TAVR Today: Expanding Indications and Outcomes

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Who should be considered for TAVR?

- Everyone!
  - Does not mean everyone should get TAVR, but everyone should be *considered* by a multidisciplinary heart team.
  - Guidelines support this.
  - MOST AVR's in the US are now TAVR.

Heart Team

The Multidisciplinary Heart Valve Team and Heart Valve Centers

AMERICAN COLLEGE of CARDIOLOGY FOUNDATION

COR	LOE	Recommendations
1	C-EO	1. Patients with severe VHD should be evaluated by a Multidisciplinary Heart Valve Team (MDT) when intervention is considered.

Progress of Transcatheter Aortic Valve Replacement (TAVR)

- First in human – 2002 by Dr. Cribier
- 276,316 patients underwent TAVR from 2011 to 2019
- FDA Approvals
  - Extreme risk – 2011
  - High risk – 2012
  - Intermediate risk – 2016
  - Low risk - 2019
- July 2021 – We at UofL Health did our 1000th TAVR
- At least 730+ TAVR centers in the U.S. now
  - In 2019, most centers performed an average of 84 TAVR procedures, while 161 sites each performed fewer than 50 cases.

The road to TAVR approvals

- In the U.S., the two series of investigational device exemption (IDE) trials leading to FDA approval started in 2007.
  - PARTNER trials of the balloon-expandable valve
  - CoreValve/Evolut trials of self expanding valve
- Initially with inoperable patients (TAVR superior to medical therapy).
- Then, high and intermediate risk pts (TAVR noninferior to SAVR).
- Low risk trials – TAVR either superior or noninferior to SAVR at 1-2 years.

FDA approvals

- 2011 November - FDA approval of Edwards SAPIEN (Edwards Lifesciences, Irvine, California) using femoral access for inoperable patients with severe aortic stenosis.
- 2012 October - FDA approval of Edwards SAPIEN expands TAVR indication to high-risk patients using femoral or other forms of access.
- 2013 September - FDA updates approval of Edwards SAPIEN for inoperable patients for all forms of vascular access.
- 2014 January - FDA approval of Medtronic CoreValve (Medtronic, Dublin, Ireland) for extreme-risk patients.

FDA approvals

- 2014 June - FDA approval of Medtronic CoreValve expands indication to high-risk patients.
- 2014 June - FDA approval of Edwards SAPIEN XT for high-risk and inoperable patients using femoral and alternative access delivery systems.
- 2015 March - FDA approval of Medtronic CoreValve for aortic V-in-V for degenerated surgically implanted bioprosthetic valves, in high- and extreme-risk patients.
- 2015 June - FDA approval of Medtronic CoreValve Evolut R System for high- and extreme-risk patients.

FDA approvals

- 2015 October - FDA approval of Edwards SAPIEN XT for aortic V-in-V for high-risk patients.
- 2016 August - FDA approval of Edwards SAPIEN XT and SAPIEN 3 for intermediate-risk patients.
- 2017 May - FDA approval of Edwards SAPIEN 3 for aortic and mitral V-in-V for high-risk and inoperable patients.
- 2018 December - FDA approval of Edwards SAPIEN 3 Ultra for mitral V-in-V.
- 2019 April - FDA approval of Boston Scientific Lotus Edge for high- and extreme-risk patients.

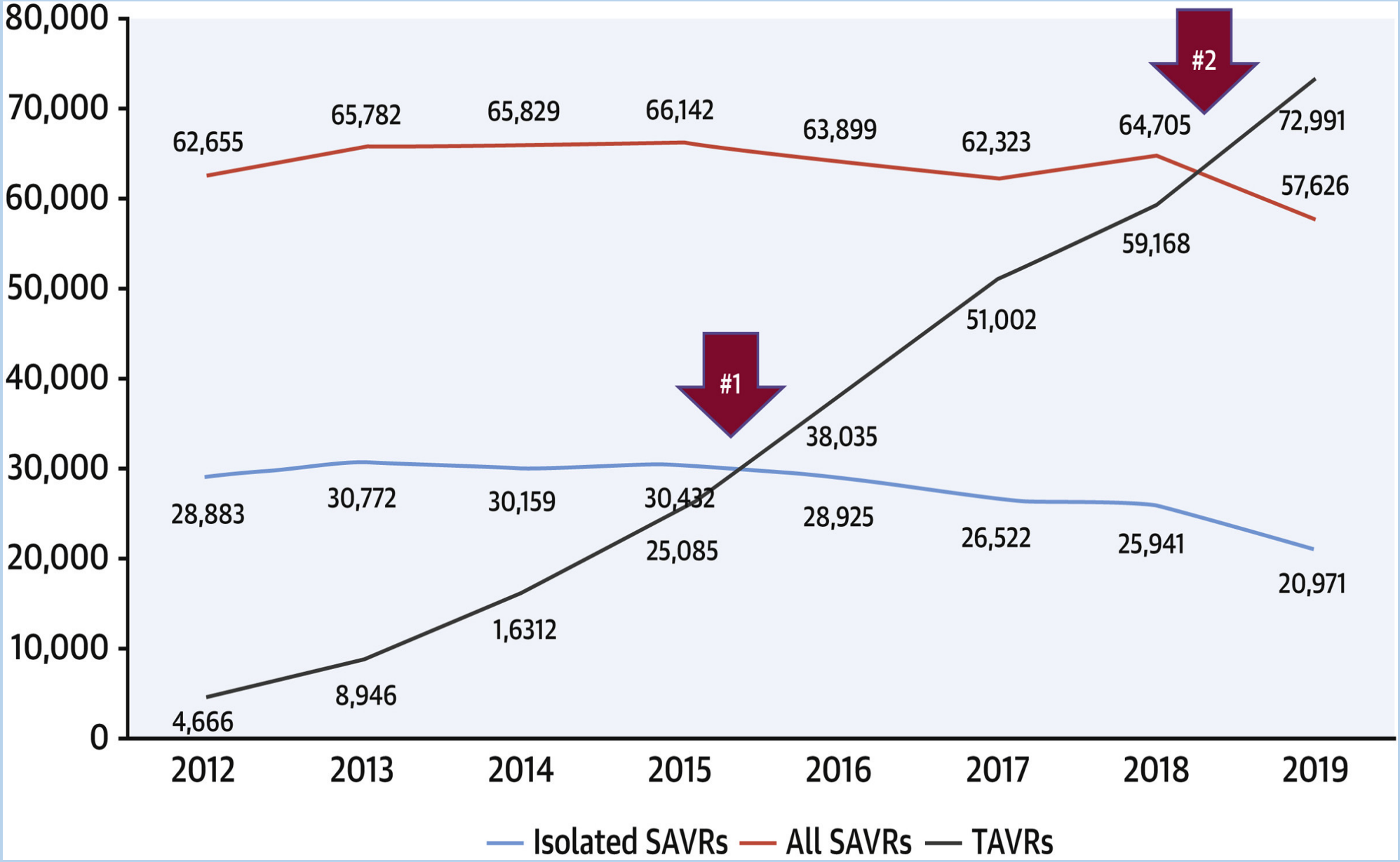
FDA approvals

- 2019 August - FDA approval for SAPIEN 3, SAPIEN 3 Ultra, CoreValve Evolut R, and CoreValve Evolut PRO for **low-risk patients**.

All 50 states

- 2020 March - Casper, Wyoming, performs their first TAVR, which signifies TAVR programs being present in all 50 U.S. states.

SAVR vs TAVR numbers in the U.S.



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  - MOST AVR's in the US are now TAVR.

2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease

Developed in collaboration with and endorsed by the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

Top 10 Take Home Messages

4. All patients with severe valvular heart disease being considered for valve intervention should be evaluated by a multidisciplinary team, with either referral to or consultation with a Primary or Comprehensive Valve Center.

Top 10 Take Home Messages

5. Treatment of severe aortic stenosis with either a transcatheter or surgical valve prosthesis should be based primarily on symptoms or reduced ventricular systolic function. Earlier intervention may be considered if indicated by results of exercise testing, biomarkers, rapid progression, or the presence of very severe stenosis.

Top 10 Take Home Messages

6. Indications for transcatheter aortic valve implantation are expanding as a result of multiple randomized trials of transcatheter aortic valve implantation versus surgical aortic valve replacement. The choice of type of intervention for a patient with severe aortic stenosis should be a shared decision-making process that considers the lifetime risks and benefits associated with type of valve (mechanical versus bioprosthetic) and type of approach (transcatheter versus surgical).

Evaluation of Surgical and Interventional Risk

COR	LOE	Recommendation
1	C-EO	1. For patients with VHD for whom intervention is contemplated, individual risks should be calculated for specific surgical and/or transcatheter procedures, using online tools when available, and discussed before the procedure as a part of a shared decision-making process.

Table 8. Risk Assessment for Surgical Valve Procedures

Footnote text located on the next slide

Criteria	Low-Risk SAVR (Must Meet ALL Criteria in This Column)	Low-Risk Surgical Mitral Valve Repair for Primary MR (Must Meet ALL Criteria in This Column)	High Surgical Risk (Any 1 Criterion in This Column)	Prohibitive Surgical Risk (Any 1 Criterion in This Column)
STS-predicted risk of death*	<3% AND	<1% AND	>8% OR	Predicted risk of death or major morbidity (all-cause) >50% at 1 y OR
Frailty†	None AND	None AND	≥2 Indices (moderate to severe) OR	≥2 Indices (moderate to severe) OR
Cardiac or other major organ system compromise not to be improved postoperatively‡	None AND	None AND	1 to 2 Organ systems OR	≥3 Organ systems OR
Procedure-specific impediment§	None	None	Possible procedure-specific impediment	Severe procedure-specific impediment

Table 9. Examples of Procedure-Specific Risk Factors for Interventions Not Incorporated Into Existing Risk Scores

SAVR	TAVI	Surgical MV Repair or Replacement	Transcatheter Edge-to-Edge Mitral Valve Repair
Technical or anatomic			
• Prior mediastinal radiation	• Aorto-iliac occlusive disease precluding transfemoral approach	• Prior sternotomy	• Multivalve disease
• Ascending aortic calcification (porcelain aorta may be prohibitive)	• Aortic arch atherosclerosis (protuberant lesions) • Severe MR or TR • Low-lying coronary arteries • Basal septal hypertrophy • Valve morphology (e.g., bicuspid or unicuspid valve) • Extensive LV outflow tract calcification	• Prior mediastinal radiation • Ascending aortic calcification (porcelain aorta may be prohibitive)	• Valve morphology (e.g., thickening, perforations, clefts, calcification, and stenosis) • Prior mitral valve surgery

Table 9. Examples of Procedure-Specific Risk Factors for Interventions Not Incorporated Into Existing Risk Scores

SAVR	TAVI	Surgical MV Repair or Replacement	Transcatheter Edge-to-Edge Mitral Valve Repair
Comorbidities			
• Severe COPD or home oxygen therapy • Pulmonary hypertension • Severe RV dysfunction • Hepatic dysfunction • Frailty*	• Severe COPD or home oxygen therapy • Pulmonary hypertension • Severe RV dysfunction • Hepatic dysfunction • Frailty*	• Severe COPD or home oxygen therapy • Pulmonary hypertension • Hepatic dysfunction • Frailty*	• Severe COPD or home oxygen therapy • Pulmonary hypertension • Hepatic dysfunction • Frailty*

Table 9. Examples of Procedure-Specific Risk Factors for Interventions Not Incorporated Into Existing Risk Scores

SAVR	TAVI	Surgical MV Repair or Replacement	Transcatheter Edge-to-Edge Mitral Valve Repair
Futility			
• STS score >15 • Life expectancy <1 y • Poor candidate for rehabilitation	• STS score >15 • Life expectancy <1 y • Poor candidate for rehabilitation	• STS score >15 • Life expectancy <1 y • Poor candidate for rehabilitation	• STS score >15 • Life expectancy <1 y • Poor candidate for rehabilitation

Table 10. Median Operative Mortality Rates for Specific Surgical Procedures (STS Adult Cardiac Surgery Database, 2019)

Procedure	Mortality Rate (%)
AVR	2.2
AVR and CABG	4
AVR and Mitral Valve replacement	9
Mitral Valve replacement	5
Mitral Valve replacement and CABG	9
Mitral Valve repair	1
Mitral Valve repair and CABG	5

The Multidisciplinary Heart Valve Team and Heart Valve Centers

COR	LOE	Recommendations
1	C-EO	1. Patients with severe VHD should be evaluated by a Multidisciplinary Heart Valve Team (MDT) when intervention is considered.
2a	C-LD	2. Consultation with or referral to a Primary or Comprehensive Heart Valve Center is reasonable when treatment options are being discussed for 1) asymptomatic patients with severe VHD, 2) patients who may benefit from valve repair versus valve replacement, or 3) patients with multiple comorbidities for whom valve intervention is considered.

Table 13. Stages of Valvular Aortic Stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	• BAV (or other congenital valve anomaly) • Aortic valve sclerosis	Aortic V_{max} <2 m/s with normal leaflet motion	None	None
B	Progressive AS	• Mild to moderate leaflet calcification/fibrosis of a bicuspid or trileaflet valve with some reduction in systolic motion or • Rheumatic valve changes with commissural fusion	• Mild AS: aortic V_{max} 2.0–2.9 m/s or mean P <20 mm Hg • Moderate AS: aortic V_{max} 3.0–3.9 m/s or mean P 20-39 mm Hg	• Early LV diastolic dysfunction may be present • Normal LVEF	None

Table 13. Stages of Valvular Aortic Stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
C: Asymptomatic Severe AS					
C1	Asymptomatic severe AS	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic V_{max} ≥4 m/s or mean P ≥40 mm Hg • AVA typically is ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS • Very severe AS is an aortic V_{max} ≥5 m/s or mean P >60 mm Hg	• LV diastolic dysfunction • Mild LV hypertrophy • Normal LVEF	• None • Exercise testing is reasonable to confirm symptom status
C2	Asymptomatic severe AS with LV systolic dysfunction	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic V_{max} ≥4 m/s or mean P ≥40 mm Hg • AVA typically ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS	LVEF <50%	None

Table 13. Stages of Valvular Aortic Stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
D: Symptomatic severe AS					
D1	Symptomatic severe high-gradient AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic V_{max} ≥4 m/s or mean P ≥40 mm Hg • AVA typically ≤1.0 cm^2 (or AVAi ≤ 0.6 cm^2/m^2) but may be larger with mixed AS/AR	• LV diastolic dysfunction • LV hypertrophy • Pulmonary hypertension may be present	• Exertional dyspnea, decreased exercise tolerance, or HF • Exertional angina • Exertional syncope or presyncope
D2	Symptomatic severe low-flow, low-gradient AS with reduced LVEF	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	• AVA ≤1.0 cm^2 with resting aortic V_{max} <4 m/s or mean P <40 mm Hg • Dobutamine stress echocardiography shows AVA <1.0 cm^2 with V_{max} ≥4 m/s at any flow rate	• LV diastolic dysfunction • LV hypertrophy • LVEF <50%	• HF • Angina • Syncope or presyncope

Table 13. Stages of Valvular Aortic Stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
D: Symptomatic severe AS					
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	• AVA ≤1.0 cm^2 (indexed AVA ≤0.6 cm^2/m^2) with an aortic V_{max} <4 m/s or mean P <40 mm Hg AND Stroke volume index <35 mL/m^2 • Measured when patient is normotensive (systolic blood pressure <140 mm Hg)	• Increased LV relative wall thickness • Small LV chamber with low stroke volume • Restrictive diastolic filling • LVEF ≥50%	• HF • Angina • Syncope or presyncope

Diagnosis and Follow-up: initial diagnosis of AS

COR	LOE	Recommendations
2a	B-NR	5. In patients with suspected low-flow, low-gradient severe AS with normal or reduced LVEF (Stages D2 and D3), measurement of aortic valve calcium score by CT imaging is reasonable to further define severity.

Timing of Intervention of AS

COR	LOE	Recommendations
1	A	1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated.
1	B-NR	2. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated.
1	B-NR	3. In asymptomatic patients with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated.

Timing of Intervention of AS

COR	LOE	Recommendations
1	B-NR	4. In symptomatic patients with low-flow, low-gradient severe AS with reduced LVEF (Stage D2), AVR is recommended.
1	B-NR	5. In symptomatic patients with low-flow, low-gradient severe AS with normal LVEF (Stage D3), AVR is recommended if AS is the most likely cause of symptoms.

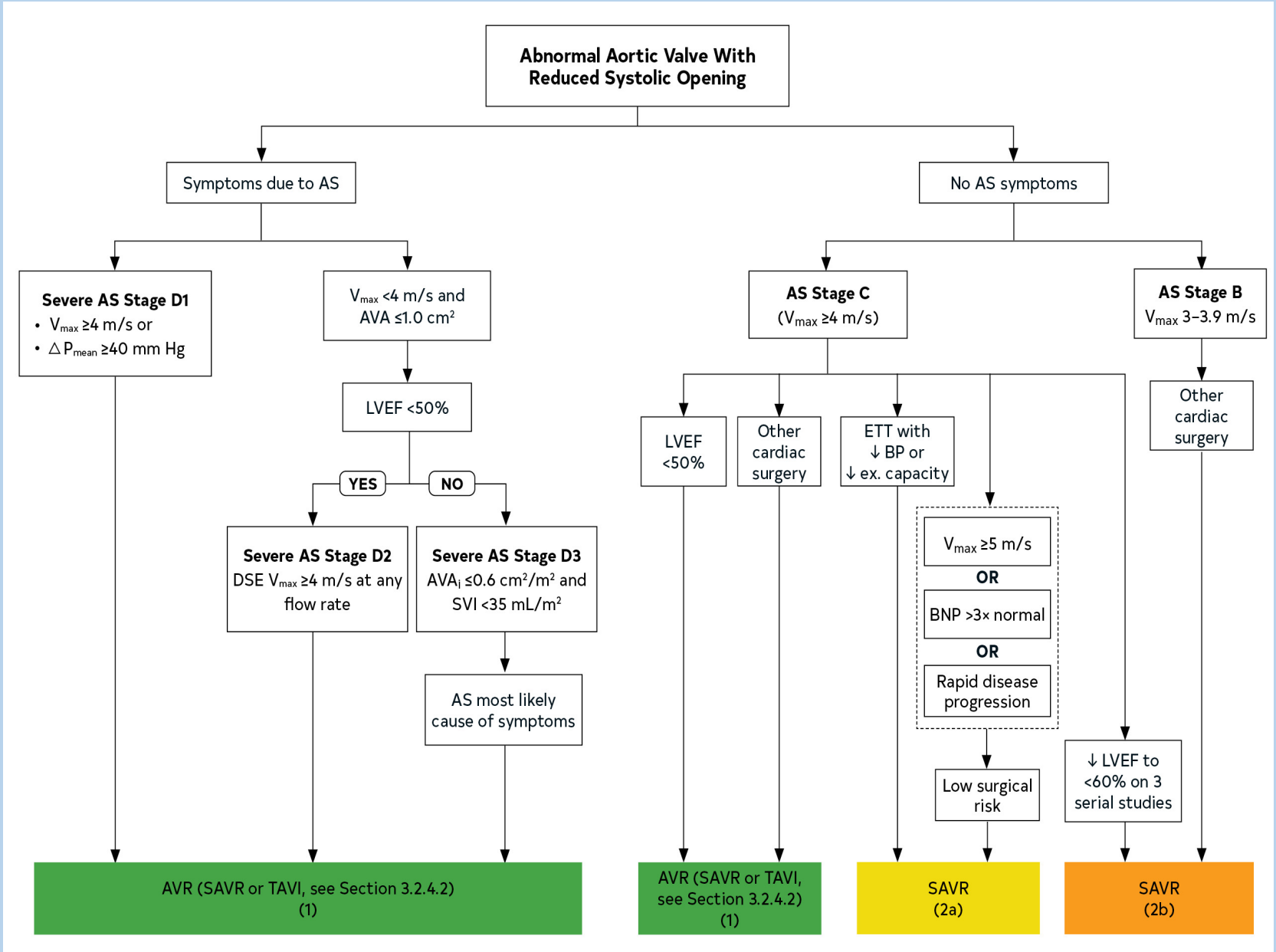
Figure 2. Timing of Intervention for AS

Colors correspond to Table 2.

Arrows show the decision pathways that result in a recommendation for AVR.

Periodic monitoring is indicated for all patients in whom AVR is not yet indicated, including those with asymptomatic (Stage C) and symptomatic (Stage D) AS and those with low-gradient AS (Stage D2 or D3) who do not meet the criteria for intervention.

See Section 3.2.4 for choice of valve type (mechanical versus bioprosthetic [TAVI~~R~~ or SAVR]) when AVR is indicated.



Age by the guidelines

- <65 years old: SAVR
- 65 to 80 years old: TAVR or SAVR
- >80 years old: TAVR

- BEWARE of CAVEATS

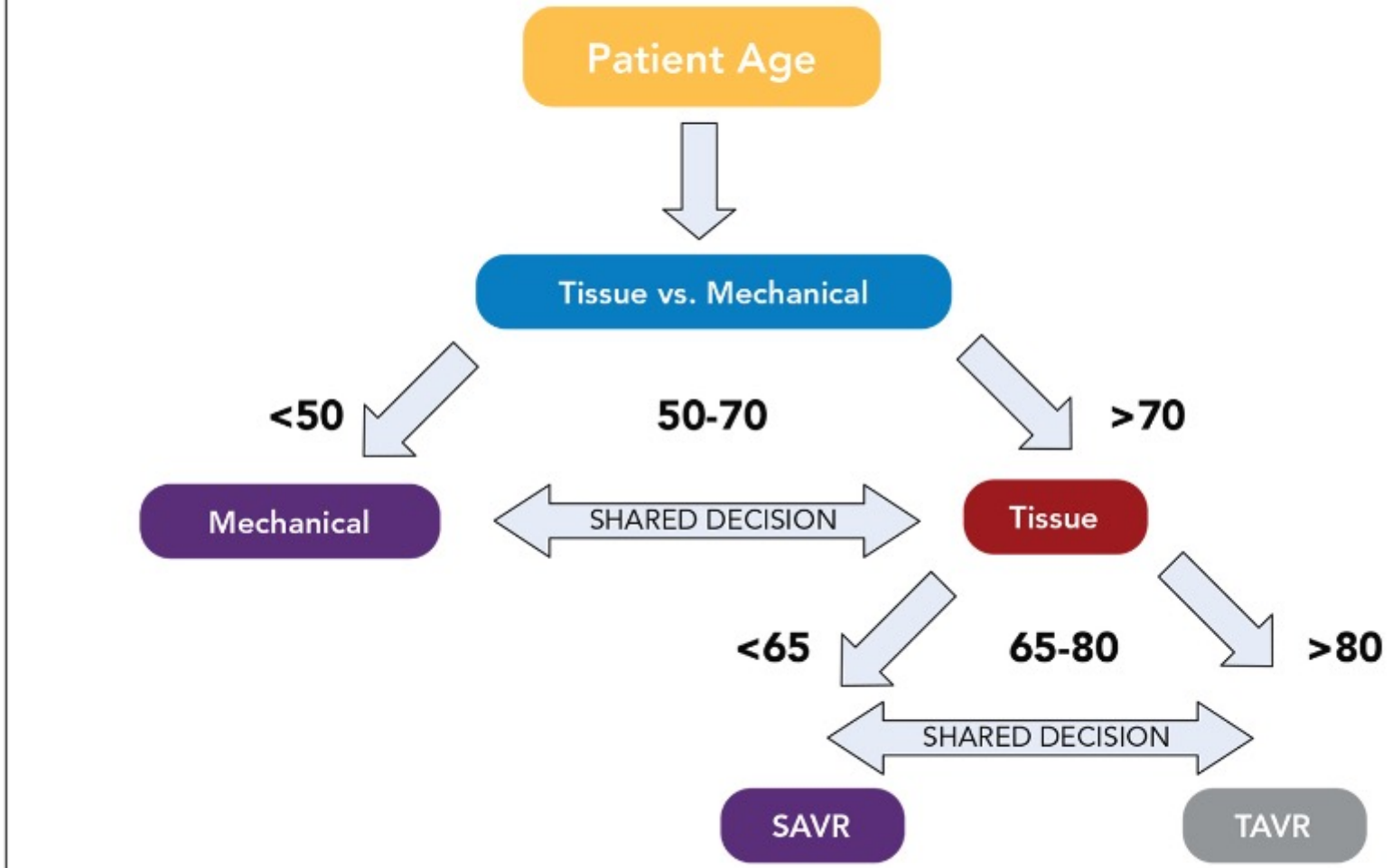
Choice of Intervention: SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR is Appropriate

COR	LOE	Recommendations
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.
1	A	2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.

Age by the guidelines

- <65 years old: SAVR
- 65 to 80 years old: TAVR or SAVR
- >80 years old: TAVR

Figure 2 Possible Clinical Decision Making in Aortic Stenosis



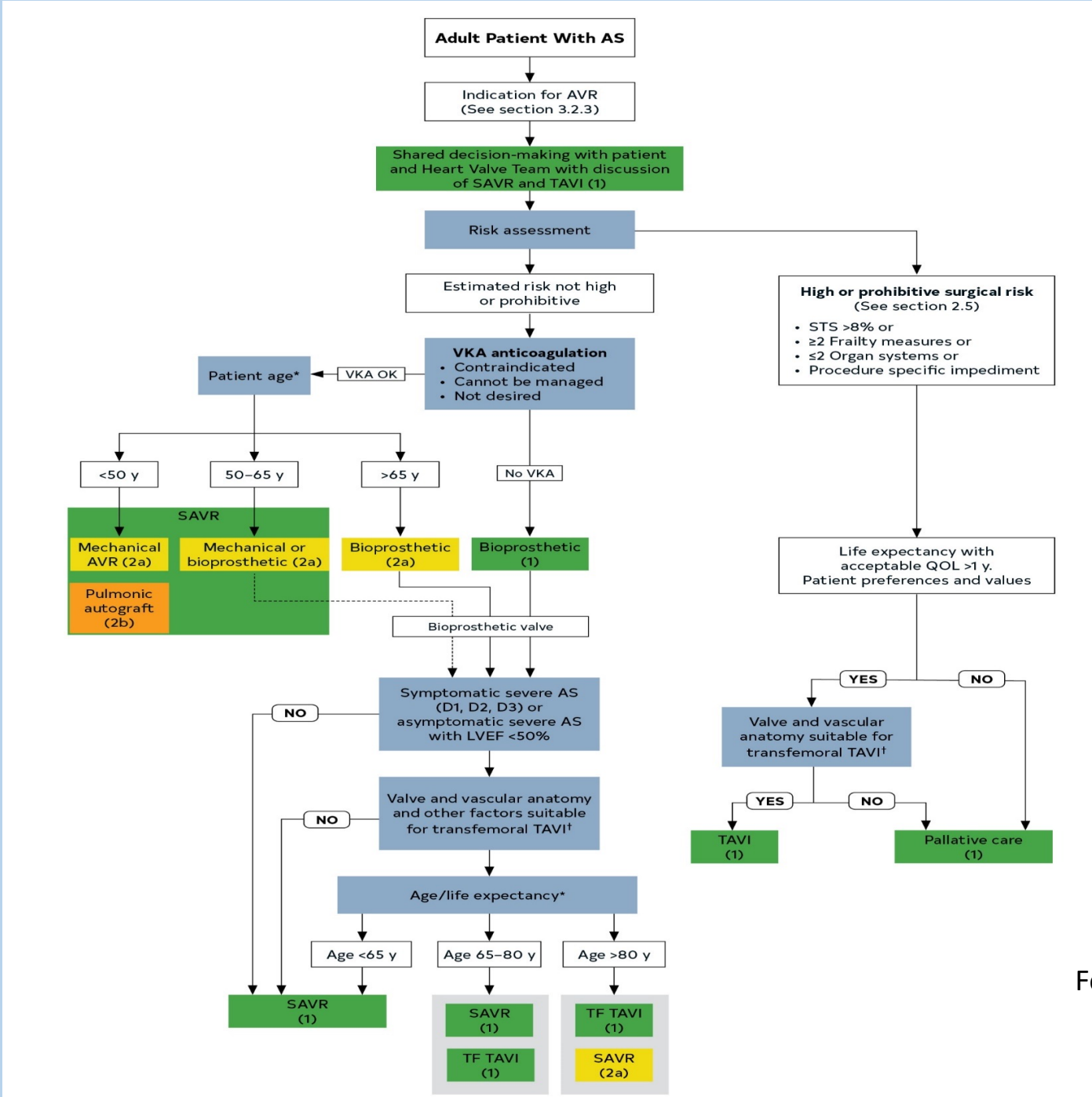
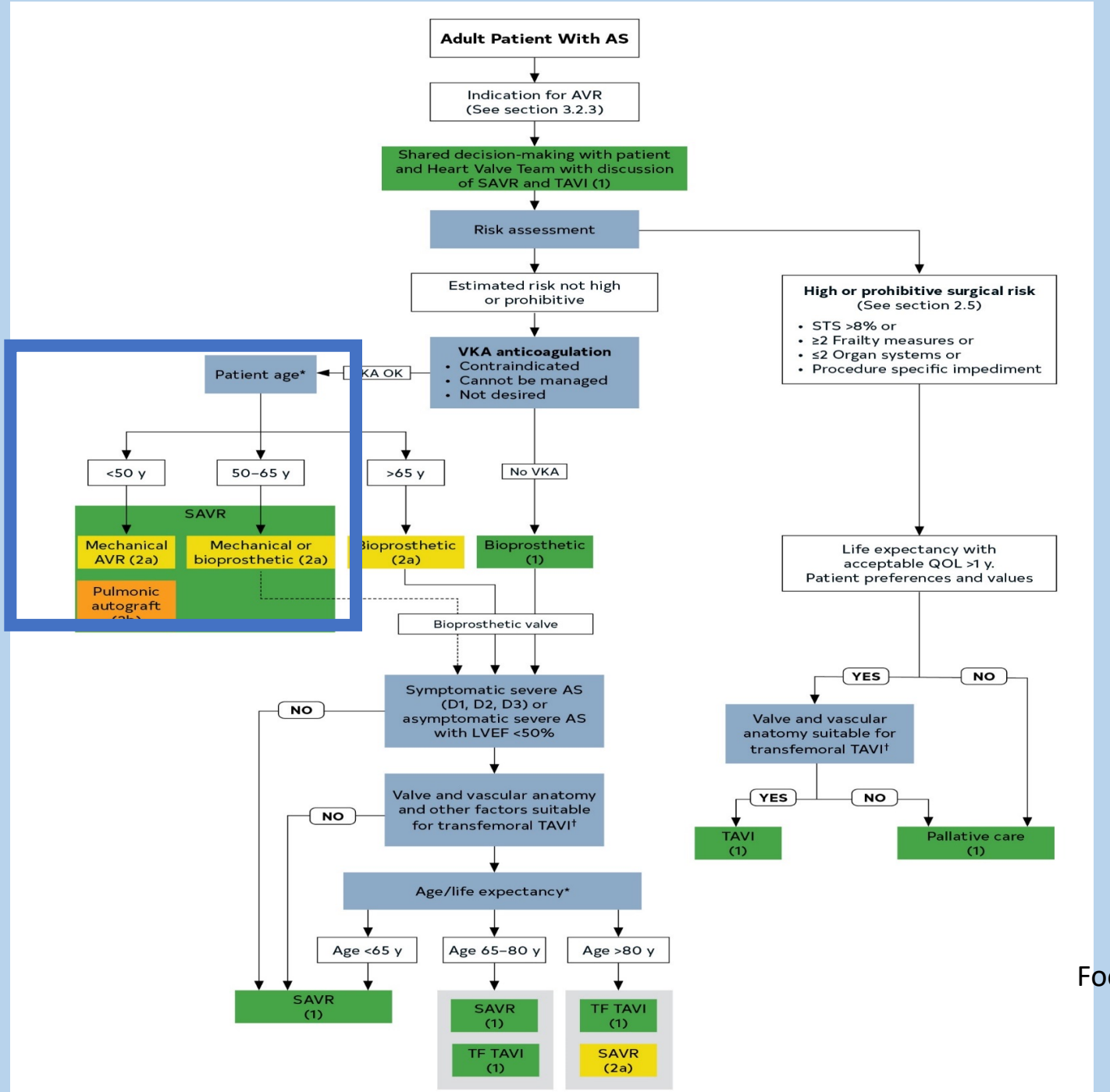


Figure 3. Choice of SAVR versus TAVI when AVR is indicated for valvular AS.

Colors correspond to Table 2

Footnote text located on the next slide



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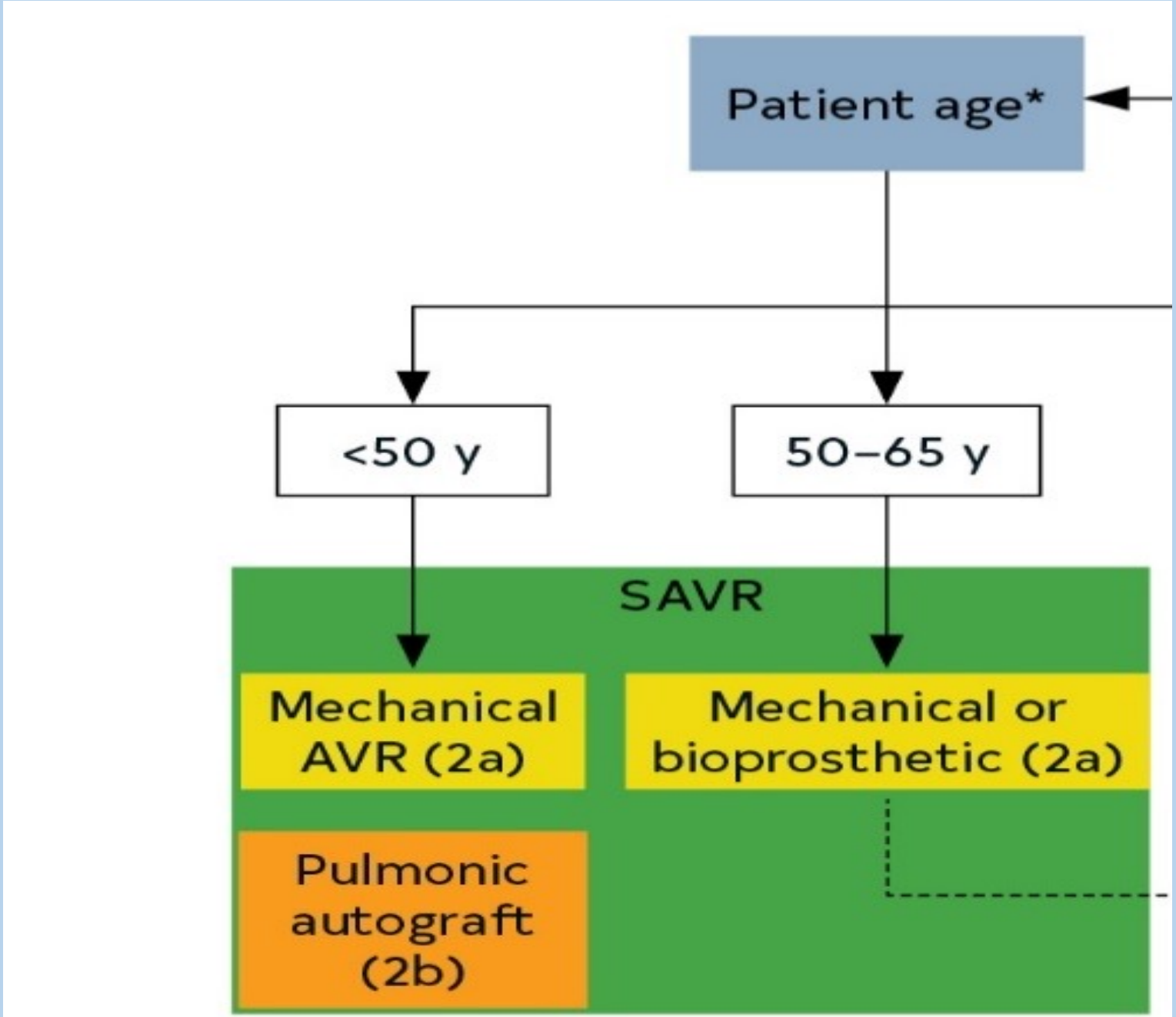
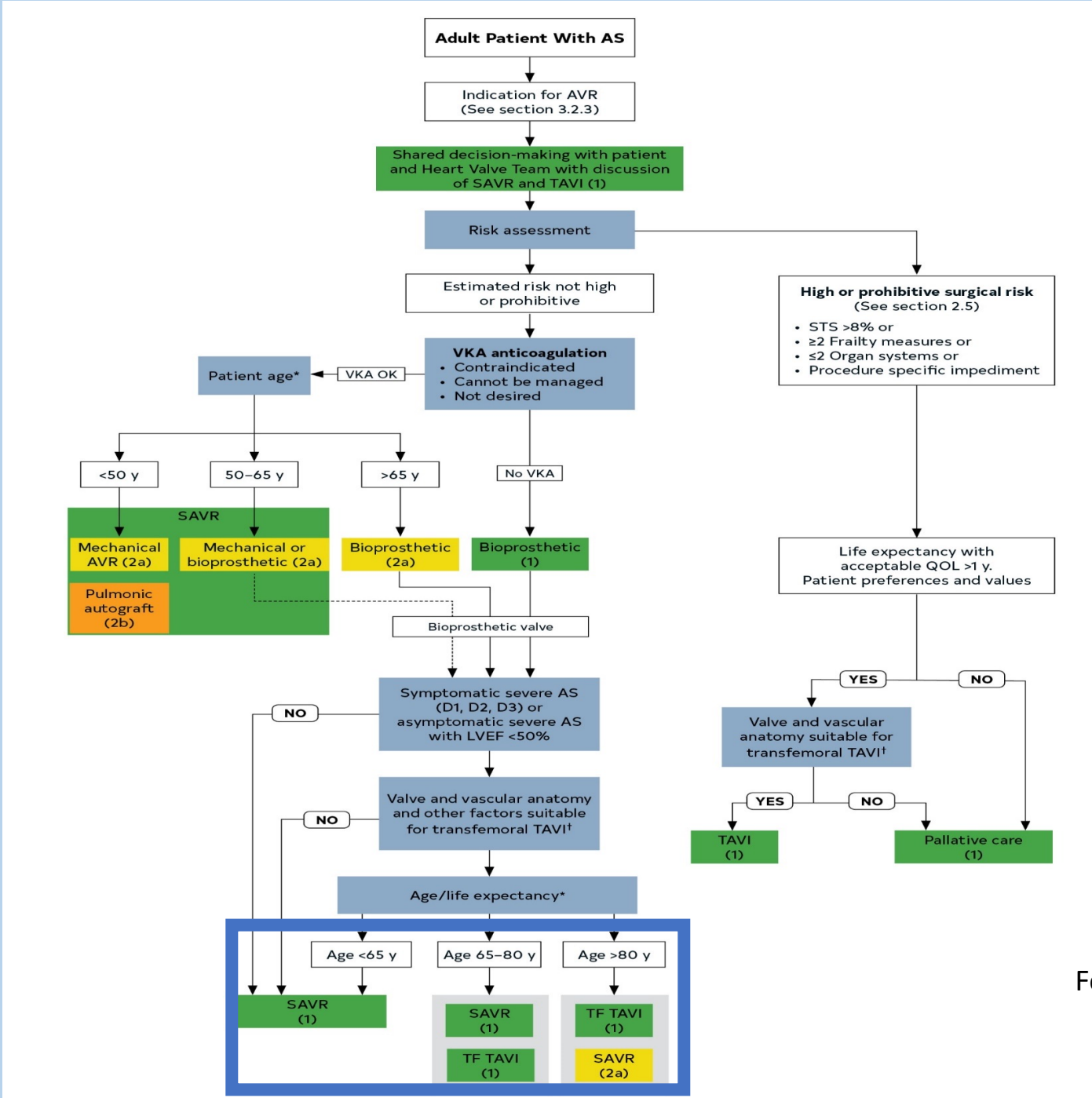

Patient age*
<50 y
50–65 y
SAVR
Mechanical AVR (2a)
Mechanical or bioprosthetic (2a)
Pulmonic autograft (2b)



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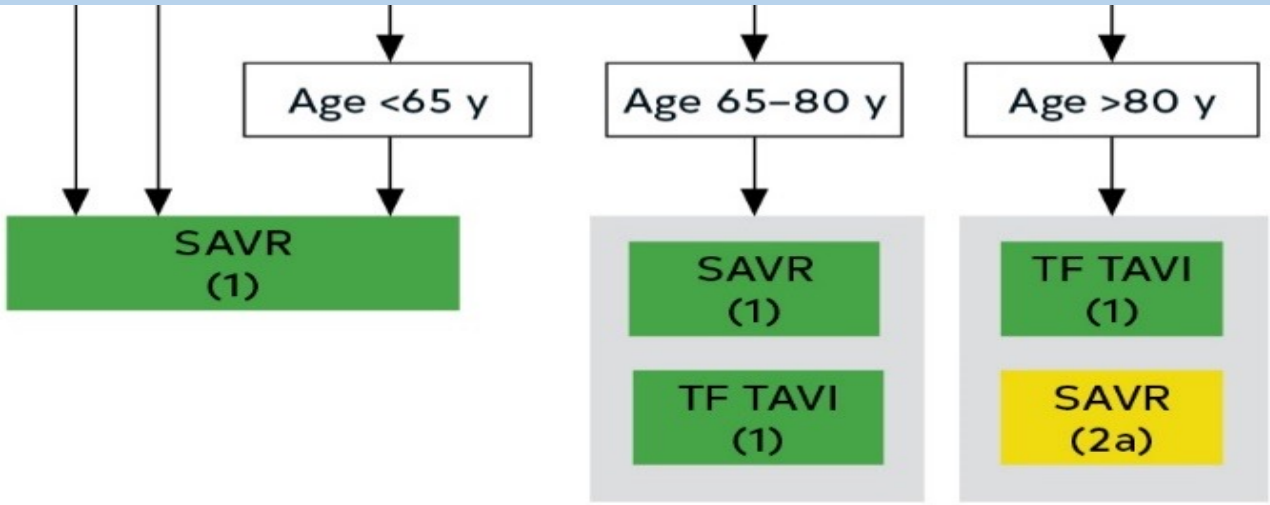
Age <65 y
Age 65–80 y
Age >80 y
SAVR
(1)
SAVR
(1)
TF TAVI
(1)
TF TAVI
(1)
SAVR
(2a)

Figure 2 Possible Clinical Decision Making in Aortic Stenosis

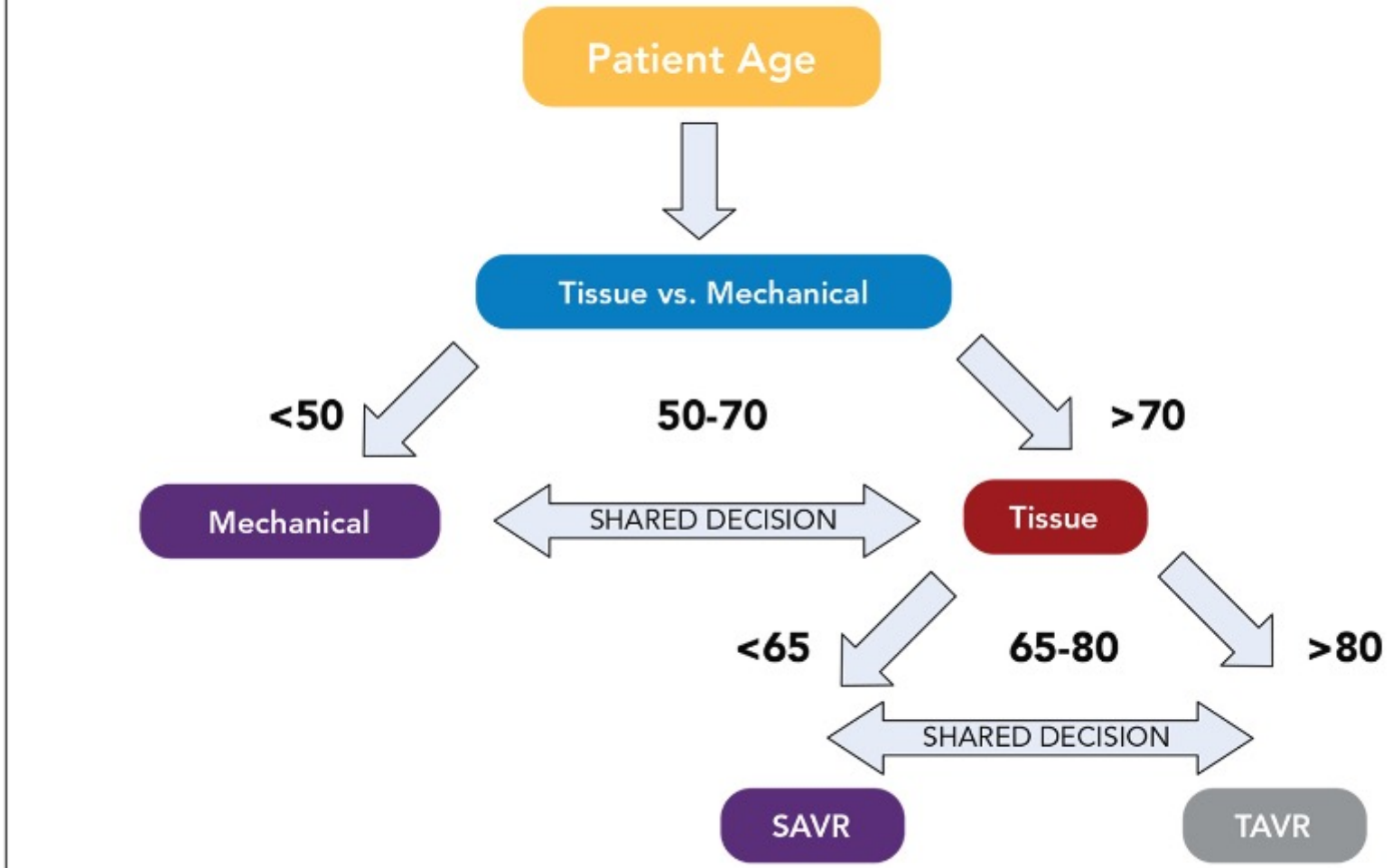

Table 14. A Simplified Framework With Examples of Factors Favoring SAVR, TAVI, or Palliation Instead of Aortic Valve Intervention

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	Favors SAVR	Favors TAVI	Favors Palliation
Age/life expectancy*	• Younger age/longer life expectancy	• Older age/fewer expected remaining years of life	• Limited life expectancy
Valve anatomy	• BAV • Subaortic (LV outflow tract) calcification • Rheumatic valve disease • Small or large aortic annulus†	• Calcific AS of a trileaflet valve	
Prosthetic valve preference	• Mechanical or surgical bioprosthetic valve preferred • Concern for patient–prosthesis mismatch (annular enlargement might be considered)	• Bioprosthetic valve preferred • Favorable ratio of life expectancy to valve durability • TAVI provides larger valve area than same size SAVR	
Concurrent cardiac conditions	• Aortic dilation‡ • Severe primary MR • Severe CAD requiring bypass grafting • Septal hypertrophy requiring myectomy • AF	• Severe calcification of the ascending aorta (“porcelain” aorta)	• Irreversible severe LV systolic dysfunction • Severe MR attributable to annular calcification

Table 14. A Simplified Framework With Examples of Factors Favoring SAVR, TAVI, or Palliation Instead of Aortic Valve Intervention

	Favors SAVR	Favors TAVI	Favors Palliation
Noncardiac conditions		• Severe lung, liver, or renal disease • Mobility issues (high procedural risk with sternotomy)	• Symptoms likely attributable to noncardiac conditions • Severe dementia • Moderate to severe involvement of ≥2 other organ systems
Frailty	• Not frail or few frailty measures	• Frailty likely to improve after TAVI	• Severe frailty unlikely to improve after TAVI
Estimated procedural or surgical risk of SAVR or TAVI	• SAVR risk low • TAVI risk high	• TAVI risk low to medium • SAVR risk high to prohibitive	• Prohibitive SAVR risk (>15%) or post-TAVI life expectancy <1 y
Procedure-specific impediments	• Valve anatomy, annular size, or low coronary ostial height precludes TAVI • Vascular access does not allow transfemoral TAVI	• Previous cardiac surgery with at-risk coronary grafts • Previous chest irradiation	• Valve anatomy, annular size, or coronary ostial height precludes TAVI • Vascular access does not allow transfemoral TAVI

In my practice

- Lean towards SAVR
  - Less than 65 years old
  - Severe CAD with benefit of CABG + SAVR
  - Aortic dilation
  - Multivalve replacement
  - Mechanical valve candidate
  - True Bicuspids
- Lean towards TAVR
  - Everyone else

STS-ACC TVT - TAVR Registry

- STS-ACC TVT database registry gave a special report in 2021 – now encompassing first ever outcomes on the low risk patients started to be treated in 2019.

- Comprehensive database information has shaped the most recent guidelines relevant to TAVR.

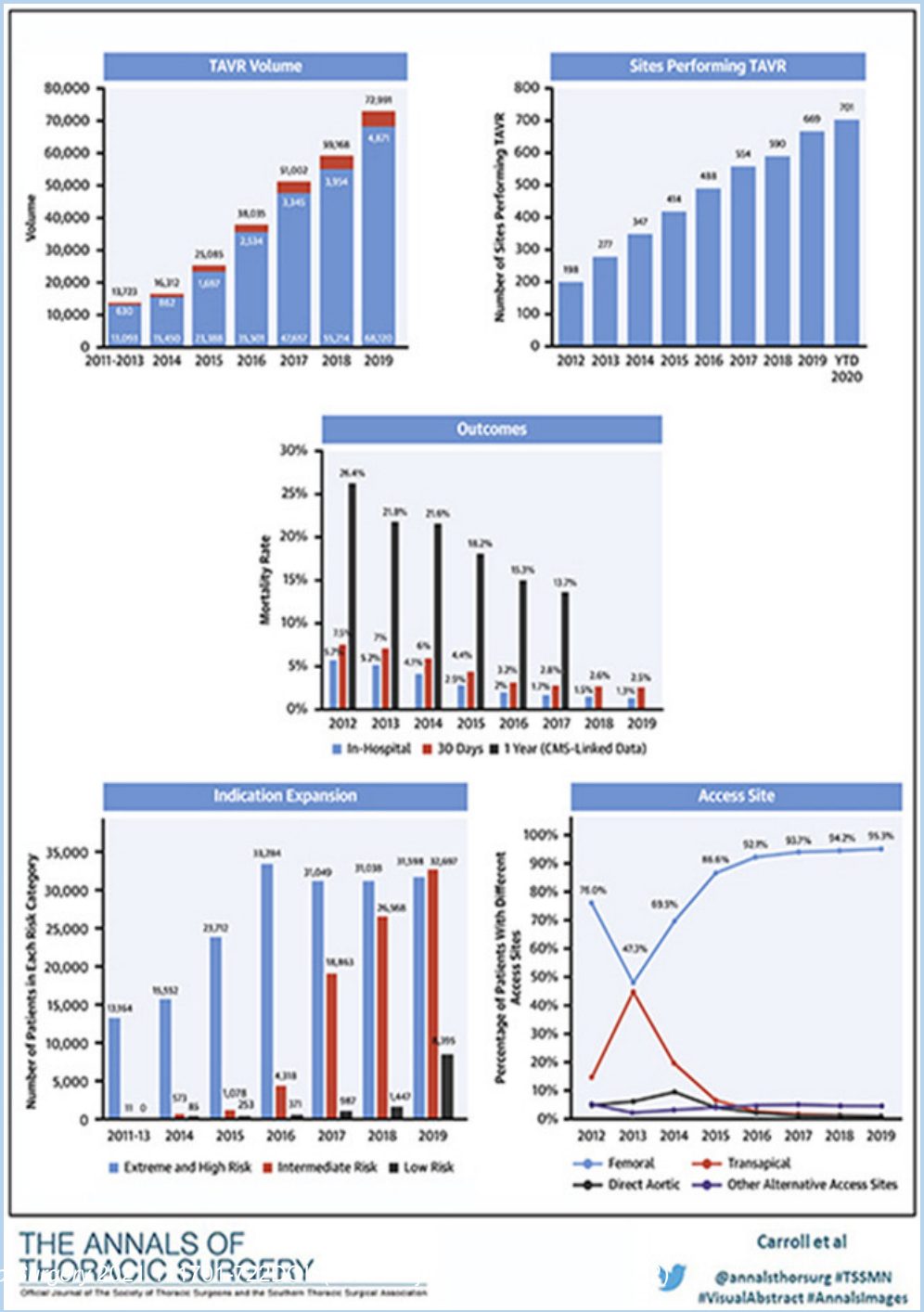
STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

John D. Carroll, MD, Michael J. Mack, MD, Sreekanth Vemulapalli, MD, Howard C. Herrmann, MD, Thomas G. Gleason, MD, George Hanzel, MD, G. Michael Deeb, MD, Vinod H. Thourani, MD, David J. Cohen, MD, MSc, Nimesh Desai, MD, PhD, Ajay J. Kirtane, MD, SM, Susan Fitzgerald, MSN, RN, Joan Michaels, MSN, RN, Carole Krohn, BSN, RN, Frederick A. Masoudi, MD, MSPH, Ralph G. Brindis, MD, MPH, and Joseph E. Bavaria, MD

Division of Cardiology, Department of Medicine, University of Colorado School of Medicine, Aurora Colorado; Baylor Scott and White Health Heart Hospital–Plano, Plano, Texas; Duke Clinical Research Institute and Division of Cardiology, Department of Medicine, Duke University Health Care System, Durham, North Carolina; Cardiovascular Division, Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania; Division of Cardiac Surgery, Brigham & Women's Hospital & Harvard Medical School, Boston Massachusetts; Department of Cardiovascular Medicine, Beaumont Hospital, Royal Oak, Michigan; Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; Department of Surgery, Piedmont Hospital, Atlanta, Georgia; University of Missouri-Kansas City School of Medicine, Kansas City, Missouri; Division of Cardiovascular Surgery, University of Pennsylvania, Philadelphia, Pennsylvania; Cardiovascular Research Foundation and Department of Medicine, Columbia University, New York, New York; American College of Cardiology, Washington, DC; The Society of Thoracic Surgeons, Chicago, Illinois; and Philip R. Lee Institute for Health Policy Studies, University of California-San Francisco, San Francisco, California

The STS-ACC TVT Registry (Society of Thoracic Surgeons–American College of Cardiology Transcatheter Valve Therapy Registry) from 2011 to 2019 has collected data on 276,316 patients undergoing transcatheter aortic valve replacement (TAVR) at sites in all U.S. states. Volumes have increased every year, exceeding surgical aortic valve replacement in 2019 (72,991 vs. 57,626), and it is now performed in all U.S. states. TAVR now extends from extreme- to low-risk patients. This is the first presentation on 8,395 low-risk patients treated in 2019. In 2019, for the entire cohort, femoral access increased to 95.3%, hospital stay was 2 days, and 90.3% were discharged home. Since 2011, the 30-day mortality rate has decreased (7.2% to 2.5%), stroke has started to decrease (2.75% to 2.3%), but pacemaker need is unchanged (10.9% to 10.8%). Alive with acceptable patient-reported outcomes is achieved in 8 of 10 patients at 1 year. The Registry is a national resource to improve care and analyze TAVR's evolution. Real-world outcomes, site performance, and the impact of coronavirus disease 2019 will be subsequently studied. (STS/ACC Transcatheter Valve Therapy Registry [TVT Registry]; NCT01737528).

Ann Thorac Surg 2021;111:701-22



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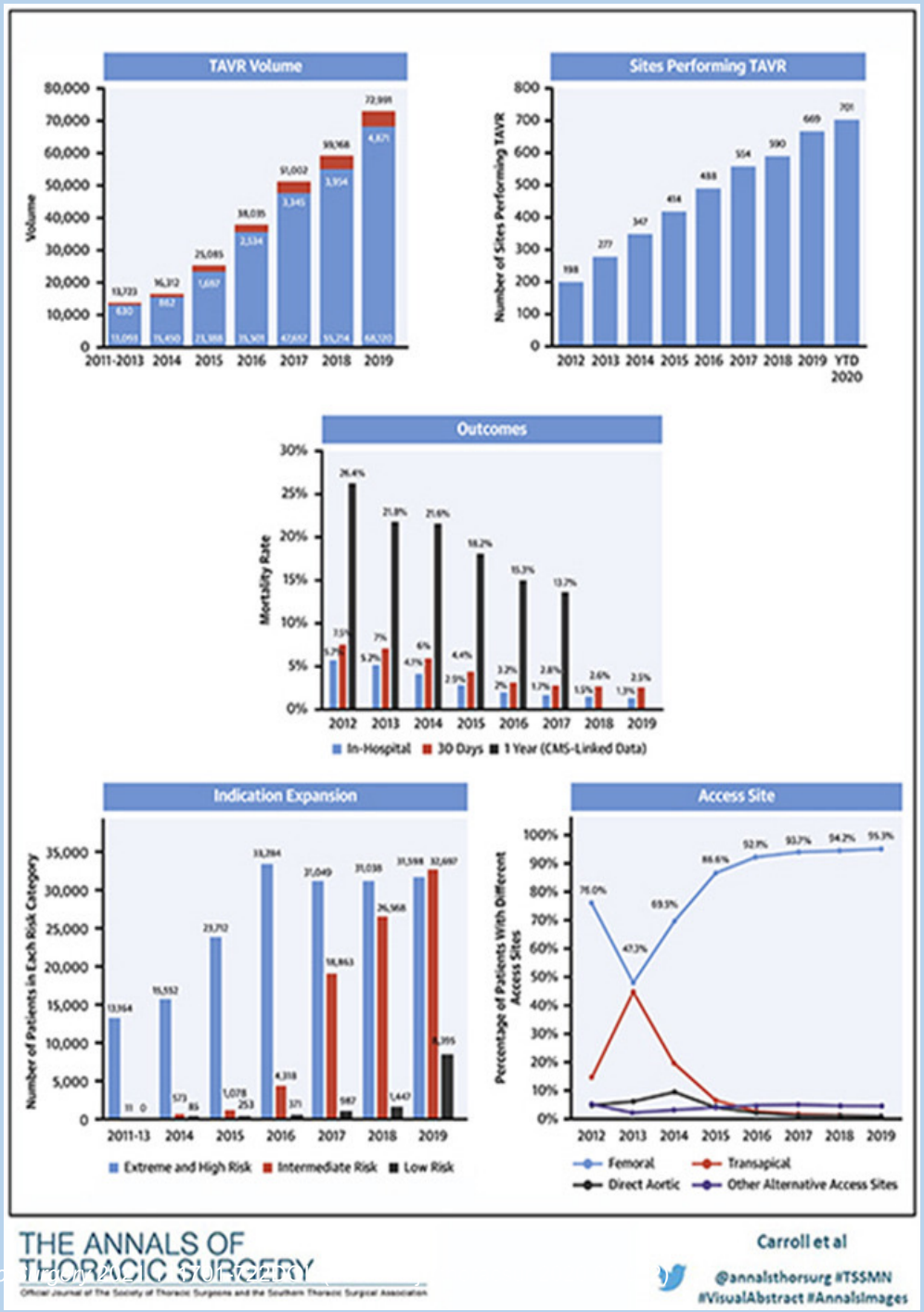
Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Carroll et al

@annalsthorsurg #TSSMN
#VisualAbstract #AnnalsImages

All cohorts of TAVR

- >95% of TAVR are via femoral access
- Hospital stay around 2 days
- 30 day mortality has decreased from 7.2% to 2.5% since 2011
- Stroke has decreased from 2.75% to 2.3%
- Pacemaker rate around 10%, depending on dataset



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TAVR: Median LOS in Days

STS National Database™
Trusted. Transformed. Real-Time.

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

The Annals of Thoracic Surgery 2021 111701-722DOI: (10.1016/j.athoracsur.2020.09.002)

Access sites

- Percutaneous Transfemoral – today is the most common

- Carotid/Inominate Artery
- Subclavian Artery
- Direct Aortic
- Apical
- Transcaval

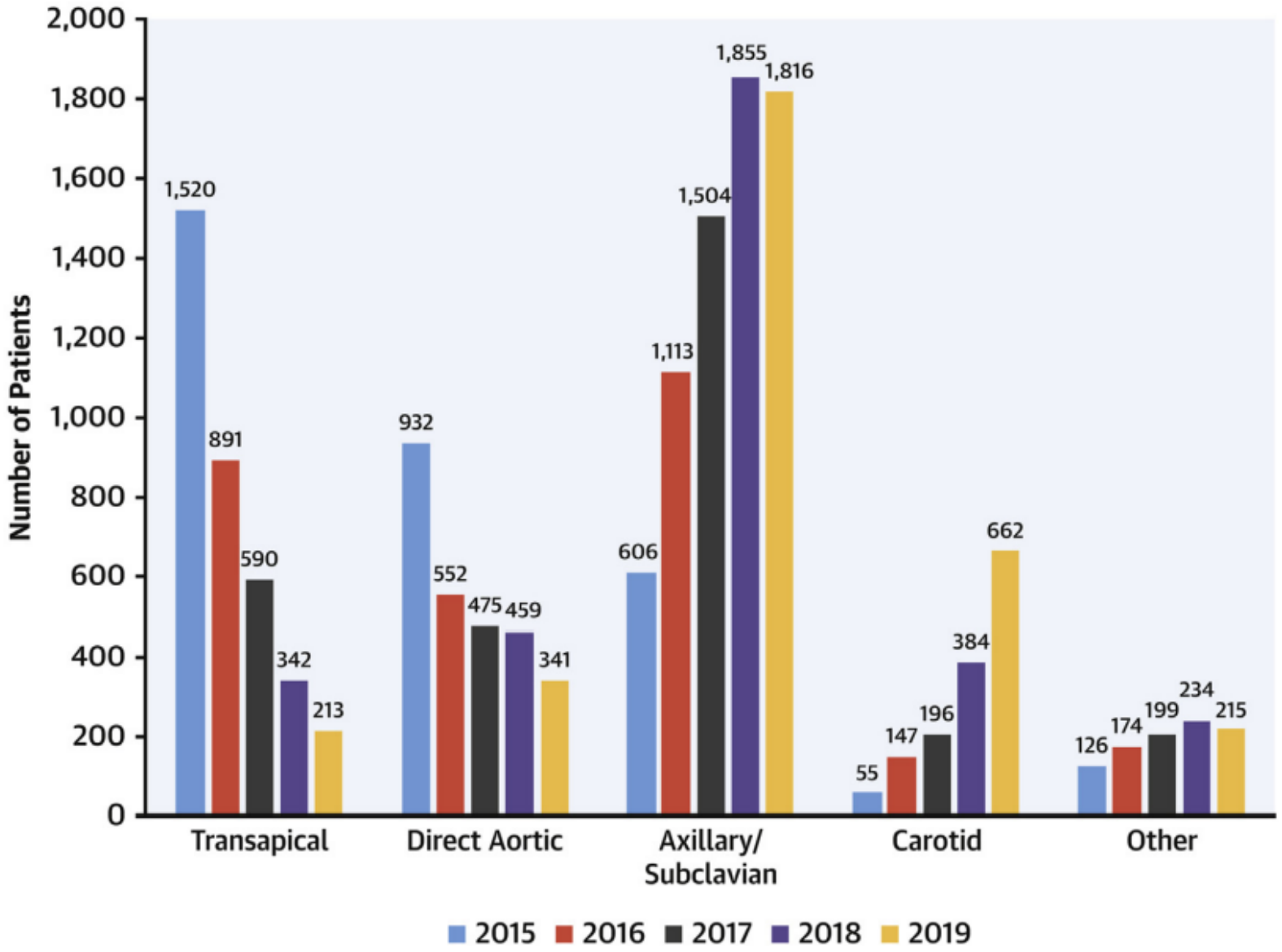
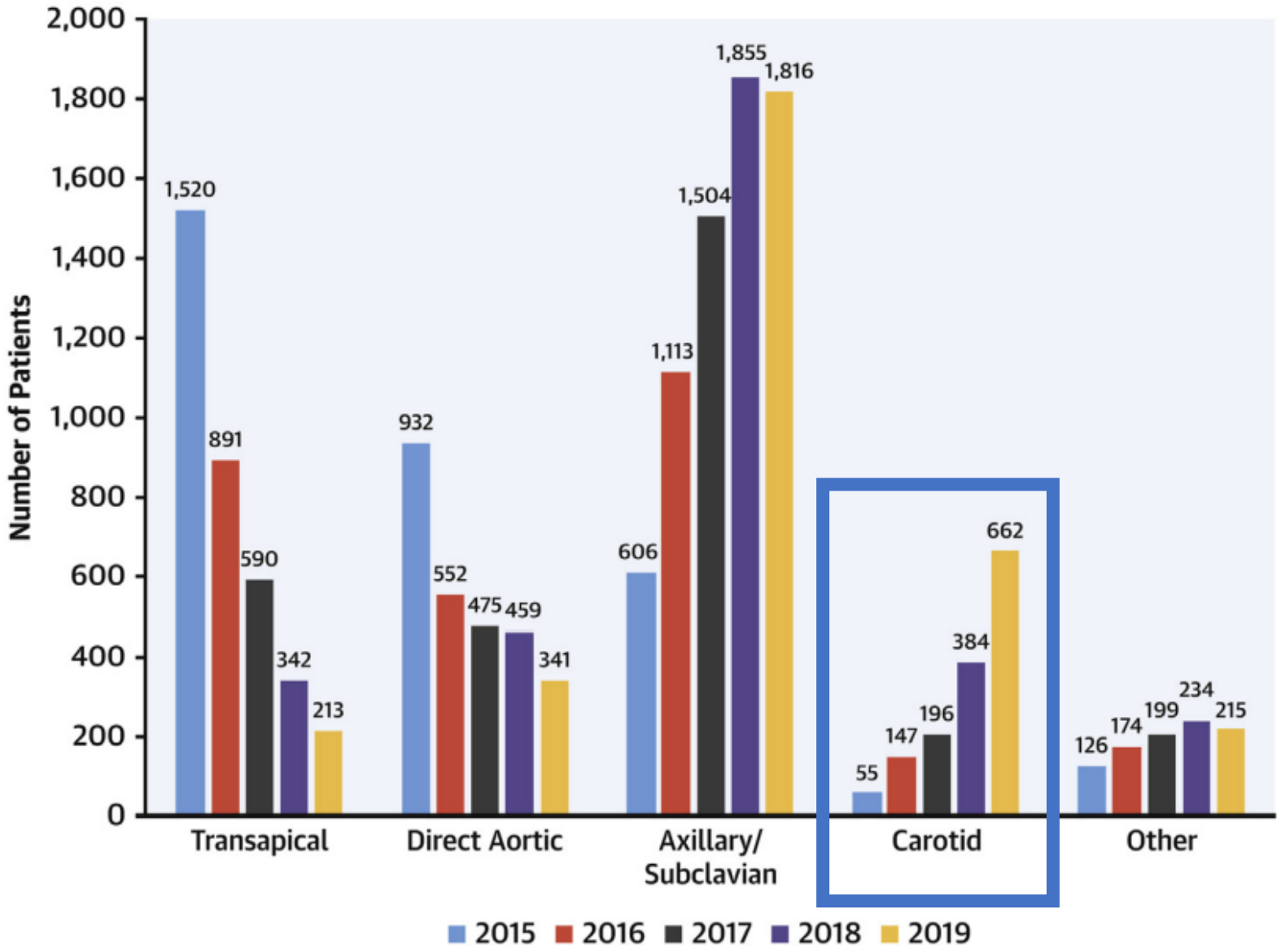


Figure 5. Forms of alternative access. Since 2015, there has been evolution of the preferred alternative access sites. This figure shows year-by-year trends of different forms of alternative access that have been used, typically when femoral access is not feasible. The other category includes iliac, transseptal, and transcaval approaches to alternative access. The dramatic shift away from central forms of alternative access (transapical and direct aortic) coincides with the rise of more peripheral forms of alternative access (axillary-subclavian and carotid).



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Pacemaker

Ann Thorac Surg
2021;111:701-22

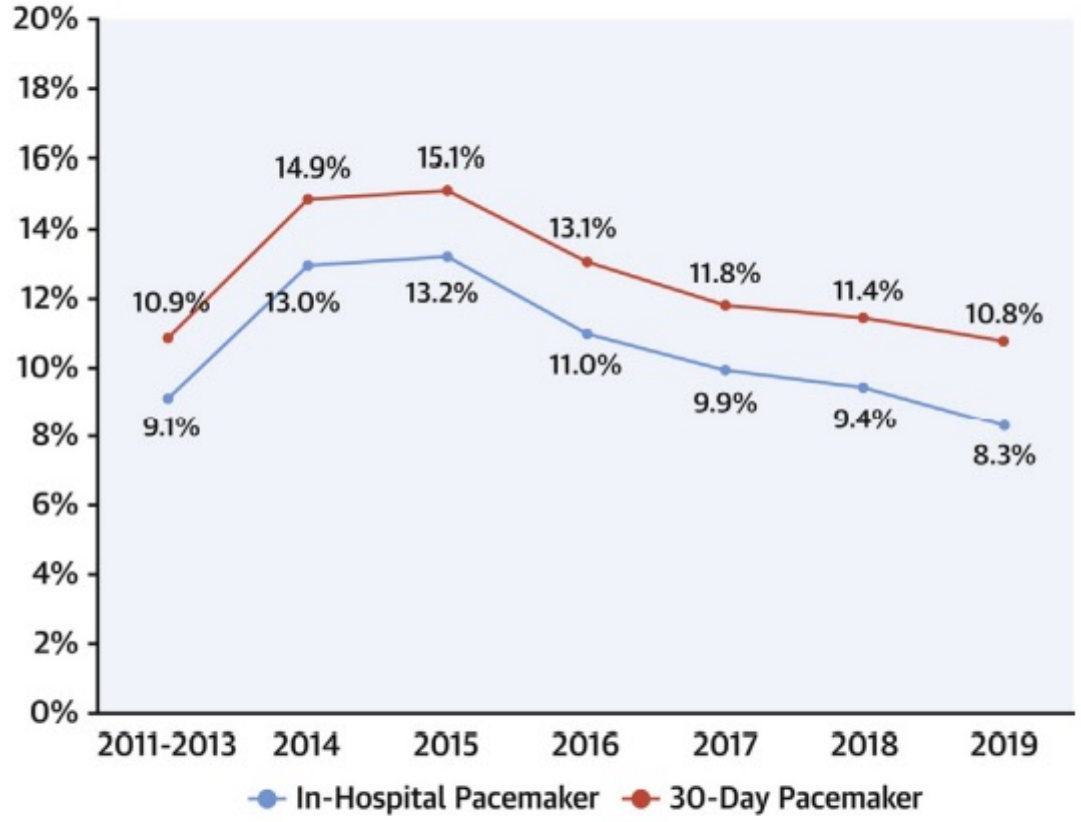


Figure 9. Pacemaker rates after TAVR. Annual proportion of patients without a previous permanent pacemaker who received a permanent pacemaker during TAVR procedure hospitalization ***(blue)*** *or within 30 days* ***(red)*** *from 2011 to 2013 until 2019. (TAVR, transcatheter aortic valve replacement.)*

Stroke

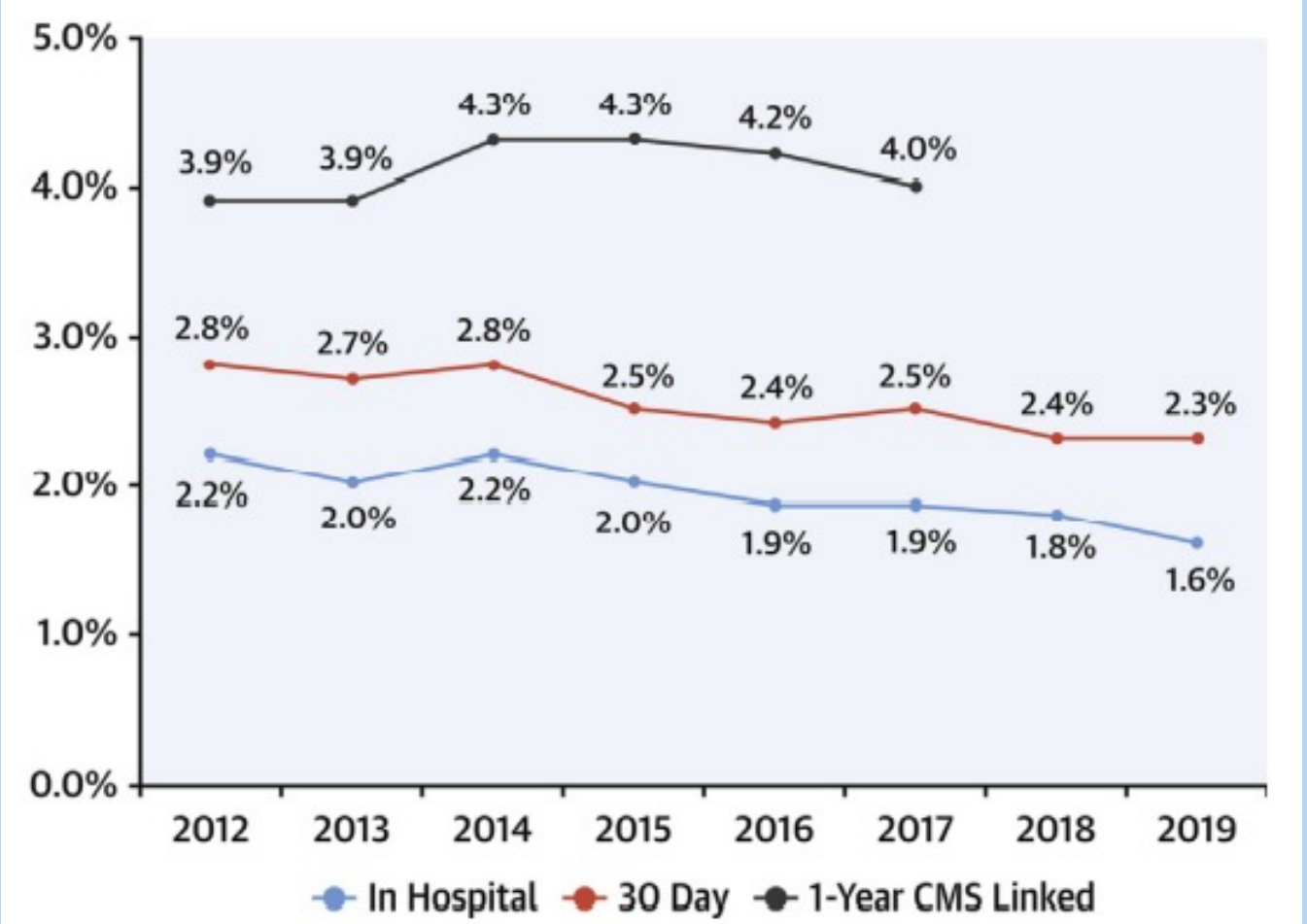
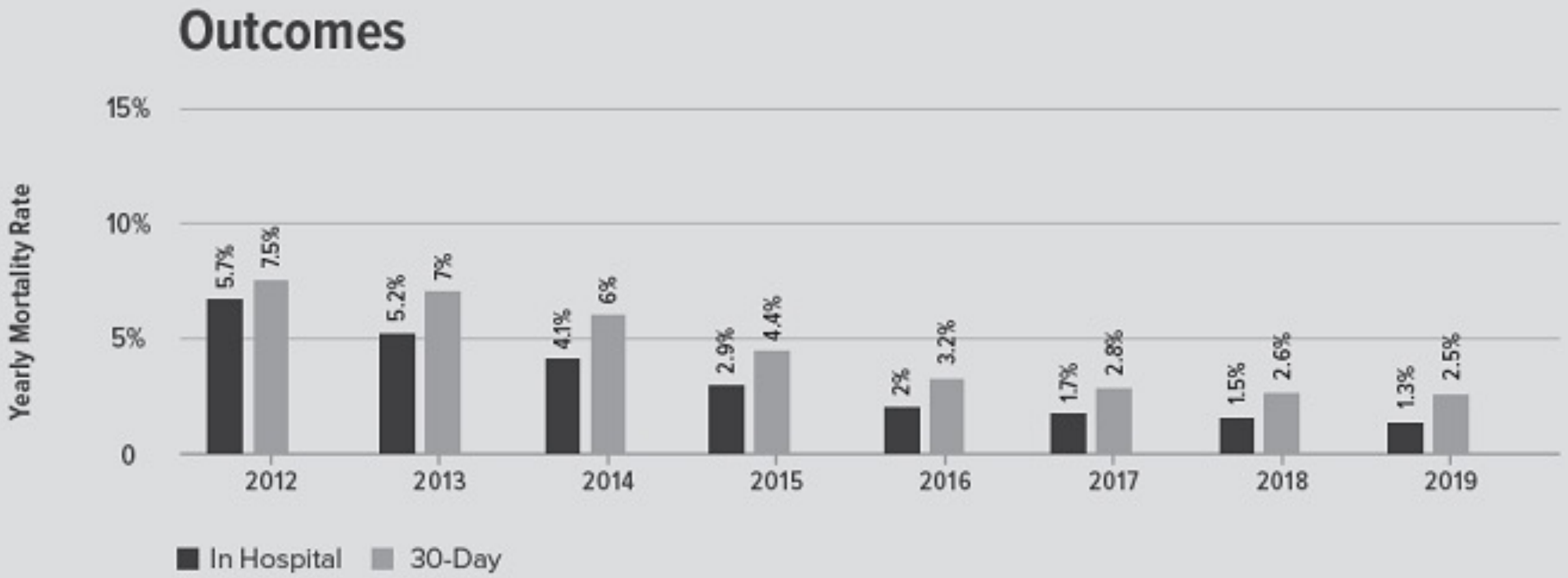


Figure 8. Stroke rates after TAVR. Yearly average rate of stroke after TAVR from 2012 through 2019. In-hospital rates are in ***blue****, 30-day in* ***red****, and 1-year in* ***gray*** *(1-year values are from CMS-linked data, unavailable after 2017). There has been a small, slow, downward trend in stroke rates. (CMS, Centers for Medicare & Medicaid; TAVR, transcatheter aortic valve replacement).*

Mortality


Outcomes
Yearly Mortality Rate
15%
10%
5%
0
5.7%
7.5%
5.2%
7%
4.1%
6%
2.9%
4.4%
2%
3.2%
1.7%
2.8%
1.5%
2.6%
1.3%
2.5%
2012
2013
2014
2015
2016
2017
2018
2019
In Hospital
30-Day

Numbers increasing

- In 2013 – 13,723 TAVRs in the U.S.
- In 2019 – 72,991 TAVRs in the U.S.

- The # of patients undergoing any form of AVR—TAVR or SAVR—grew by 94% from 2012 to 2019.

SAVR will continue to be important

- Extensive CAD
- With other concomitant valvular heart disease
- Dilation of the ascending aorta
- Young patients with bicuspid valves
- Indications for mechanical valves
- Endocarditis

Who should be considered for TAVR?

- Everyone!
  - Does not mean everyone should get TAVR, but everyone should be *considered* by a multidisciplinary heart team.
  - Guidelines support this.
  - MOST AVR's in the US are now TAVR.