

Trattamento della patologia tricuspidale: Attualità e prospettive

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CORONARY IMAGING & PHYSIOLOGY INNOVATION IN TRANSCATHETER INTERVENTIONS



M. Adamo received speaker honoraria from Abbott and Medtronic

# Tricuspid regurgitation and long-term clinical outcomes

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## N=33305

## TR<u>></u>1+ in 31% Moderate/severe TR in 9%

Mean age: 67 years



### **Circulation**

#### **ORIGINAL RESEARCH ARTICLE**

Excess Mortality Associated With Functional Tricuspid Regurgitation Complicating Heart Failure With Reduced Ejection Fraction

N=13026

TR in 55% Moderate/severe 23%

Mean age: 68 years

Benfari et al. Circulation 2019 140(3):196-206



#### **META-ANALYSIS**



### Tricuspid regurgitation is associated with increased mortality independent of pulmonary pressures and right heart failure: a systematic review and meta-analysis

Nelson Wang<sup>1</sup>, Jordan Fulcher<sup>2,3</sup>, Nishan Abeysuriya<sup>4</sup>, Michele McGrady<sup>2</sup>, Ian Wilcox<sup>1,2</sup>, David Celermajer<sup>1,2</sup>, and Sean Lal<sup>1,2</sup>\*

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## **TR classification**

	Leaflet structure	Pathophysiology	Aetiology	Imaging
Secondary (functi	onal)			
A. Atrial	Normal	RA enlargement and dysfunction leading to significant isolated annular dilation; RV often normal*	Carpentier I: Atrial fibrillation/flutter <sup>101</sup> Age <sup>102</sup> Heart failure with preserved ejection fraction <sup>103,104</sup>	Marked <b>TV annular dilation</b> is the dominant mechanism
				TV leaflet tethering is absent or minimal (except for late stages with secondary RV dysfunction)
				TV leaflet mobility is typically normal (Carpentier type I)
				RA is significantly dilated
				RV volume is typically normal (except in late stages)
B. Ventricular	Normal	RV enlargement and/or dysfunction leading to significant leaflet tethering and annular dilation	Carpentier IIIB: Left-sided ventricular or valve disease <sup>11,12</sup> Pulmonary hypertension <sup>102</sup> RV cardiomyopathy RV infarction	Marked <b>TV leaflet tethering</b> is the dominant mechanism
				TV leaflet mobility is typically restricted in systole (Carpentier type IIIB)
				TV annulus, RV and RA are dilated and/or dysfunctional
CIED-related	Normal/ abnormal	Leaflet impingement Leaflet/chordal entanglement/ chordal rupture Leaflet adherence Leaflet laceration/perforation	Pacemaker Implantable cardiac defibrillator (ICD) Cardiac resynchronisation therapy (CRT) dovices105108	TV leaflet structural abnormalities may be present TV leaflet mobility is variable (all Carpentier types) TV annulus, RV and RA are typically dilated
		lead extraction)	devices	(except for acute TR)
Primary (organic)	Abnormal	Lack of leaflet coaptation due to intrinsic changes leading to restricted or excessive leaflet mobility or leaflet perforation	Carpentier I: Congenital Endocarditis	TV leaflet structural abnormalities characteristic of each primary aetiology are the dominant mechanisms
			Carpentier II: Myxomatous disease Traumatic Post biopsy	TV leaflet mobility is variable (all Carpentier types)
				TV annulus, RV and RA are typically dilated (except in acute TR)
			Carpentier IIIA: Carcinoid <sup>109</sup> Rheumatic	
			Radiotherapy Tumours	
*RV basal diameter therapy; ICD: impla	r may appear antable cardia	abnormal due to the conical RV sh c defibrillator; RA: right atrium; R	ape. CIED: cardiac implantable V: right ventricle; TR: tricuspid	e electronic device; CRT: cardiac resynchronisation regurgitation; TV: tricuspid valve

Praz et al. EuroInt 2021; 17:791-808

## Indications for TV interventions



# 2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian () \* (ESC Chairperson) (France), Friedhelm Beyersdorf\*<sup>1</sup> (EACTS Chairperson) (Germany), Fabien Praz (ESC Task Force Coordinator) (Switzerland), Milan Milojevic<sup>1</sup> (EACTS Task Force Coordinator) (Serbia), Stephan Baldus (Germany), Johann Bauersachs (Germany), Davide Capodanno (Italy), Lenard Conradi<sup>1</sup> (Germany), Michele De Bonis<sup>1</sup> (Italy), Ruggero De Paulis<sup>1</sup> (Italy), Victoria Delgado (Netherlands), Nick Freemantle<sup>1</sup> (United Kingdom), Martine Gilard (France), Kristina H. Haugaa (Norway), Anders Jeppsson<sup>1</sup> (Sweden), Peter Jüni (Canada), Luc Pierard (Belgium), Bernard D. Prendergast (United Kingdom), J. Rafael Sádaba<sup>1</sup> (Spain), Christophe Tribouilloy (France), Wojtek Wojakowski (Poland), ESC/EACTS Scientific Document Group



# **Tricuspid regurgitation after TAVI**

Prevalence of severe TR in TAVI candidates = 2.8%



About 70% improvement of at least 1 grade



Tomii et al. JACC Cardiovasc Interv. 2021;14(20):2246-2256.

# **Tricuspid regurgitation after M-TEER**



Adamo et al. Eur J Heart Fail. 2022;24(11):2175-2184.

## Indications for TV interventions

ESC/EACTS GUIDELINES

# 2021 ESC/EACTS Guidelines for the management of valvular heart disease

European Heart Journal (2021) 00, 1-72

European Society doi:10.1093/eurhearti/ehab395

ESC

of Cardiology

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

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## **Clinical course of TR & Late presentation**



- Limited time window
- Aspecific symptoms
- Low awarness

Chang et al. Eur Heart J. 2020;41(20):1932-1940

## Treatment of patients with tricuspid regurgitation

Medical therapy is very limited and possibly ineffective



**Surgery** is burdened by a high intra-operative risk

# Surgery for isolated tricuspid regurgitation



Zack et al JACC 2017; 70 (24)



CLINICAL RESEARCH Valvular heart disease

## TRI-SCORE: a new risk score for in-hospital mortality prediction after isolated tricuspid valve surgery

Julien Dreyfus <sup>(1)</sup>\*\*<sup>†</sup>, Etienne Audureau<sup>2,3,†</sup>, Yohann Bohbot<sup>4,5</sup>, Augustin Coisne <sup>(6,7)</sup>, Yoan Lavie-Badie <sup>(6)</sup> <sup>8</sup>, Maxime Bouchery<sup>9</sup>, Michele Flagiello <sup>(1)</sup>, Baptiste Bazire <sup>(1)</sup><sup>11</sup>, Florian Eggenspieler<sup>12</sup>, Florence Viau<sup>13</sup>, Elisabeth Riant <sup>(1)</sup><sup>1,14</sup>, Yannick Mbaki<sup>15</sup>, Damien Eyharts <sup>(0)</sup> <sup>8</sup>, Thomas Senage<sup>16</sup>, Thomas Modine<sup>6</sup>, Martin Nicol <sup>(2)</sup>, Fabien Doguet <sup>(2)</sup> <sup>17,18</sup>, Virginia Nguyen<sup>1</sup>, Thierry Le Tourneau<sup>19</sup>, Christophe Tribouilloy <sup>(3)</sup> <sup>4,5</sup>, Erwan Donal <sup>(15)</sup>, Jacques Tomasi <sup>(20)</sup>, Gilbert Habib <sup>(13,21)</sup>, Christine Selton-Suty <sup>(12)</sup>, Richard Raffoul<sup>22</sup>, Bernard Iung <sup>(2)</sup> <sup>23</sup>, Jean-François Obadia <sup>(10)</sup>, and David Messika-Zeitoun <sup>(2)</sup> <sup>24</sup>\*

## N=466 In-hospital mortality=10%

Mean age 60 years

Risk factors (final model from multivariate analysis)	Scoring
Age ≥ 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide ≥ 125mg	2
Glomerular filtration rate < 30 ml/min	2
Elevated total bilirubin	2
Left ventricular ejection fraction < 60%	1
Moderate/severe right ventricular dysfunction	1
Total	12





## Treatment of patients with tricuspid regurgitation

Medical therapy is very limited and possibly ineffective



**Surgery** is burdened by a high intra-operative risk

## Transcatheter TV intervention to fill an unmet need



# **Transcatheter devices for TR**



# Selection of transcatheter devices for TR



Praz et al. EuroInt 2021; 17:791-808

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#### Outcomes After Current Transcatheter Tricuspid Valve Intervention

#### Mid-Term Results From the International TriValve Registry

Maurizio Taramasso, MD, PHD,<sup>a</sup> Hannes Alessandrini, MD,<sup>b</sup> Azeem Latib, MD,<sup>c</sup> Masahiko Asami, MD,<sup>d</sup> Adrian Attinger-Toller, MD,<sup>c</sup> Luigi Biasco, MD,<sup>f</sup> Daniel Braun, MD,<sup>g</sup> Eric Brochet, MD,<sup>h</sup> Kim A. Connelly, MD,<sup>i</sup> Paolo Denti, MD,<sup>c</sup> Florian Deuschl, MD,<sup>j</sup> Andrea Englmeier, MD,<sup>g</sup> Neil Fam, MD,<sup>i</sup> Christian Frerker, MD,<sup>b</sup> Jörg Hausletter, MD,<sup>g</sup> Dominique Himbert, MD,<sup>h</sup> Edwin C. Ho, MD,<sup>n,ij</sup> Jean-Michel Juliard, MD,<sup>h</sup> Ryan Kaple, MD,<sup>k</sup> Felix Kreidel, MD,<sup>b</sup> Karl-Heinz Kuck, MD,<sup>b</sup> Marco Ancona, MD,<sup>c</sup> Alexander Lauten, MD,<sup>1</sup> Philipp Lurz, MD,<sup>m</sup> Michael Mehr, MD,<sup>g</sup> Tamin Nazif, MD,<sup>n</sup> Georg Nickening, MD,<sup>o</sup> Giovanni Pedrazzini, MD,<sup>f</sup> Alberto Pozzoli, MD,<sup>a</sup> Fabien Praz, MD,<sup>d</sup> Rishi Puri, MD,<sup>c</sup> Josep Rodés-Cabau, MD,<sup>p</sup> Ulrich Schäfer, MD,<sup>1</sup> Joachim Schofer, MD,<sup>q</sup> Horst Sievert, MD,<sup>f</sup> Kolja Sievert, MD,<sup>f</sup> Gilbert H.L. Tang, MD, MSc, MBA,<sup>s</sup> Felix C. Tanner, MD,<sup>a</sup> Alec Vahanian, MD,<sup>h</sup> John G. Webb, MD,<sup>o</sup> Stephan Windecker, MD,<sup>d</sup> Ermela Yzeiray, MD,<sup>q</sup> Michel Zuber, MD,<sup>a</sup> Francesco Maisano, MD,<sup>a</sup>

VOL. 12, NO. 2, 2019

PROCEDURAL SUCCESS reduction in at least 1 TR degree



Taramasso et al. JACC int. 2019; 12(2)

## **Transcatheter Versus Medical Treatment** of Patients With Symptomatic **Severe Tricuspid Regurgitation**



TRIVALVE versus

Taramasso, M. et al. J Am Coll Cardiol. 2019:74(24):2998-3008.

## **TRILUMINATE-PIVOTAL RCT**

# **Primary Endpoint**

## **Finkelstein-Schoenfeld Analysis**



## **TRILUMINATE-PIVOTAL RCT**

# **Safety Profile**

Major Adverse Event (MAE) Through 30 Days Post-Procedure – no.(%)	Device N=172†
Total	3 (1.7%)
Cardiovascular mortality	1 (0.6%)
Endocarditis requiring surgery	0 (0%)
New-onset renal failure	2 (1.2%)
Non-elective CV Surgery, TVRS for device- related AE	0 (0%)

Other Clinical Safety Endpoints Through 30 Days Post-Procedure– no.(%)	Device N=172 <sup>†</sup>
Any-cause mortality	1 (0.6%)
Tricuspid valve surgery	1 (0.6%)
Tricuspid valve re-intervention	3 (1.7%)
Major bleeding#	8 (4.7%)
Tricuspid mean gradient ≥ 5mmHg	8 (4.7%)
Single leaflet device attachment (SLDA)*	12 (7.0%)
Stroke	1 (0.6%)
Myocardial Infarction	0 (0%)
Embolization*	0 (0%)
Thrombosis	0 (0%)
New CRT/CRT-D/ICD/perm. pacemaker^	1 (0.6%)

†Attempted procedure population (3 subjects randomized to Device withdrew consent prior to index procedure) #Defined as bleeding ≥ Type 3 based on a modified Bleeding Academic Research Consortium (BARC) definition \*SLDA and embolization evaluated through 30-day follow-up ^Assessed through adverse event reporting



## Patient selection for treatment of isolated TR



- 1) Right ventricular function (global evaluation)
- 2) Congestion/organ damage (renal and hepatic markers)
- 3) Pulmonary hypertension (RHC)

# **Right ventricular function (global evaluation)**

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### Right Ventricular Contraction Patterns in Patients Undergoing Transcatheter Tricuspid Valve Repair for Severe Tricuspid Regurgitation

Karl-Patrik Kresoja, MD,<sup>a</sup> Karl-Philipp Rommel, MD,<sup>a</sup> Christian Lücke, MD,<sup>b</sup> Matthias Unterhuber, MD,<sup>a</sup> Christian Besler, MD,<sup>a</sup> Maximilian von Roeder, MD,<sup>a</sup> Anne Rebecca Schöber, MD,<sup>a</sup> Thilo Noack, MD,<sup>c</sup> Matthias Gutberlet, MD,<sup>b</sup> Holger Thiele, MD,<sup>3,\*</sup> Philipp Lurz, MD, PhD<sup>a,\*</sup>



# **Congestion/organ damage**

Circulation: Cardiovascular Interventions

### **ORIGINAL ARTICLE**

Transcatheter Tricuspid Valve Intervention in Patients With Right Ventricular Dysfunction or Pulmonary Hypertension

Insights From the TriValve Registry



Muntané-Carol et al. Circ Cardiovasc Interv. 2021;14(2):e009685

# **Pulmonary hypertension (RHC)**

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## Cardiopulmonary Hemodynamic Profile Predicts Mortality After Transcatheter Tricuspid Valve Repair in Chronic Heart Failure

Thomas J. Stocker, MD,<sup>a,b</sup> Helene Hertell,<sup>a,b</sup> Mathias Orban, MD,<sup>a,b</sup> Daniel Braun, MD,<sup>a,b</sup> Karl-Philipp Rommel, MD,<sup>c</sup> Tobias Ruf, MD,<sup>d</sup> Geraldine Ong, MD,<sup>e</sup> Michael Nabauer, MD,<sup>a,b</sup> Simon Deseive, MD,<sup>a,b</sup> Neil Fam, MD,<sup>e</sup> Ralph S. von Bardeleben,<sup>d</sup> Holger Thiele, MD,<sup>c</sup> Steffen Massberg, MD,<sup>a,b</sup> Philipp Lurz, MD, PHD,<sup>c,\*</sup> Jörg Hausleiter, MD<sup>a,b,\*</sup>



## **Patient selection for TR treatment**



EARLY INTERVENTION

**FUTILITY OF INTERVENTION**