“Composite” outcome

“Non-inferiority requires a smaller sample size and smaller effects size to reach statistical significance.



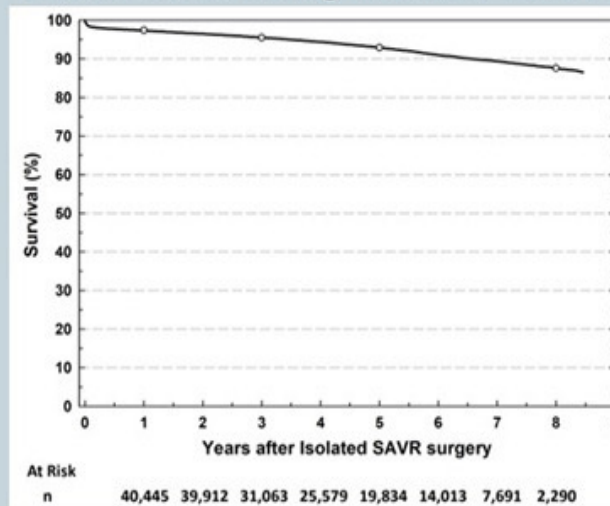
Survival Following Surgical Aortic Valve Replacement in Low-Risk Patients: A Contemporary Trial Benchmark

STUDY POPULATION

42,586 Low Risk Isolated SAVR
STS Adult Cardiac Surgery Database
Matched with National Death Index

Study Inclusions/Exclusions
Matched Those Used in
Contemporary Low Risk
TAVR SAVR Trials
Partner 3 and Evolut Low Risk

Survival Following Isolated SAVR



The Survival Following SAVR is 92.9% at 5 years

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THORACIC SURGERY

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Thourani VH et al, 2023

#VisualAbstract #AnnalsImages

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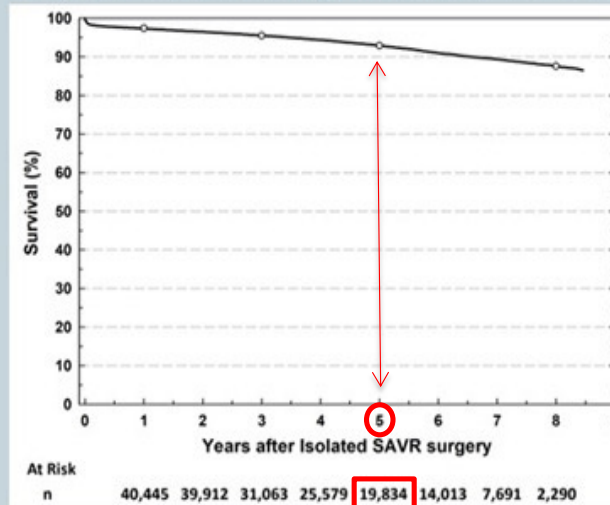
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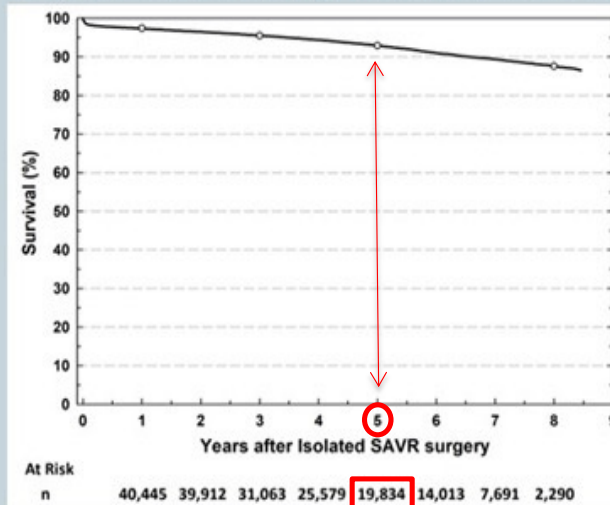
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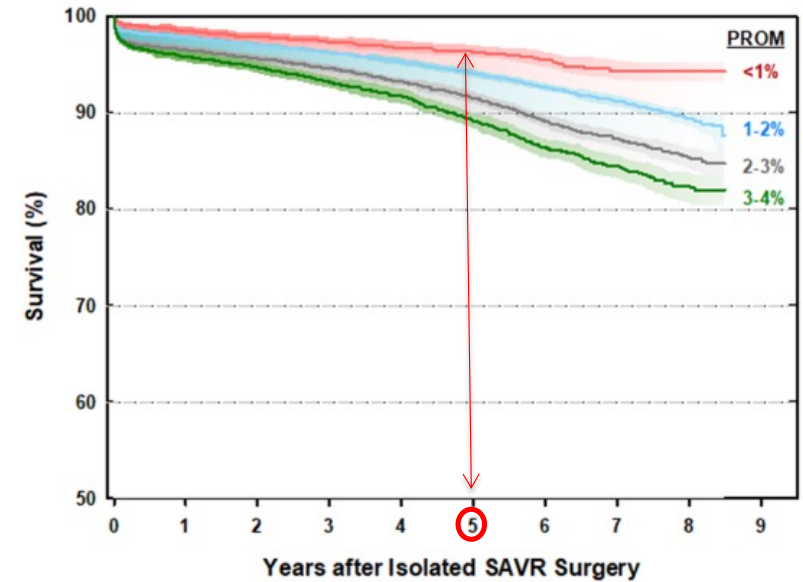
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Patients at Risk (n)	1-yr	3-yr	5-yr	8-yr
PROM <1% (N=5,127)	4,758	2,692	1,744	219
PROM 1-2% (N=20,289)	19,338	14,480	9,079	1,062
PROM 2-3% (N=11,596)	11,045	9,226	5,877	708
PROM 3-4% (N=5,574)	5,313	4,705	3,128	332
Survival (%)	1-yr	3-yr	5-yr	8-yr
PROM <1%	98.5%	97.5%	96.4%	94.3%
PROM 1-2%	97.9%	96.2%	94.1%	89.4%
PROM 2-3%	96.6%	94.7%	91.6%	85.4%
PROM 3-4%	95.9%	93.2%	89.2%	82.5%



Joint Statement from STS and European Association for Cardio-Thoracic Surgery Regarding Aortic Valve Replacement in Low-Risk Patients

📅 October 30, 2023

- Given this benchmark for isolated SAVR, it is important to note that *aortic valve replacement is largely an isolated procedure in transcatheter clinical practice*, but up to **26%** of the surgical patients in the PARTNER 3 and Evolut Low-Risk trials **underwent concomitant procedures**, including CABG surgery. Concomitant operations are associated with worse operative outcomes compared to isolated AVR procedures.
- ✧ In the Evolut Low Risk Trial, there were some minor KM curve separation in follow-up, but the majority of the outcome expense of SAVR was at the initial operative procedure. With 26% of SAVR cases in this Trial undergoing concomitant operations (e.g., CABG, MV surgery, surgical ablation, and others), we feel this may hold possible significant interpretive explanation for these data.



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- Despite these points, when taking the Evolut Low Risk *trial endpoints separately*, all-cause mortality, cardiovascular mortality, and disabling stroke were *not statistically significant between groups*. Therefore, statements of superiority of TAVI compared to a heterogeneous surgical comparator, are not appropriate at this time and may lead to unintended consequences.
- ✧ Given that the fastest growing operation in the STS National Database over the last five years is TAVI explantation or surgery after TAVI, STS and EACTS would advise that more follow-up time be given from the existing low-risk trials prior to embracing TAVI's clinical utility in low-risk patients.



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 - ✧ Given that the fastest growing operation in the STS National Database over the last five years is TAVI explantation or surgery after TAVI, STS and EACTS would advise that more follow-up time be given from the existing low-risk trials prior to embracing TAVI's clinical utility in low-risk patients.
- Furthermore, in order for all valve therapy specialists, including general cardiologists, interventional cardiologists, and surgeons, to compare low-risk TAVI all-cause mortality outcomes to the STS benchmark for isolated SAVR, we call on investigators from both the PARTNER 3 and Evolut Low-Risk trials to **publish their results for the isolated SAVR and isolated TAVI sub-cohorts from their trial arms**.



The International Society for Minimally Invasive Cardiothoracic Surgery Expert Consensus Statement on Transcatheter and Surgical Aortic Valve Replacement in Low- and Intermediate-Risk Patients: A Meta-Analysis of Randomized and Propensity-Matched Studies

Innovations
2021, 16(1) 3–16
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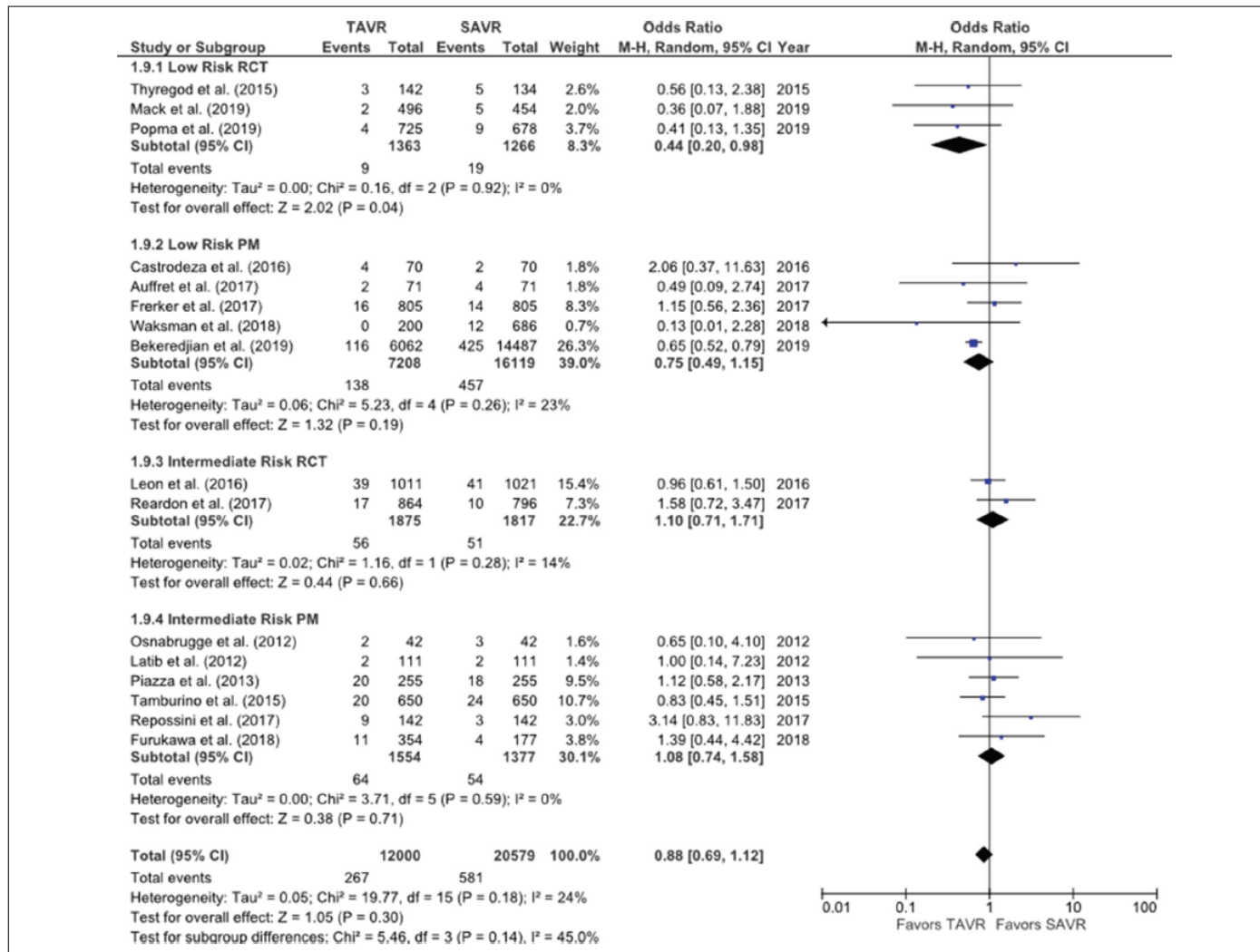


Fig. 1. Forest plot for 30-day mortality by risk group and study type.



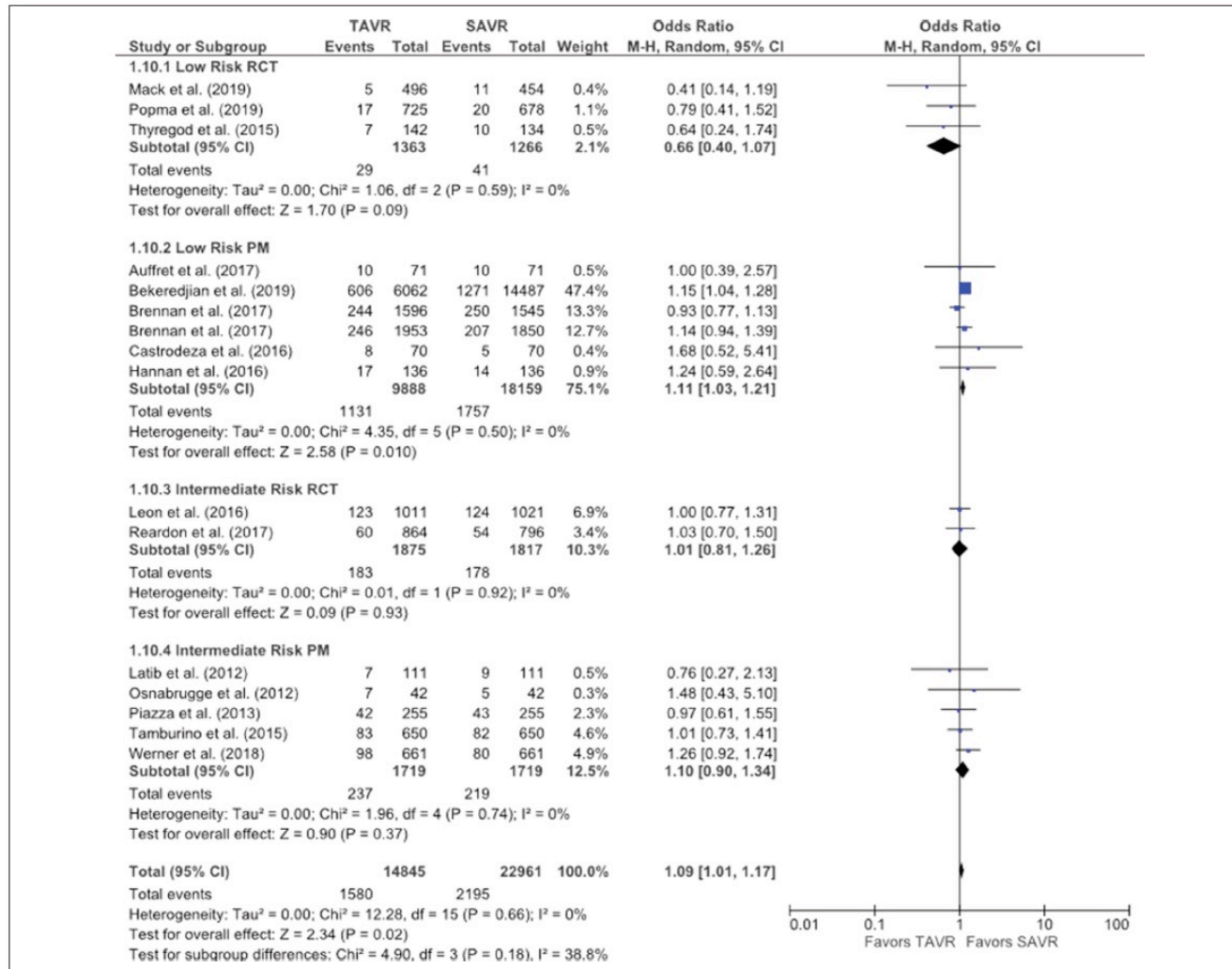


Fig. 2. Forest plot for 1-year mortality by risk group and study type.



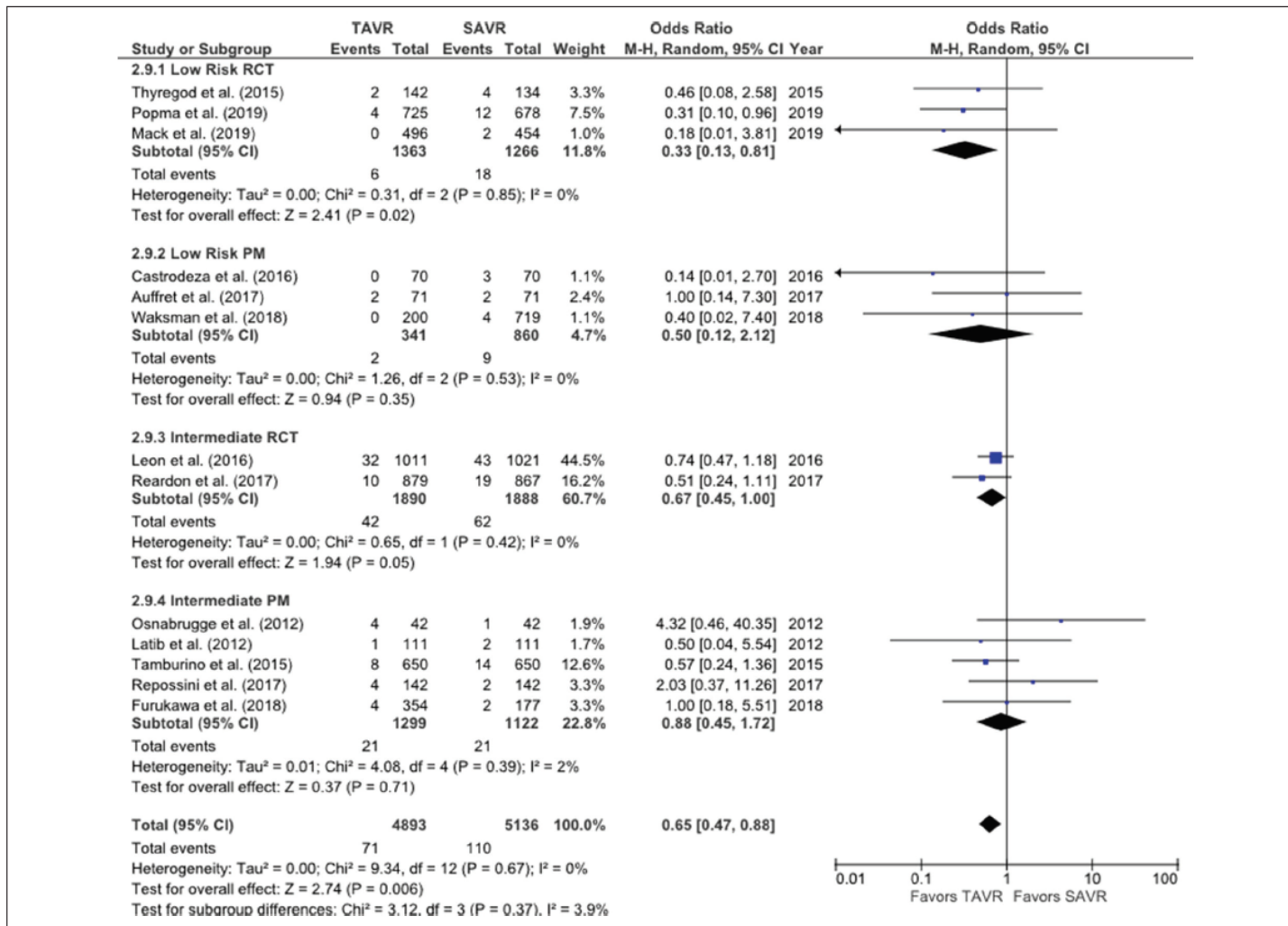


Fig. 3. Forest plot for perioperative stroke by risk group and study type.



Table 2. Multidisciplinary Heart Team Consensus in Areas of Uncertainty.

Clinical scenario	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Intermediate-risk patient		
STS ≤5%, indication for bioprosthesis	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
STS >5%	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if TAVR contraindicated
Low-risk patient		
Patients without LVOT calcification or aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Severe LVOT calcification, coronary arteries at risk of obstruction	Should not have TAVR	Should have SAVR
Bicuspid aortic valve		
TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only	Reasonable to have SAVR/CABG as determined by the Heart Team • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease • STS <5%	Should not have TAVR/PCI	Should have SAVR/CABG



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TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team <ul style="list-style-type: none"> • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only 	Reasonable to have SAVR/CABG as determined by the Heart Team <ul style="list-style-type: none"> • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution 	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS <5% 	Should not have TAVR/PCI	Should have SAVR/CABG



Table 2. Multidisciplinary Heart Team Consensus in Areas of Uncertainty.

Clinical scenario	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Intermediate-risk patient		
STS ≤5%, indication for bioprosthesis	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
STS >5%	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if TAVR contraindicated
Low-risk patient		
Patients without LVOT calcification or aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Severe LVOT calcification, coronary arteries at risk of obstruction	Should not have TAVR	Should have SAVR
Bicuspid aortic valve		
TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only	Reasonable to have SAVR/CABG as determined by the Heart Team • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease • STS <5%	Should not have TAVR/PCI	Should have SAVR/CABG



Table 2. Multidisciplinary Heart Team Consensus in Areas of Uncertainty.

Clinical scenario	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Intermediate-risk patient		
STS ≤5%, indication for bioprosthesis	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
STS >5%	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if TAVR contraindicated
Low-risk patient		
Patients without LVOT calcification or aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Severe LVOT calcification, coronary arteries at risk of obstruction	Should not have TAVR	Should have SAVR
Bicuspid aortic valve		
TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team <ul style="list-style-type: none"> • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only 	Reasonable to have SAVR/CABG as determined by the Heart Team <ul style="list-style-type: none"> • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution 	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS <5% 	Should not have TAVR/PCI	Should have SAVR/CABG



Table 2. Multidisciplinary Heart Team Consensus in Areas of Uncertainty.

Clinical scenario	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Intermediate-risk patient		
STS ≤5%, indication for bioprosthesis	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
STS >5%	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if TAVR contraindicated
Low-risk patient		
Patients without LVOT calcification or aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Severe LVOT calcification, coronary arteries at risk of obstruction	Should not have TAVR	Should have SAVR
Bicuspid aortic valve		
TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only	Reasonable to have SAVR/CABG as determined by the Heart Team • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease • STS <5%	Should not have TAVR/PCI	Should have SAVR/CABG



Table 2. Multidisciplinary Heart Team Consensus in Areas of Uncertainty.

Clinical scenario	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Intermediate-risk patient		
STS ≤5%, indication for bioprosthesis	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
STS >5%	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if TAVR contraindicated
Low-risk patient		
Patients without LVOT calcification or aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Severe LVOT calcification, coronary arteries at risk of obstruction	Should not have TAVR	Should have SAVR
Bicuspid aortic valve		
TAVR for intermediate- to high-risk patients (STS >5%)	Should have TAVR unless contraindicated for anatomical reasons	Reasonable to have SAVR if there are anatomical contraindications to TAVR
High calcium burden, aortic root or ascending aorta >45 mm and low-risk patient	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Low-intermediate calcium burden, no aortopathy	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR as determined by the Heart Team
Concomitant aortic aneurysm >45 mm		
Intermediate-high risk patients (STS >5%)	Reasonable to have TAVR as determined by the Heart Team	Reasonable to have SAVR if aorta >55 mm
Low or low-intermediate risk (STS ≤5%)	Should not have TAVR	Should have SAVR and aortic aneurysm repair
Concomitant coronary artery disease		
SYNTAX <23 or non-LAD	Reasonable to have TAVR/PCI as determined by the Heart Team <ul style="list-style-type: none"> • Short segment disease favors TAVR/PCI • No angina or negative functional test favors TAVR only 	Reasonable to have SAVR/CABG as determined by the Heart Team <ul style="list-style-type: none"> • Good target for an arterial graft favors SAVR/CABG
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS ≥5% or • Elderly patient (>80 y) with low-risk PCI solution 	Reasonable to have TAVR with or without PCI as determined by the Heart Team	Reasonable to have SAVR with CABG as determined by the Heart Team
SYNTAX ≥ 23 or LAD disease <ul style="list-style-type: none"> • STS <5% 	Should not have TAVR/PCI	Should have SAVR/CABG



<u>Clinical scenario</u>	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Concomitant atrial fibrillation		
Intermediate-risk patient	Reasonable to have TAVR with anticoagulation or LAAO as determined by the Heart Team	Reasonable to have SAVR with Cox maze IV and resection of LAA if there is a good chance of achieving sinus rhythm and elimination of anticoagulation
Low-risk patient	Remains controversial with limited data	Should have SAVR with Cox maze IV and resection of LAA if there is a reasonable chance of achieving to SR and elimination of anticoagulation
Small aortic root		
Intermediate-risk patient	Should have TAVR unless <23 mm valve	Reasonable to have SAVR if TAVR option is small and ≥23 mm valve with root enlargement
Low risk	Reasonable to have TAVR unless <23 mm valve	Reasonable to have SAVR if ≥23 mm valve with root enlargement
Previous tissue AVR		
Intermediate-high risk (STS >5%)	Should have ViV TAVR if original SAVR size ≥23 mm or able to achieve post-ViV gradient <15 mmHg and low risk of coronary obstruction	Reasonable to have redo SAVR with root enlargement
Intermediate risk <5% or age <65 yr	Reasonable to have TAVR ViV as determined by Heart Team	Should have redo SAVR with placement of valve ≥23 mm
Low risk	Reasonable to have TAVR ViV if can achieve post-ViV gradients <10 mmHg, age >65 yr, ≥26 mm prosthesis	Should have redo SAVR with placement of valve ≥23 mm



<u>Clinical scenario</u>	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Concomitant atrial fibrillation		
Intermediate-risk patient	Reasonable to have TAVR with anticoagulation or LAAO as determined by the Heart Team	Reasonable to have SAVR with Cox maze IV and resection of LAA if there is a good chance of achieving sinus rhythm and elimination of anticoagulation
Low-risk patient	Remains controversial with limited data	Should have SAVR with Cox maze IV and resection of LAA if there is a reasonable chance of achieving to SR and elimination of anticoagulation
Small aortic root		
Intermediate-risk patient	Should have TAVR unless <23 mm valve	Reasonable to have SAVR if TAVR option is small and ≥23 mm valve with root enlargement
Low risk	Reasonable to have TAVR unless <23 mm valve	Reasonable to have SAVR if ≥23 mm valve with root enlargement
Previous tissue AVR		
Intermediate-high risk (STS >5%)	Should have ViV TAVR if original SAVR size ≥23 mm or able to achieve post-ViV gradient <15 mmHg and low risk of coronary obstruction	Reasonable to have redo SAVR with root enlargement
Intermediate risk <5% or age <65 yr	Reasonable to have TAVR ViV as determined by Heart Team	Should have redo SAVR with placement of valve ≥23 mm
Low risk	Reasonable to have TAVR ViV if can achieve post-ViV gradients <10 mmHg, age >65 yr, ≥26 mm prosthesis	Should have redo SAVR with placement of valve ≥23 mm



<u>Clinical scenario</u>	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Concomitant atrial fibrillation		
Intermediate-risk patient	Reasonable to have TAVR with anticoagulation or LAAO as determined by the Heart Team	Reasonable to have SAVR with Cox maze IV and resection of LAA if there is a good chance of achieving sinus rhythm and elimination of anticoagulation
Low-risk patient	Remains controversial with limited data	Should have SAVR with Cox maze IV and resection of LAA if there is a reasonable chance of achieving to SR and elimination of anticoagulation
Small aortic root		
Intermediate-risk patient	Should have TAVR unless <23 mm valve	Reasonable to have SAVR if TAVR option is small and ≥23 mm valve with root enlargement
Low risk	Reasonable to have TAVR unless <23 mm valve	Reasonable to have SAVR if ≥23 mm valve with root enlargement
Previous tissue AVR		
Intermediate-high risk (STS >5%)	Should have ViV TAVR if original SAVR size ≥23 mm or able to achieve post-ViV gradient <15 mmHg and low risk of coronary obstruction	Reasonable to have redo SAVR with root enlargement
Intermediate risk <5% or age <65 yr	Reasonable to have TAVR ViV as determined by Heart Team	Should have redo SAVR with placement of valve ≥23 mm
Low risk	Reasonable to have TAVR ViV if can achieve post-ViV gradients <10 mmHg, age >65 yr, ≥26 mm prosthesis	Should have redo SAVR with placement of valve ≥23 mm



<u>Clinical scenario</u>	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Indication for AVR awaiting surgery for malignancy or non-heart/lung transplant	Should have TAVR	SAVR reasonable if there are anatomical contraindications for TAVR
Predominant aortic regurgitation with low calcium burden		
Low-intermediate-risk patients	Should not have TAVR	Should have SAVR
Infective endocarditis		
Low-intermediate-risk patients	Should not have TAVR	Should have SAVR
Multivalvular disease		
Intermediate-high risk (STS >5%)	Reasonable to have TAVR followed by percutaneous mitral or tricuspid intervention	Reasonable to have multivalvular surgery
Intermediate-low or low risk (STS <5%)	Should not have TAVR	Should have multivalvular surgery
Transthoracic access only available option for TAVR	Should not have TAVR	Should have SAVR

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass graft; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; LAD, left anterior descending artery; LVOT, left ventricular outflow tract; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery; TAVR, transcatheter aortic valve replacement; ViV, valve-in-valve.



<u>Clinical scenario</u>	<u>Favors TAVR</u>	<u>Favors SAVR</u>
Indication for AVR awaiting surgery for malignancy or non-heart/lung transplant	Should have TAVR	SAVR reasonable if there are anatomical contraindications for TAVR
Predominant aortic regurgitation with low calcium burden		
Low-intermediate-risk patients	Should not have TAVR	Should have SAVR
Infective endocarditis		
Low-intermediate-risk patients	Should not have TAVR	Should have SAVR
Multivalvular disease		
Intermediate-high risk (STS >5%)	Reasonable to have TAVR followed by percutaneous mitral or tricuspid intervention	Reasonable to have multivalvular surgery
Intermediate-low or low risk (STS <5%)	Should not have TAVR	Should have multivalvular surgery
Transthoracic access only available option for TAVR	Should not have TAVR	Should have SAVR

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass graft; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; LAD, left anterior descending artery; LVOT, left ventricular outflow tract; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery; TAVR, transcatheter aortic valve replacement; ViV, valve-in-valve.





Low-Risk TAVR vs SAVR



Questions?

