

Insertion of Transcatheter Bicaval Valve System

TricValve[®]

ICD-10 Coordination & Maintenance Committee Meeting
September 13, 2022



Agenda

- Patient population
- Clinical issues and current treatment options
- Technology
- Clinical results
- Existing ICD-10-CM coding
- World wide regulatory approval status
- Clinical trial and primary outcomes
- References to published data

Patient population being addressed

- Severe tricuspid regurgitation (STR) and;
 - Patients with STR have poor survival rates at 1 (43%); 3 (27%); 5 (19%) and 7 (14%) years [Neuhold et al. Eur Hrt Jrl. 2013]
 - STR is present in 1.2-10.2% of patients [De Meester et al. Acta Cardiol. 2012; Ong et al. Echocardiog. 2014]]
- CHF, NYHA class 3-4 and;
 - Medically managed patients with STR and CHF (mainly class 3) have a 3 year survival rate of 35%. [Kadri et al. Heart 2019]
- Patient judged to be at high risk for tricuspid valve surgery

Clinical issues

- **Current treatment options:**
 - **Conservative drug therapy**
 - Poor outcomes and high mortality over short term in patients with STR and CHF
 - May improve symptoms only
 - **Tricuspid valve surgery (TVS)**
 - Rarely occurs – carries with it highest surgical valve risk among all valve procedures, with operative mortality of 10.9% [Alqahanti F, et al. Jrl Am Hrt Assoc. 2017]
 - When indicated (in approximately 1/3 of patients) - many do not undergo TVS due to advanced age or comorbidities [Kadri et al. Heart 2019]
 - Left heart surgery may result in subsequent STR [Goldstone et al. AATS 2014]; re-operative TVS is associated with even worse outcomes [Jeganathan et al. Ann Thor Surg 2013]

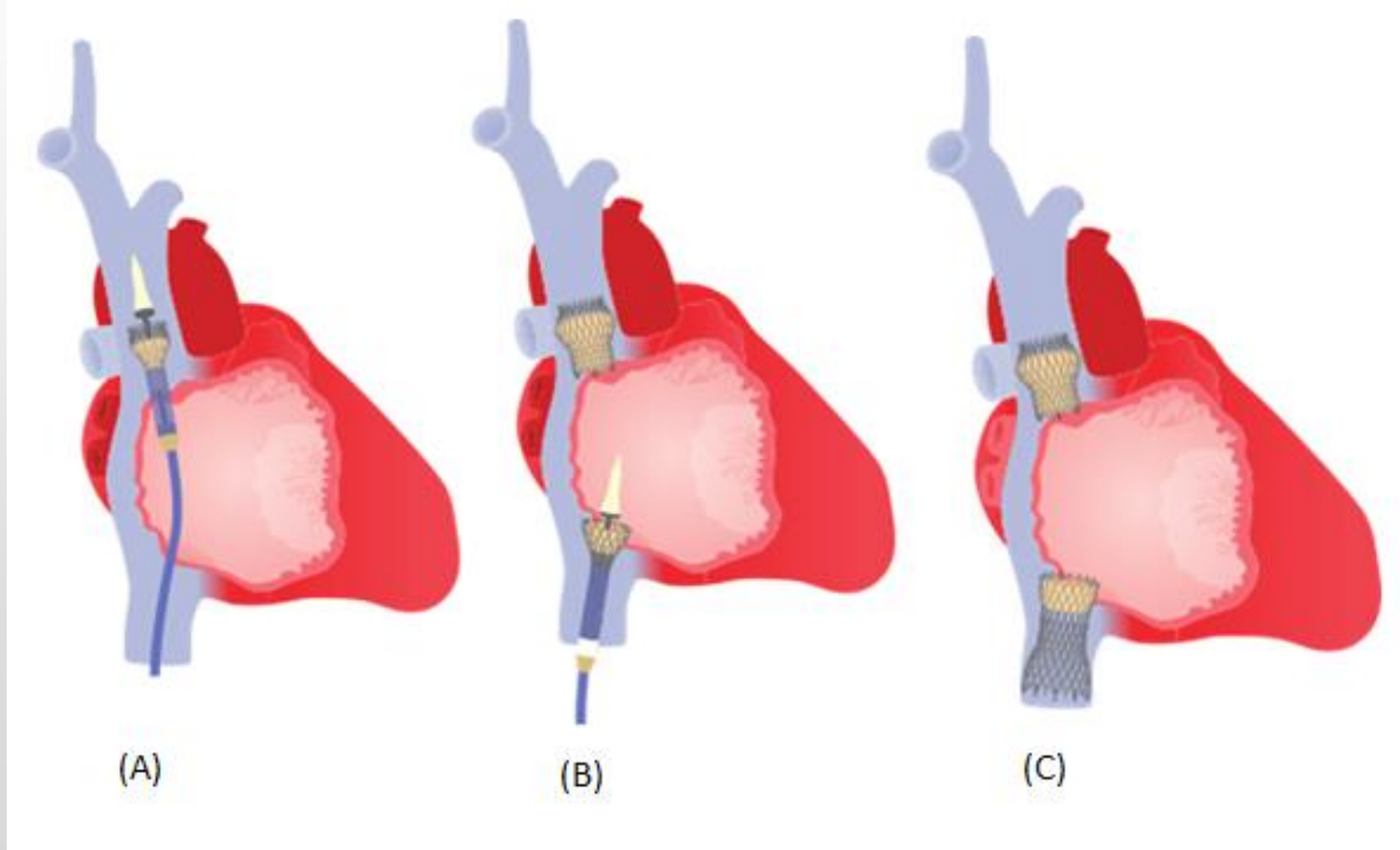
Tricuspid Regurgitation Severity Grading

<u>Parameters</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>
Qualitative doppler			
Color flow jet area	Small, narrow, central	Moderate central	Large central jet
Flow convergence zone	Not visible, transient, small	Intermediate in size and duration	Large throughout systole
Continuous wave doppler (CWD) jet	Faint/partial/parabolic	Dense, parabolic, triangular	Dense, often triangular
Semiquantitative			
Color flow jet area (cm ²)	Not defined	Not defined	>10
Vena contracta <u>width</u> (VCW) (cm)	≤0.3	0.3-0.69	≥0.7
Proximal <u>isovelocity</u> surface area (PISA) radius (cm)	≤0.5	0.6-0.9	>0.9
Hepatic vein flow	Systolic dominance	Systolic blunting	Systolic flow reversal
Tricuspid inflow	A-wave dominant	Variable	E-wave>1.0m/sec
Quantitative			
Effective regurgitant orifice area (EROA) (cm ²)	<0.2	0.2-0.39	≥0.4
<u>Regurgitant</u> volume (RVol) (2D PISA) (mL)	<30	30-44	≥0.45

Existing disease

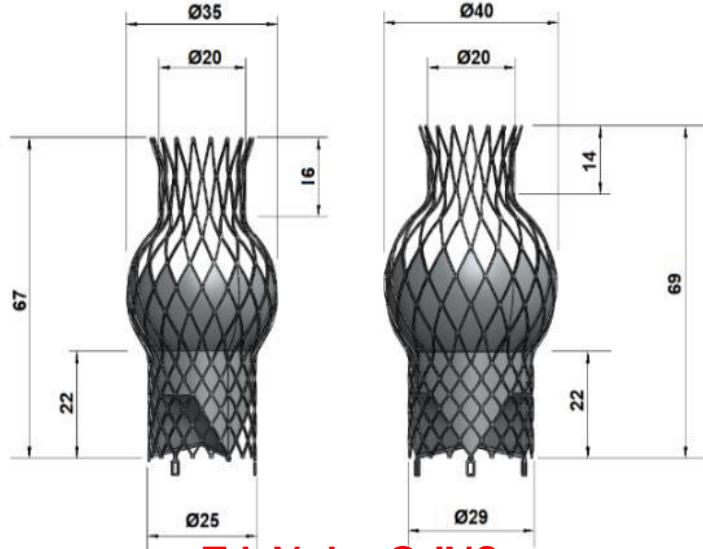
- Moderate to severe tricuspid valve regurgitation is prevalent in 1.6 million people in the US [Stuge et al. 2006; Topilsky et al. 2019]

Products & Features TricValve® Technology – heterotopic Superior Vena Cava and Inferior Vena Cava Valves delivered percutaneously via femoral vein for treatment of STR



Products & Features TricValve® Technology – heterotopic Superior Vena Cava and Inferior Vena Cava Valves

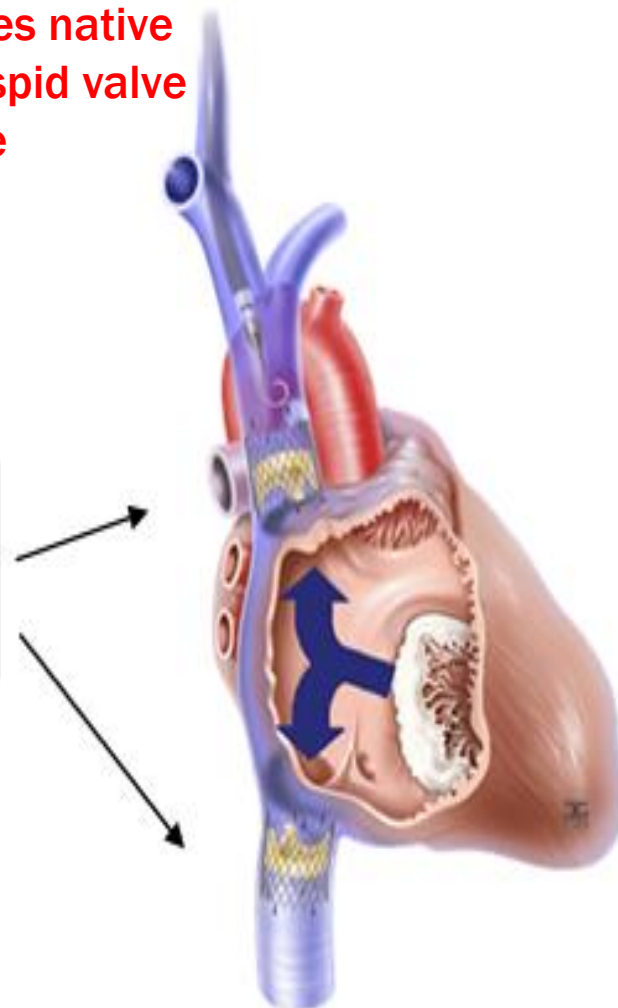
TricValve® SVC



TricValve® IVC

Leaves native tricuspid valve alone

Biological Valve (TricValve)



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Published clinical results to date SVC & IVC valves (TricValve®) – Pubmed, EBSCO, Cochrane on-line searches

Study	Study design	# patients	LFU	Outcomes
Altisent OA-J et al, Jrl Clin Med, 2021	Compassionate use; case series in 11 non-US countries	47; severe TVR; NYHA Class 3-4; LVEF≥40%	30 days	98% procedural success 4% mortality at 30 days
Lauten A, et al. Circ Cardiovasc Interv. 2018	Compassionate use; case series, Germany	6; severe TVR; NYHA Class 3-4;LVEF: 51±15%; Age: 73.9±7.6 yrs	12 months	83% procedural success
Lauten A, et al. JACC 2018	Compassionate use; Germany; duplicate of Lauten Circ Cardio Interv. 2018 study.	6; severe TVR; NYHA Class 3-4;LVEF: 51±15%; Age: 73.9±7.6 yrs	Longest FU of 51 months.	Not clear due to no breakout of TricValve (bicaval; n=6) vs. Edwards Sapien (IVC valve; n=15)
Aparisi Á et al. Rev Esp Cardiol. 2020	Compassionate use; Spain	1; TVR; age 74, female	30 days	Improvement to NYHA class 2; 6 MWT from 158 to 239 meters
Lauten A, et al. Circ Cardiovasc Interv. 2014	Compassionate use; Germany	1; severe TVR; NYHA Class 4; LVEF 45%; Age 83; female	12 months	NYHA class 2; resolution peripheral edema; improvement cardiac output

Published clinical results to date SVC & IVC valves (TricValve®) – Pubmed, EBSCO, Cochrane on-line searches

Study	Study design	# patients	LFU	Outcomes
Estévez-Louriero R, et al. JACC Cardiovasc Int. 2022	Non-blinded, non-randomized, single arm, prospective multicenter trial (12 European Centers)	35 patients; mean age 76±6.8 years, 83% women. NYHA ≥ 3	6 months	Significant increase in QoL (baseline KCCQ 42.01±22.3 vs. 59.7±23.6; P=0.004); significant improvement in NYHA functional class with 79% class I or II at 6 mths (P=0.0006)
Sharma NK et al. Annals Card Anaesth. 2021	Compassionate use; India	1; severe TVR; NYHA class 4, LVEF normal; age 80; male	3 months	NYHA class 2; significantly reduced edema
Amladi AU et al. IHJ Cardiovasc Case Reports 2021	Compassionate use; India	1; TVR; age 64; female	Not mentioned in article	Not mentioned in article

ICD-10-CM diagnosis codes that may be reported with TricValve®

- I36.1 – I36.9 Nonrheumatic tricuspid valve disorders/insufficiency
- I07.1 – I07.9 Rheumatic tricuspid valve disorders
- I08.1 – I08.9 Rheumatic multiple valve disease
- I50.20 – I50.23 Systolic (congestive) heart failure
- I50.30 – I50.33 Diastolic (congestive) heart failure
- I50.40 – I50.43 Combined systolic and diastolic (congestive) heart failure
- I50.810 - I50.814 Right heart failure
- Q22.8 - Q22.9 Congenital malformation of tricuspid valve

Regulatory approval status

- **CE Mark May 2021; certificate number: No. 1434-MDD-212/2021**
- **FDA granted breakthrough device designation December 15, 2020**
- **Undergoing review with FDA on IDE trial; the IDE was submitted July 2022**

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