

VII Congresso Novas Fronteiras em Cardiologia

Insuficiência tricúspide: a nova estrela?

Insuficiência tricúspide

Introdução

- Está presente em $\approx 70\%$ dos adultos (ligeira)
- A > parte das vezes ($\approx 90\%$) é funcional
 - Estudo em 5.223 dts (idade média 66 anos) que fizeram ETT (VA medical center) *
 - Moderada / severa em 15,7%
 - Destes só 8% tinham patologia primária
- Mecanismo – Sobrecarga de pressão e/ou volume do VD
 - Dilatação do anel
 - “Tethering” dos folhetos

* Jayant Nath, J Am Coll Cardiol 2004;43:405–9

Insuficiência Tricúspide Primária

Etiologia

- Lesão valvular
 - ✓ Eléctrodos (implantação, remoção)
 - ✓ Bióptomo
- Trauma torácico
- Endocardite infecciosa
- Anomalia de Ebstein
- Febre reumática
- S. Carcinóide
- Disfunção /ruptura do músculo papilar isquémica
- Degeneração mixomatosa com prolapso da v. Tricúspide
- Doenças do tecido conjuntivo (p.e. S. Marfan)
- Endocardite marântica (lupus, artrite reumatóide)
- Drogas

Insuficiência Tricúspide Funcional

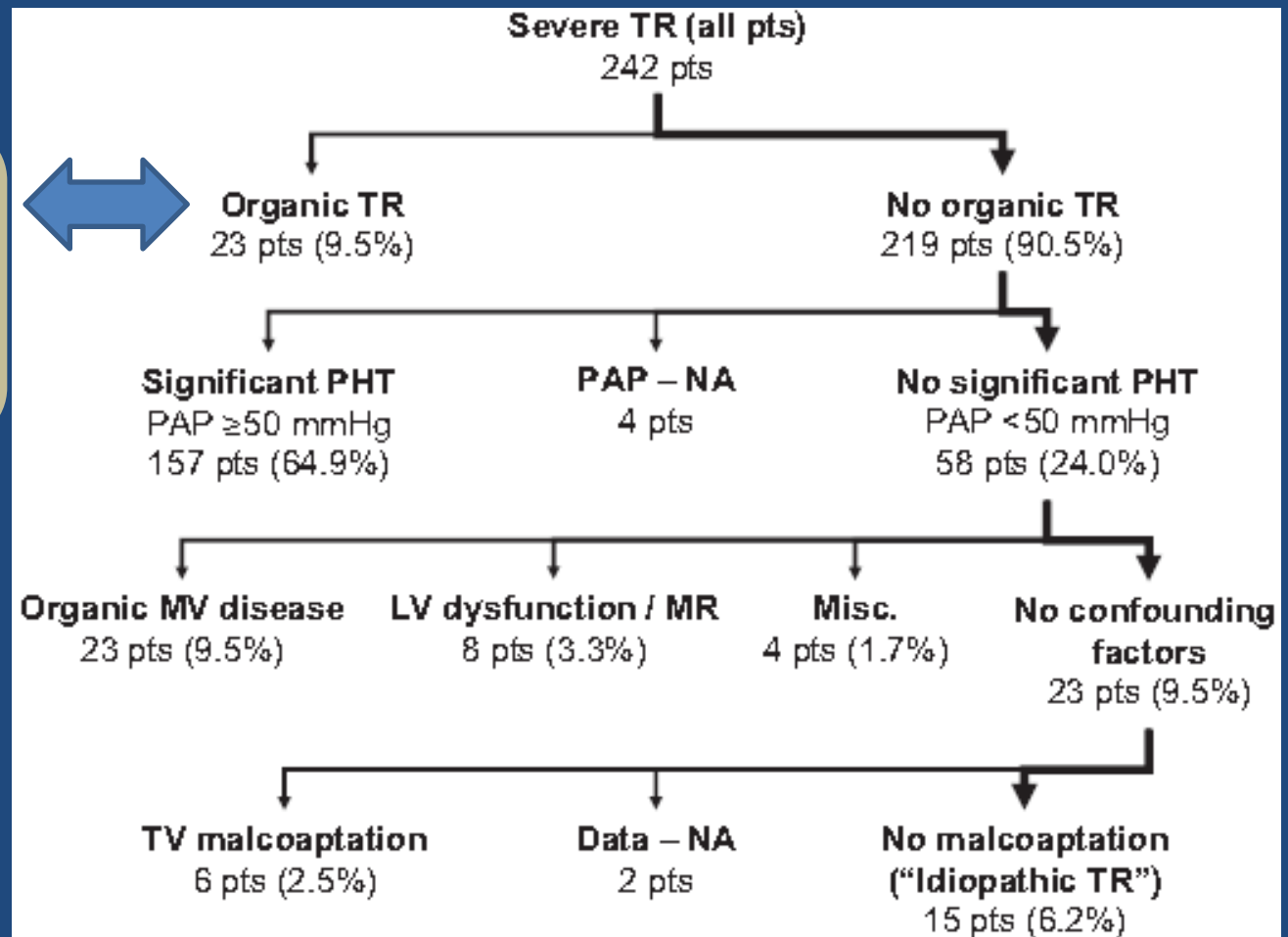
Etiologia

- **Hipertensão pulmonar com dilatação do VD:**
 - ✓ Insuficiência cardíaca esquerda
 - ✓ Estenose / regurgitação mitral
 - ✓ Patologia pulmonar primária
 - ✓ Shunt E/D
 - ✓ S. Eisenmenger
 - ✓ Estenose pulmonar (arterial ou valvular)
 - ✓ Hipertireoidismo
- **Patologia do VD**
 - ✓ Enfarte do VD
 - ✓ Cardiomiopatia a afectar o VD

Echocardiography-based Spectrum of Severe Tricuspid Regurgitation: The Frequency of Apparently Idiopathic Tricuspid Regurgitation

Organic TR

- Rheumatic 13
- After annuloplasty 6
- Myxomatous 3
- Endocarditis 1



Echocardiography-based Spectrum of Severe Tricuspid Regurgitation: The Frequency of Apparently Idiopathic Tricuspid Regurgitation

Table Selected clinical and echocardiographic characteristics of patients with idiopathic tricuspid regurgitation

Patient	Age, y	Sex	History of AF	AF during echocardiography	CAD	Chronic lung disease	LVEF, %	RVE*	RV systolic dysfunction*	RAE*	PAP, mm Hg	RAP, mm Hg
1	83	M	+	+	—	—	65	+	—	+	35	10
2	56	M	+	—	+	—	55	+	+	+	37	20
3	76	F	+	+	—	—	60	—	—	—	27	5
4	87	F	+	+	—	—	40	—	—	—	31	15
5	71	M	+	+	—	—	65	—	—	+	34	10
6	78	F	+	+	—	—	60	—	—	+	36	10
7	86	M	+	+	+	—	45	—	—	—	37	10
8	72	F	+	+	+	—	65	—	—	+	39	15
9	81	M	+	+	—	—	60	+	—	+	40	15
10	73	M	NA	+	NA	NA	60	+	—	+	43	20
11	87	F	—	—	—	—	70	—	—	+	45	15
12	75	M	+	+	+	+	50	—	—	—	45	15
13	61	F	+	+	—	—	60	+	—	+	48	20
14	64	M	+	+	—	—	45	+	—	+	48	20
15	85	M	+	+	+	—	35	+	—	+	45	15
Total†	76 ± 10	60% M	92.9%	86.7%	35.7%	7.1%	56 ± 10	46.7%	6.7%	73.3%	39 ± 6	14 ± 5

AF, Atrial fibrillation; CAD, coronary artery disease; F, female; LVEF, left ventricular ejection fraction; M, male; NA, data not available; PAP, pulmonary artery pressure (systolic); RAE, right atrial (RA) enlargement; RAP, RA pressure; RV, right ventricular; RVE, RV enlargement.

*Moderate or severe RVE, RV dysfunction, or RAE.

†Summary of data in all patients (data presented as average ± SD or percent of patients with available data).

Echocardiography-based Spectrum of Severe Tricuspid Regurgitation: The Frequency of Apparently Idiopathic Tricuspid Regurgitation

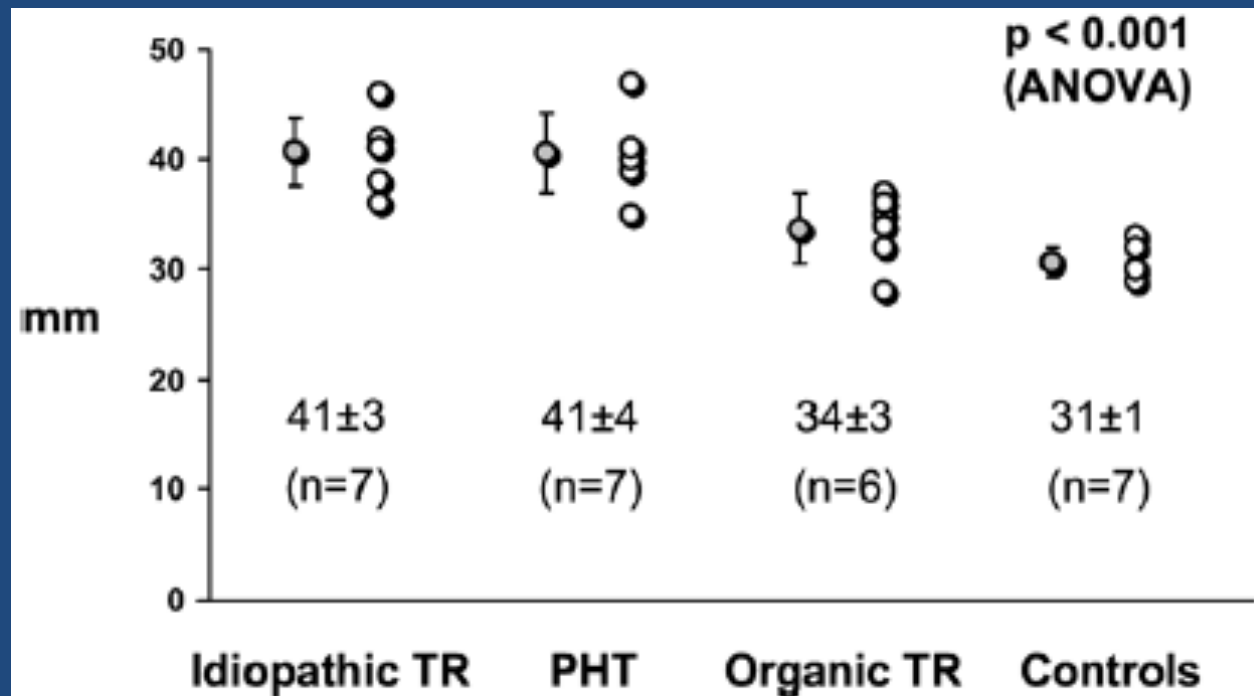


Figure 2 Annular diameter in representative patients with severe idiopathic tricuspid regurgitation (TR), severe TR associated with significant pulmonary hypertension (PHT), severe organic TR, and control patients without TR.

Impact of Tricuspid Regurgitation on Long-Term Survival

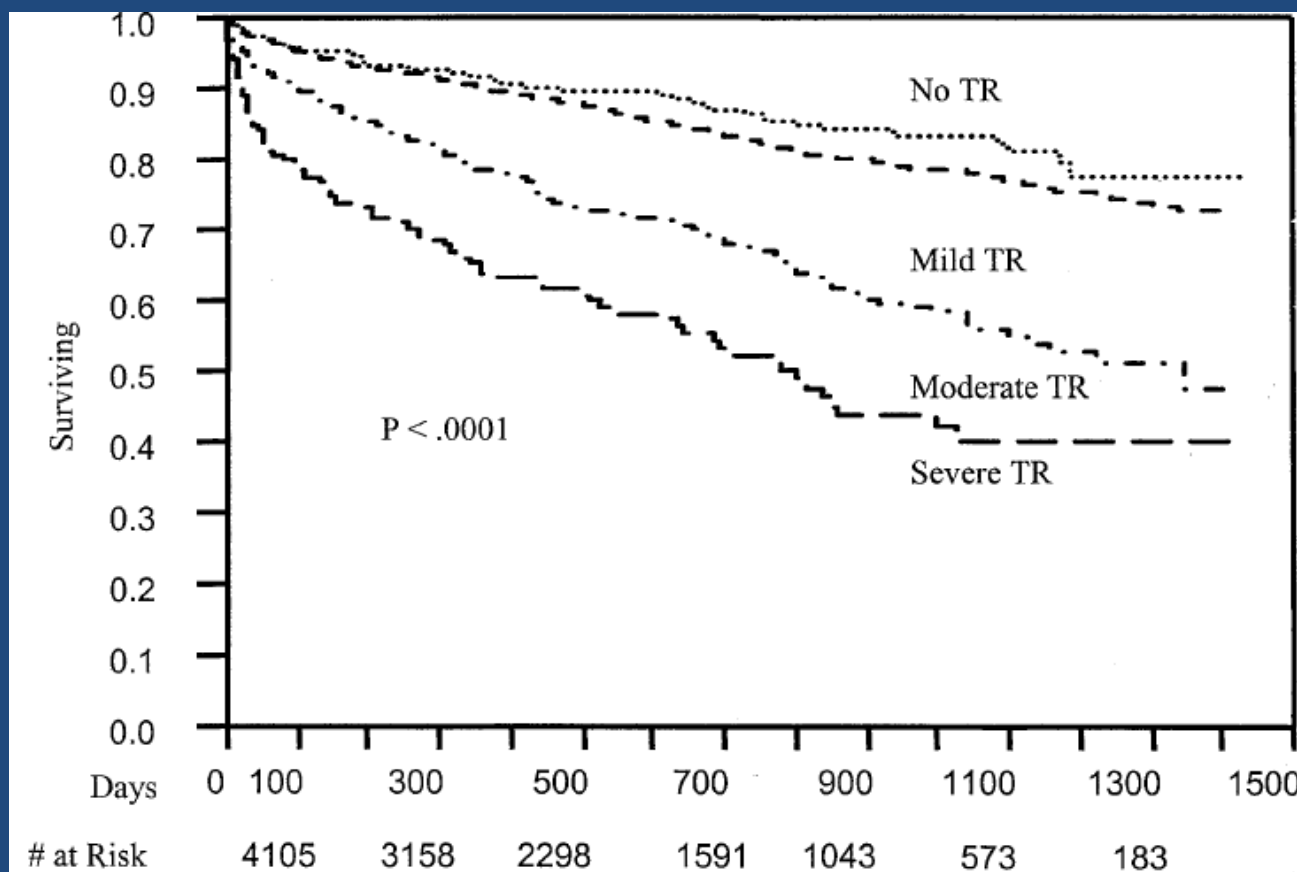
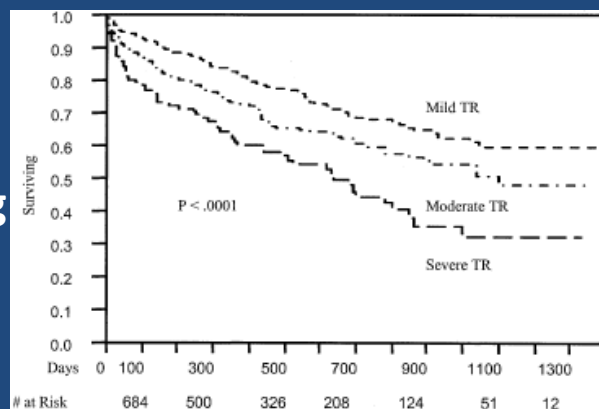


Figure 1. Kaplan-Meier survival curves for all patients with tricuspid regurgitation (TR). Survival is significantly worse in patients with moderate and severe TR.

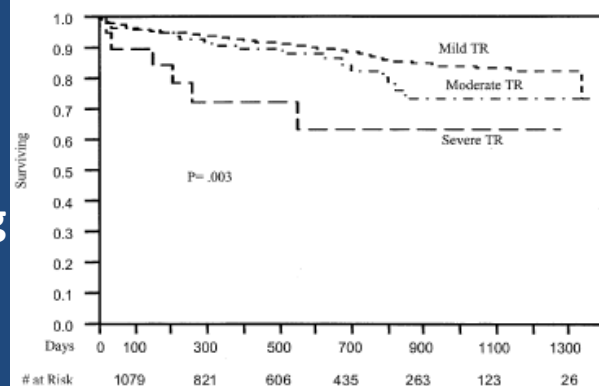
Impact of Tricuspid Regurgitation on Long-Term Survival

PSAP
≥ 40 mmHg



A

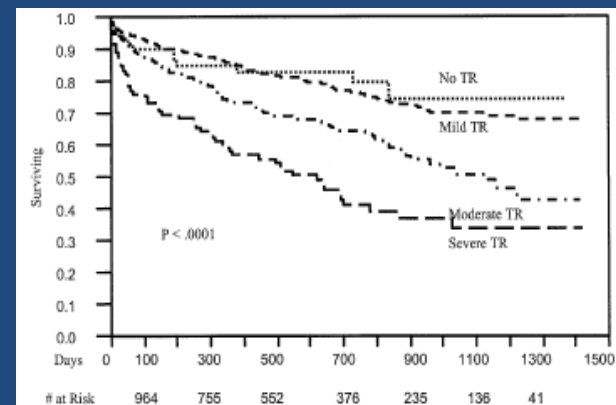
PSAP
< 40 mmHg



B

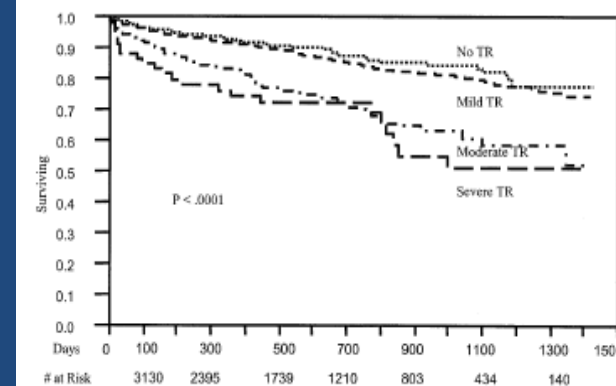
Figure 2. Kaplan-Meier survival curves for (A) patients with tricuspid regurgitation (TR) and high pulmonary artery systolic pressure (≥40 mm Hg) and (B) patients with TR and normal pulmonary artery systolic pressure (<40 mm Hg).

FE < 50 %



A

FE ≥ 50 %



B

Figure 3. Kaplan-Meier survival curve for (A) patients with tricuspid regurgitation (TR) and a low left ventricular ejection fraction (<50%) and (B) patients with TR and a normal left ventricular ejection fraction (≥50%).

Evolution of tricuspid regurgitation after mitral valve repair for functional mitral regurgitation in dilated cardiomyopathy

- Estudo retrospectivo
- 121 dts submetidos a reparação mitral por IM severa funcional ($\pm$ reparação tricúspide)
- 30 excluídos (IM $\geq 1+$ à alta, pace preop, CDI ou pace até 6 meses após cirurgia, morte < 6 meses)
- Dos 91 dts, anuloplastia tricúspide em 13 (IT $\geq 3+$)

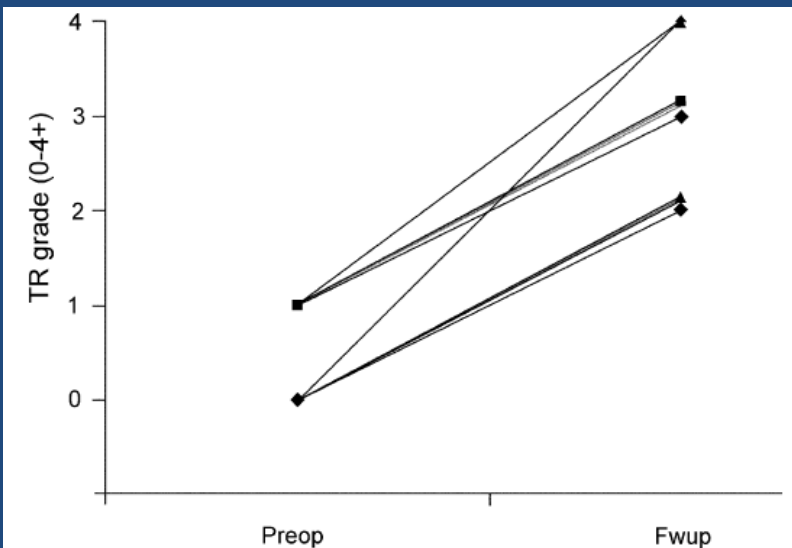


Fig. 1. Patients with progression of at least two grades of untreated pre-operative TR $< 2+$ (14/78 pts, 18%).

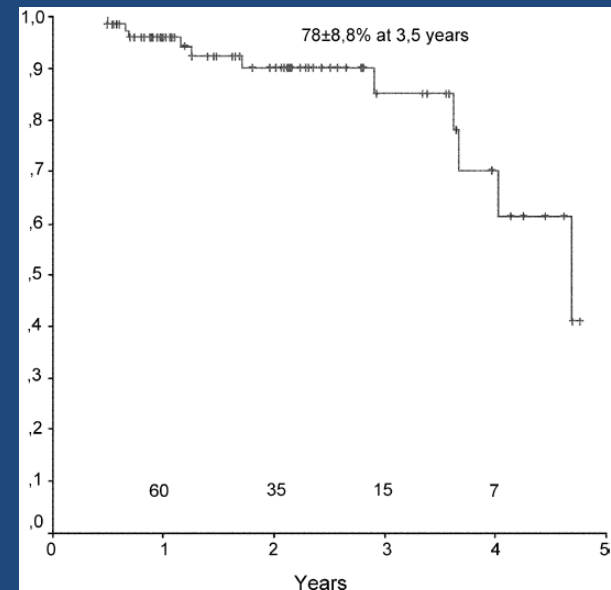


Fig. 2. Freedom from tricuspid regurgitation $> 3+$ at last follow-up.

ESC/EACTS GUIDELINES

Indications for tricuspid valve surgery

Classe 1 C

- Surgery is indicated in patients with **severe primary or secondary TR** undergoing **left-sided valve surgery**.
- Surgery is indicated in **symptomatic** patients with **severe isolated primary TR** without **severe right ventricular dysfunction**.

ESC/EACTS GUIDELINES

Indications for tricuspid valve surgery

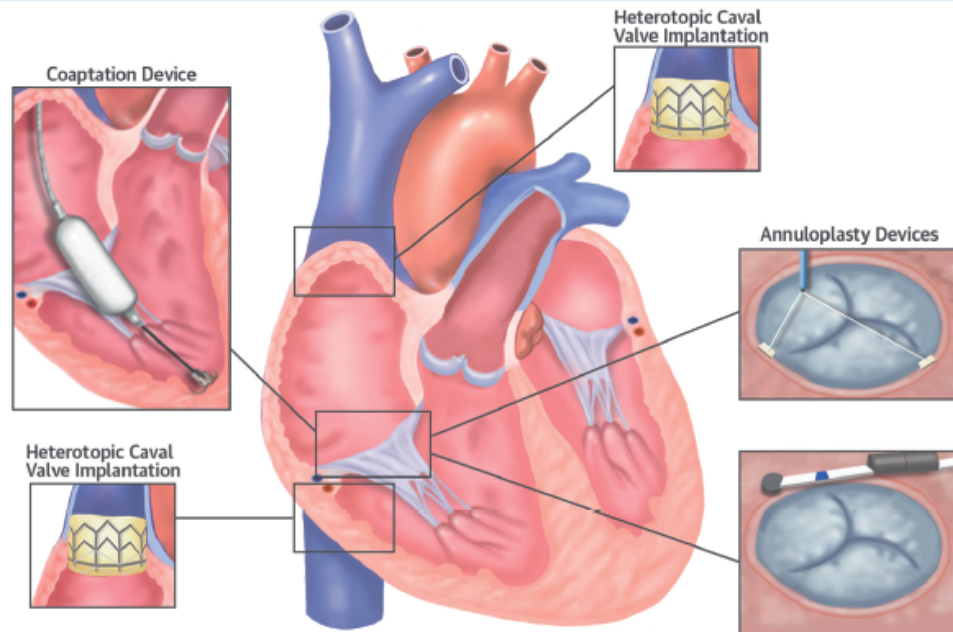
Classe IIaC

- Surgery should be considered in patients with **moderate primary TR** undergoing **left-sided valve surgery**.
- Surgery should be considered in patients with **mild or moderate secondary TR** with **dilated annulus** (≥ 40 mm or > 21 mm/m²) undergoing **left-sided valve surgery**.
- Surgery should be considered in **asymptomatic or mildly symptomatic** patients with **severe isolated primary TR** and **progressive right ventricular dilatation** or **deterioration of right ventricular function**.
- **After left-sided valve surgery**, surgery should be considered in patients with **severe TR** who are **symptomatic** or have **progressive right ventricular dilatation/dysfunction**, in the absence of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease.

Transcatheter Therapies for tricuspid Regurgitation

CENTRAL ILLUSTRATION Transcatheter Therapies for TR

Transcatheter Therapies for Tricuspid Regurgitation



Challenges of Transcatheter Therapies for Tricuspid Regurgitation

- Large tricuspid annulus dimensions
- Nonplanar and elliptical annulus shape
- Absence of calcium
- Right ventricular morphology
- Proximity of other structures (coronary sinus, AV node and His bundle, vena cava, right coronary artery)

Rodés-Cabau, J. et al. J Am Coll Cardiol. 2016;67(15):1829-45.

Transcatheter options (heterotopic caval valve implantation, coaptation devices, annuloplasty devices) and challenges for treating tricuspid regurgitation (TR).
AV = atrioventricular.

Valve-in-valve tricúspide

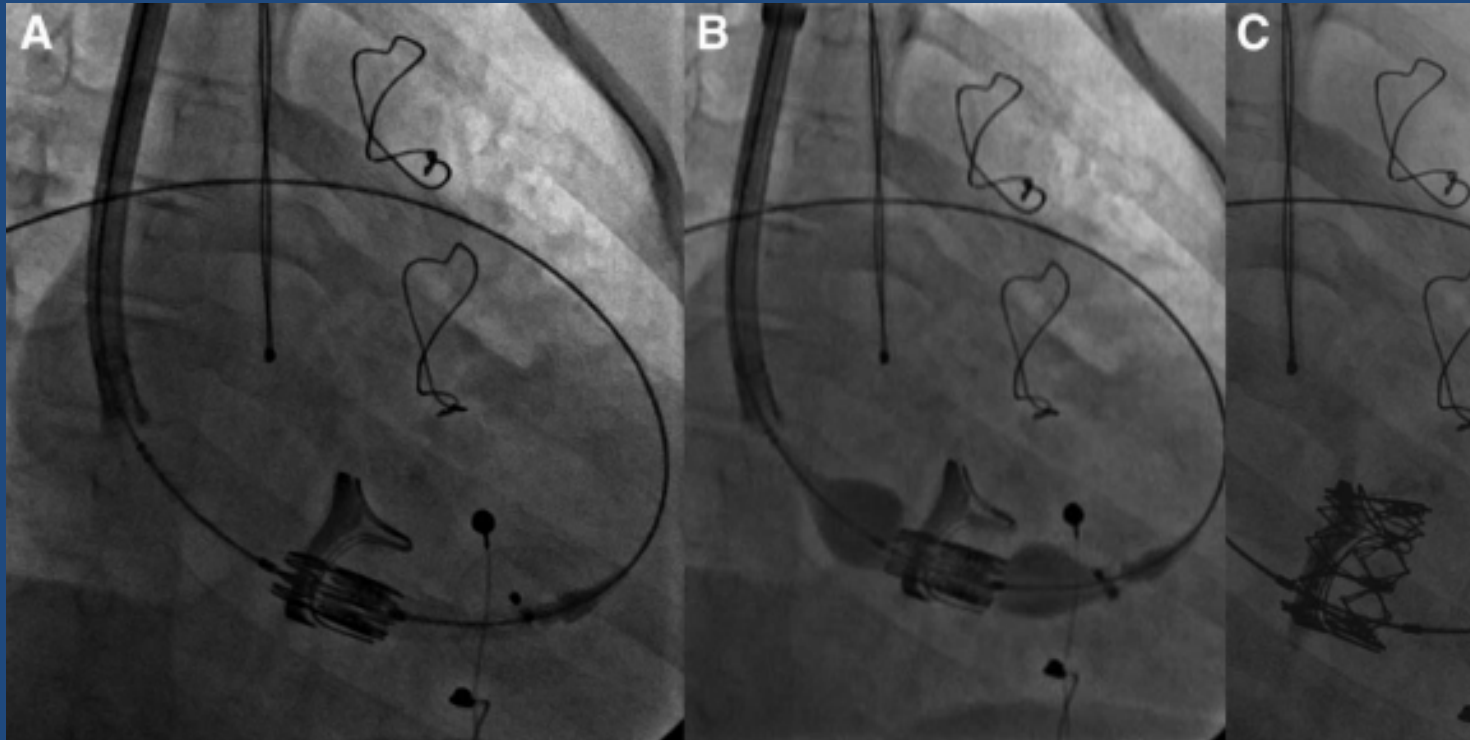
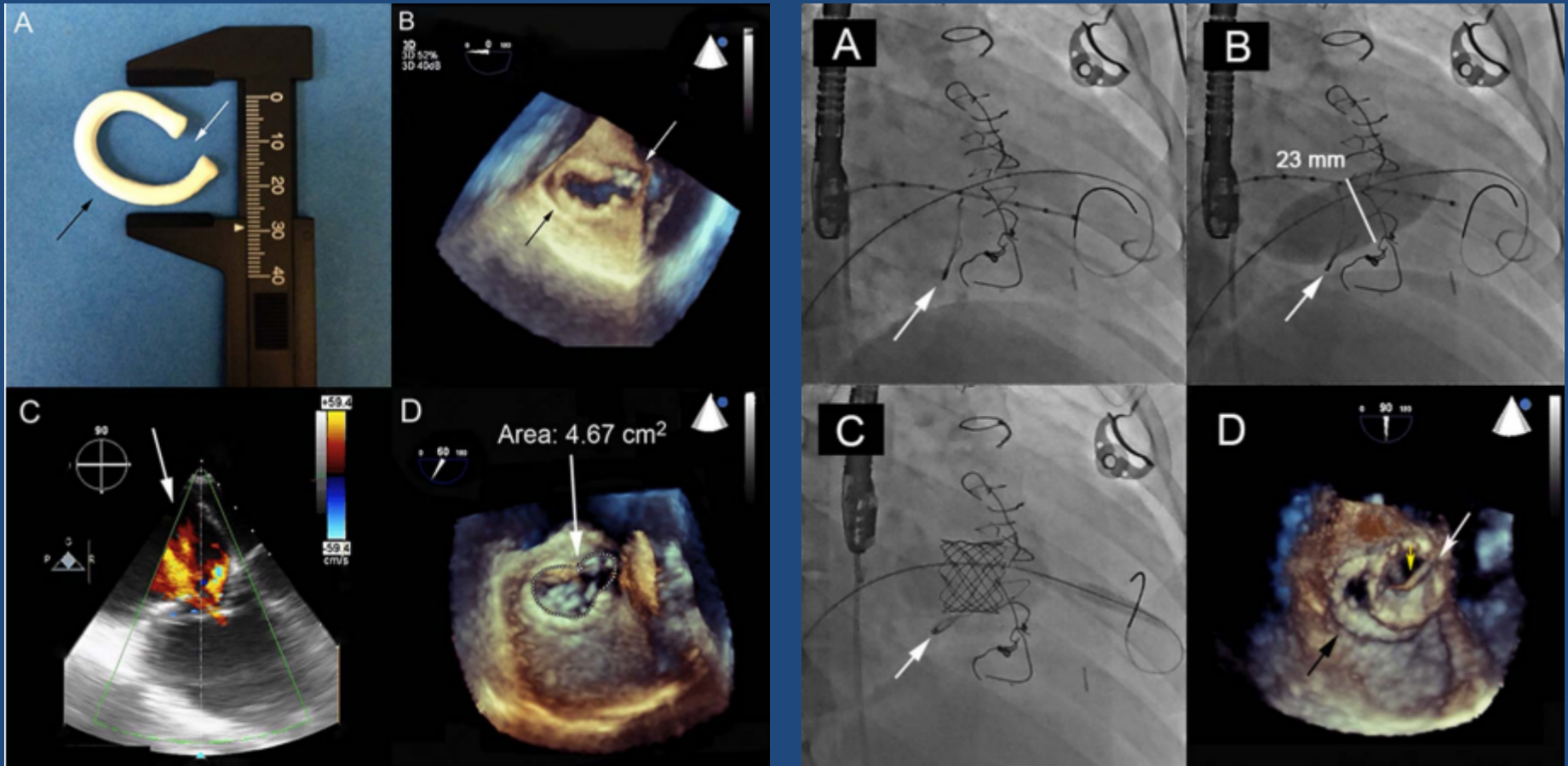


Fig. 2. A–C: Radioscopic frames from valved-stent deployment. A: Stiff 0.035" wire from right jugular vein into right pulmonary artery; mild right anterior oblique to get the Carpentier-Edwards valve ring perfectly perpendicular to the X beam; Edwards-Sapien XT ready for deployment with the proximal edge of the stent immediately proximal to the Carpentier-Edwards valve. **B:** the Sapien valve is slowly deployed during rapid ventricular pacing. **C:** the valved stent is fully deployed with tight fit at the Carpentier ring, and some flaring more distally.

Valve-in-ring Tricúspide



Valve-in-ring Tricúspide transapical

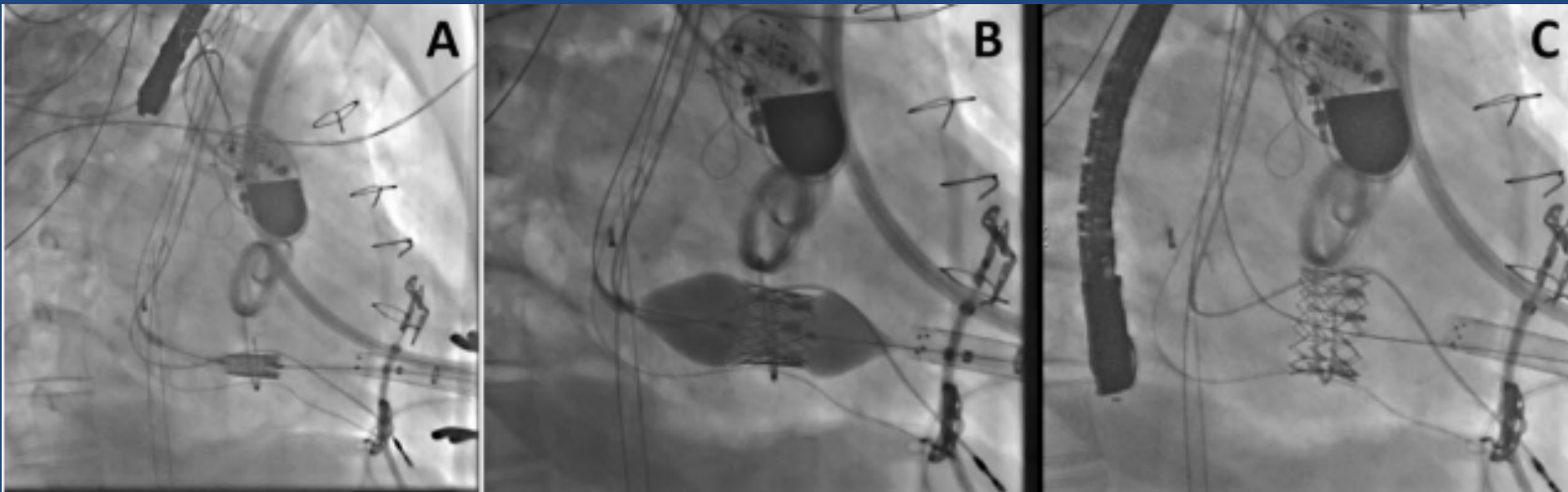
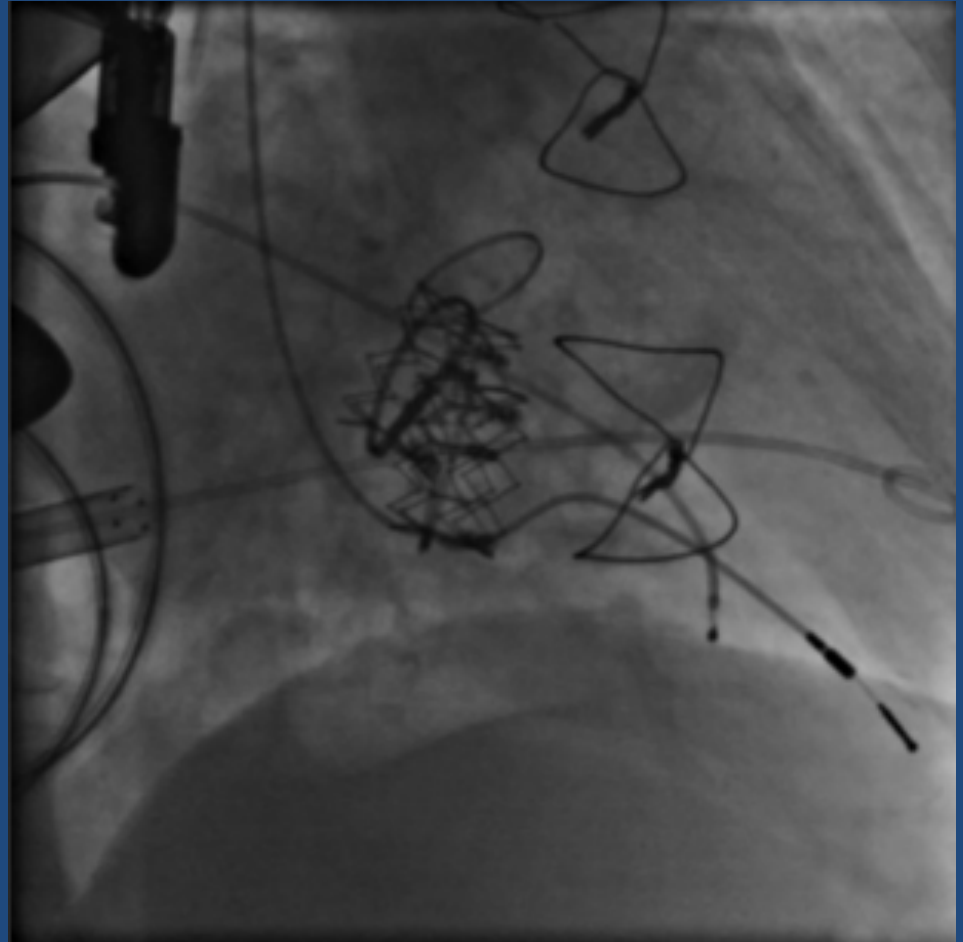
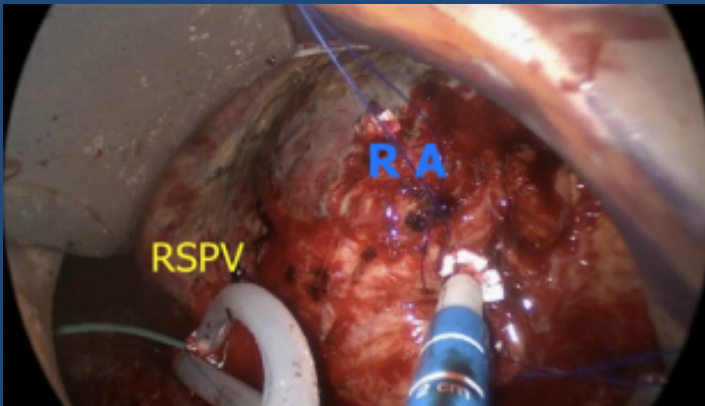
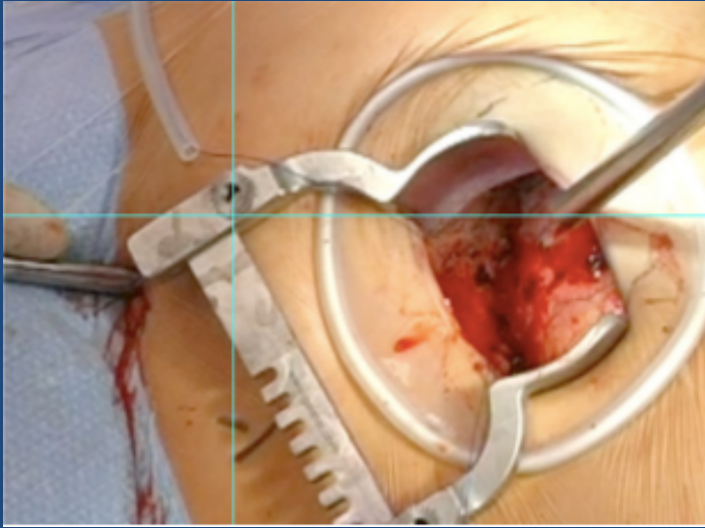


Fig. 2. (A-C) Procedural steps of transapical Sapien-XT-prosthesis implantation into tricuspid annuloplasty ring.

Transatrial Antegrade Approach for Double Mitral and Tricuspid “Valve-in-Ring” Implantation

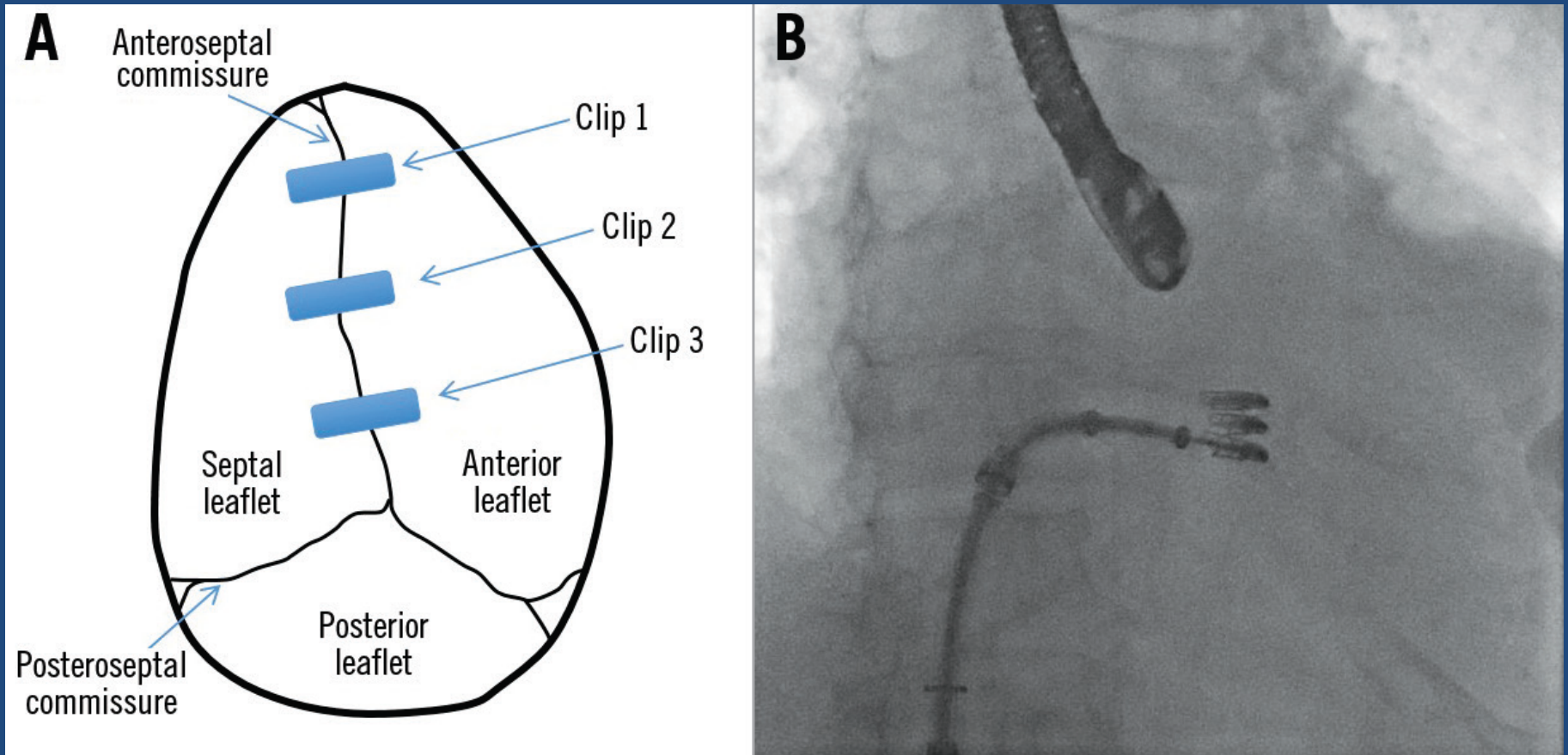


Transcatheter treatment of severe tricuspid regurgitation using the edge-to-edge repair technique

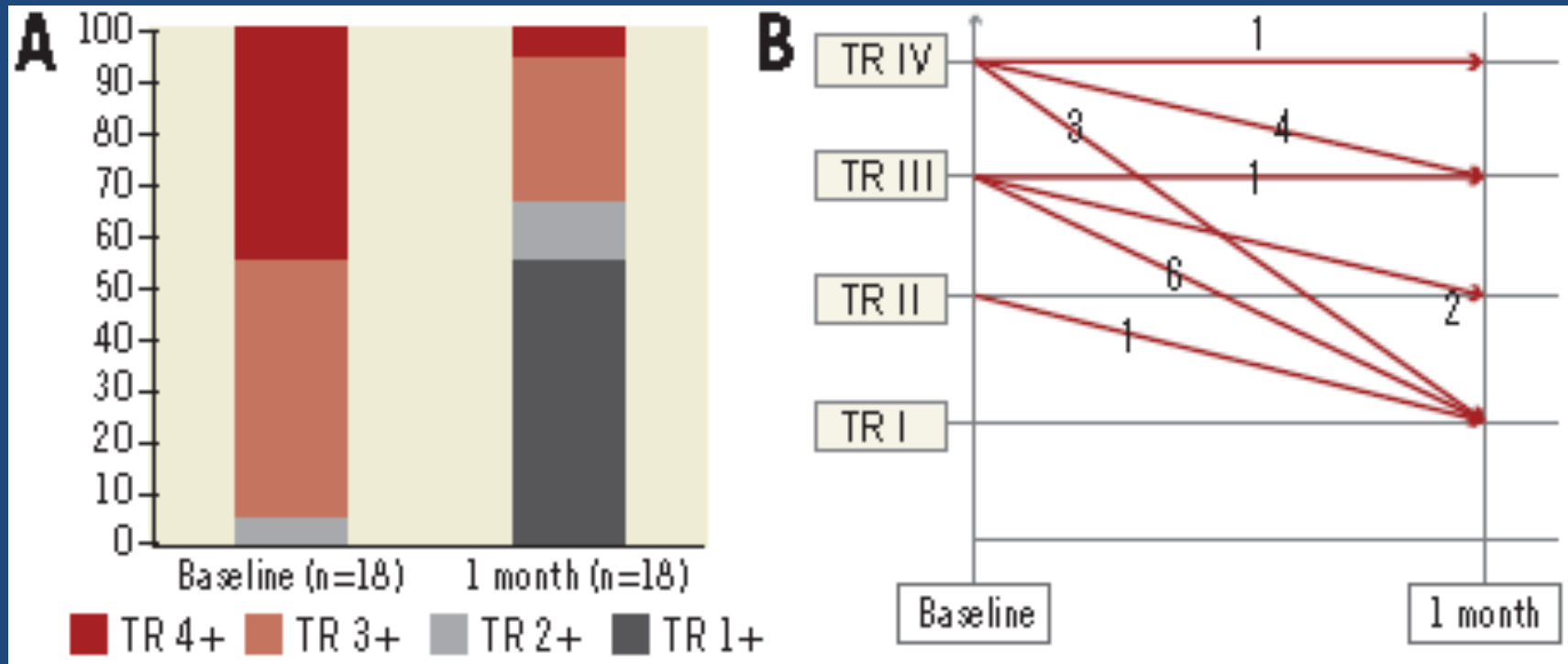
Razões que limitam o uso do Mitraclip na V. Tricúspide:

- A anatomia complexa e variável da V. Tricúspide com 3 folhetos impede a estratégia “duplo orifício” análoga à usada na V. Mitral
- A visualização dos folhetos da V. Tricúspide no ETE é difícil.
- A navegação do sistema Mitraclip na AD é limitada

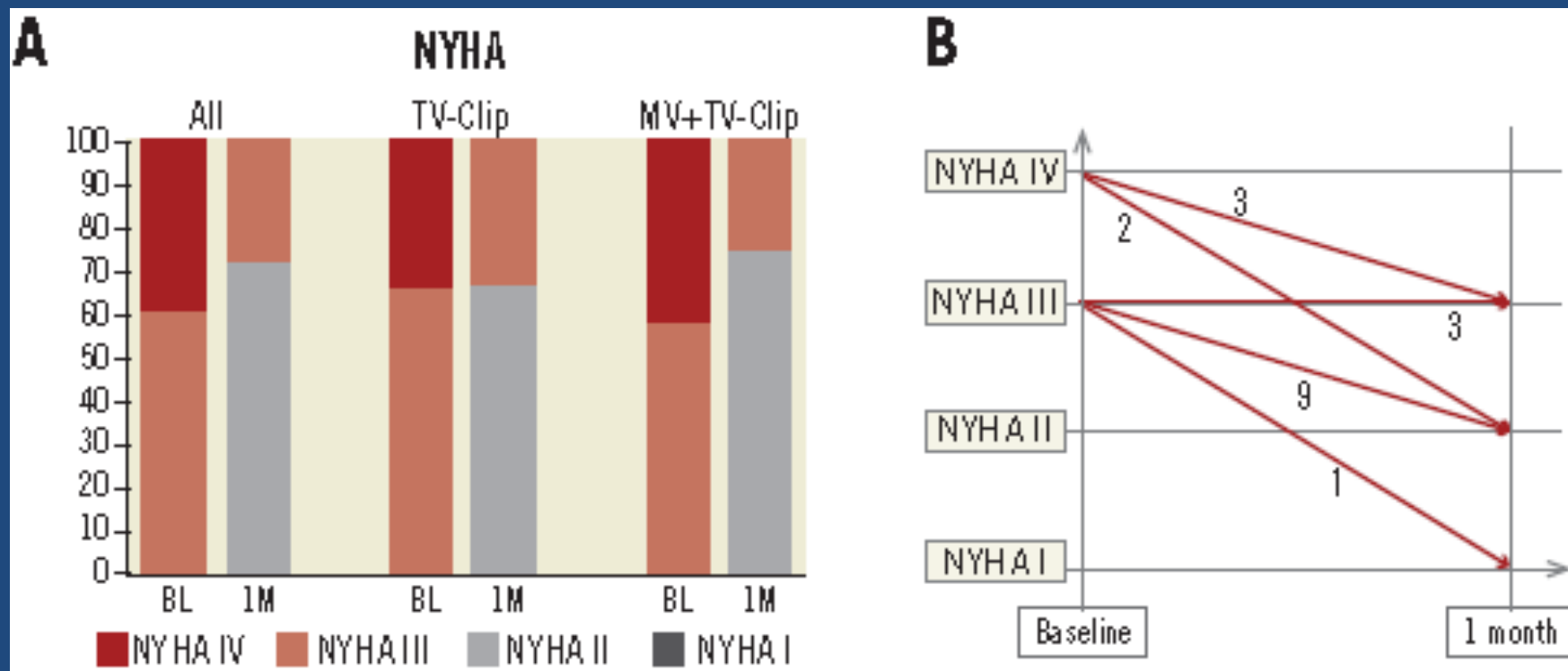
Transcatheter treatment of severe tricuspid regurgitation using the edge-to-edge repair technique



Transcatheter treatment of severe tricuspid regurgitation using the edge-to-edge repair technique



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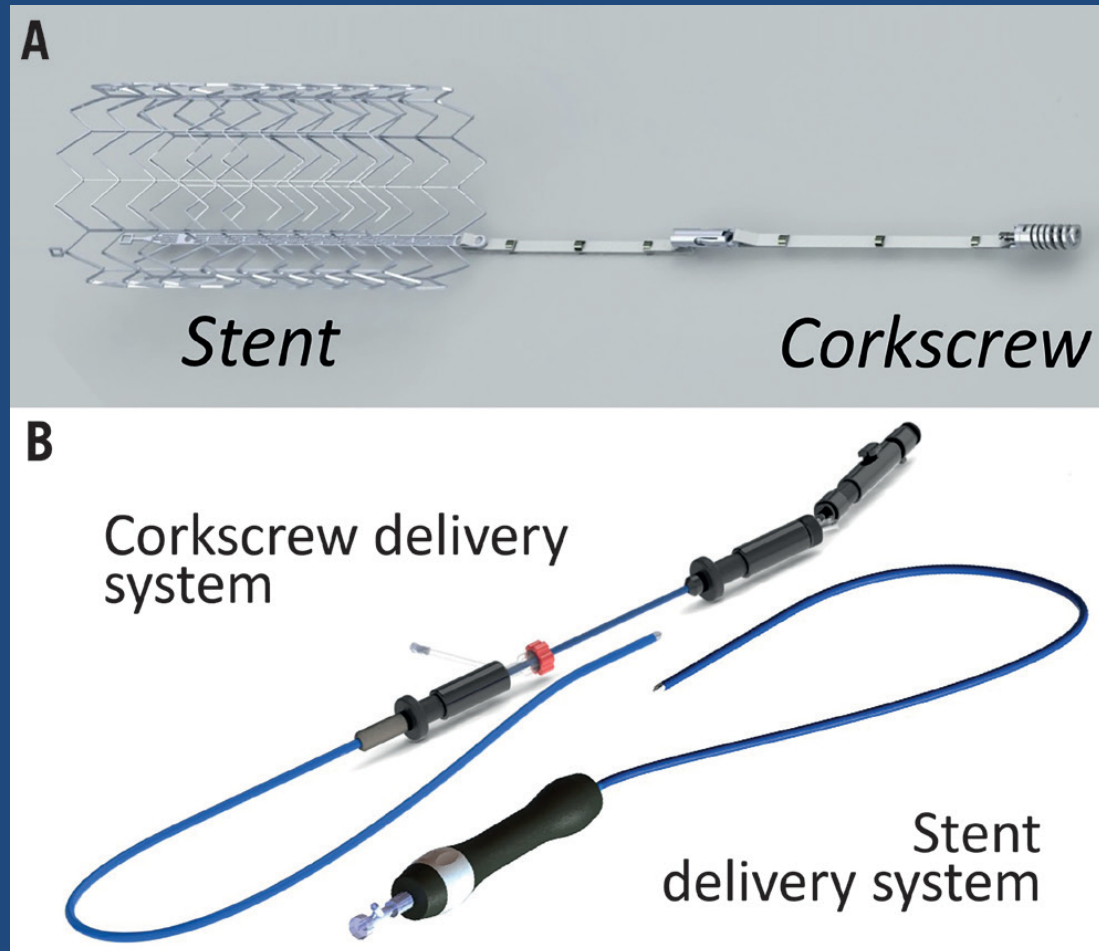
Conclusions:

- Applying a modified steering technique, the edge-to-edge repair technique can be successfully used for the treatment of TR.
- At 30-day follow-up, the short-term durability of TR reduction appeared promising and the majority of patients improved clinically.
- Further studies with larger patient populations and longer follow-up have to define the role of this novel treatment option for patients with right-sided heart failure and severe TR

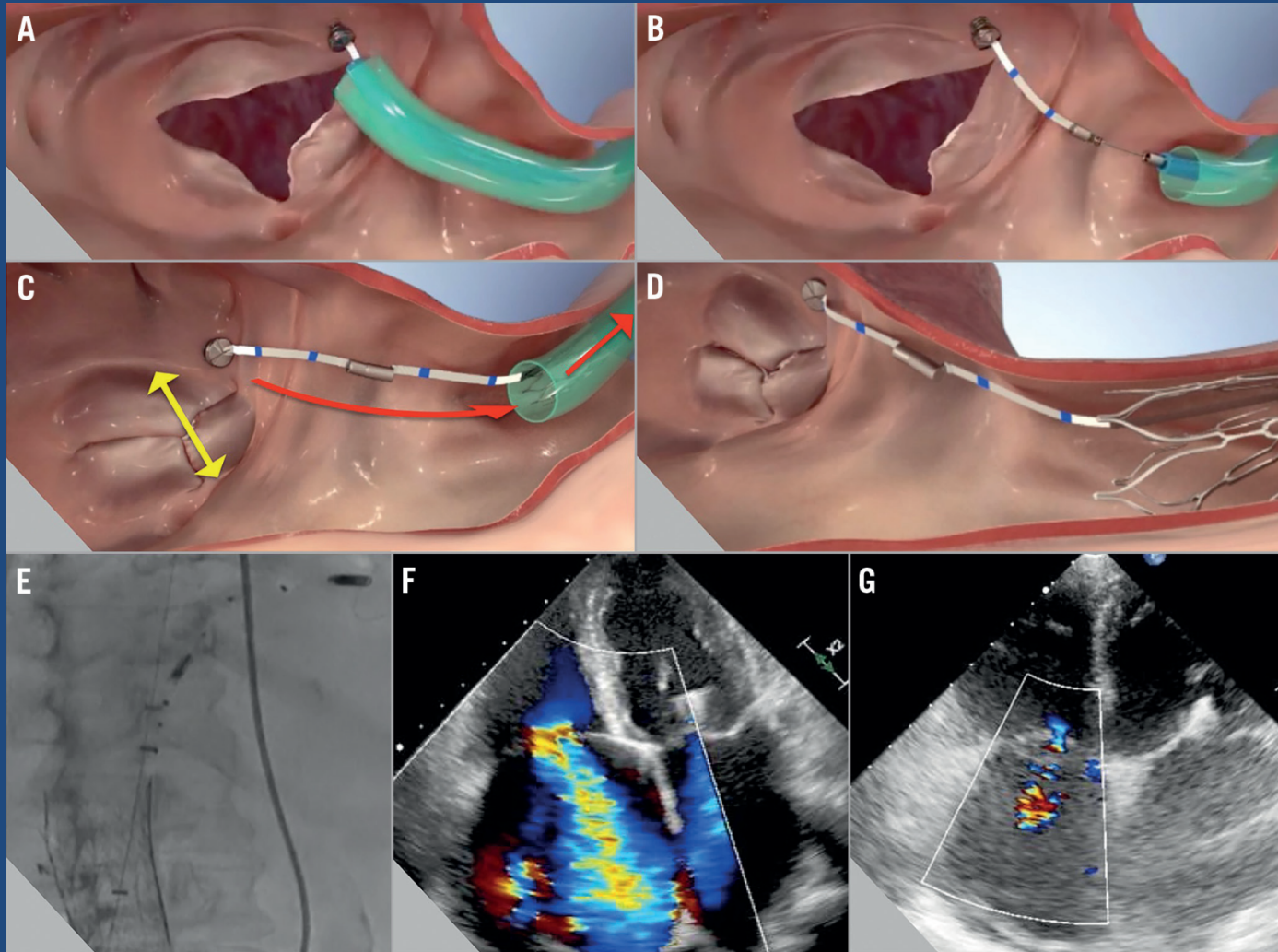
Transcatheter interventions for tricuspid regurgitation: TriCinch (4Tech)

- Técnica
 - Abordagem femoral
 - Sistema
 - ✓ Âncora “corkscrew” no *anullus*
 - ✓ Stent em nitinol auto-expansível colocado na VCI
 - ✓ Sistemas de entrega
- Estudo multicêntrico europeu *first-in-man* a decorrer
- Marca CE esperada em 2017

Transcatheter interventions for tricuspid regurgitation: TriCinch (4Tech)



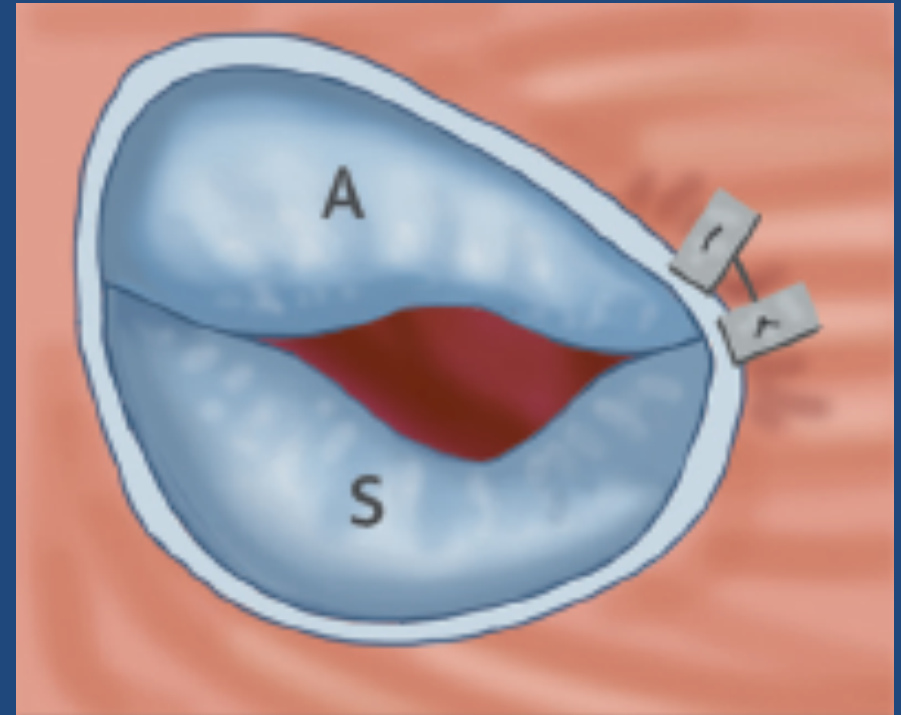
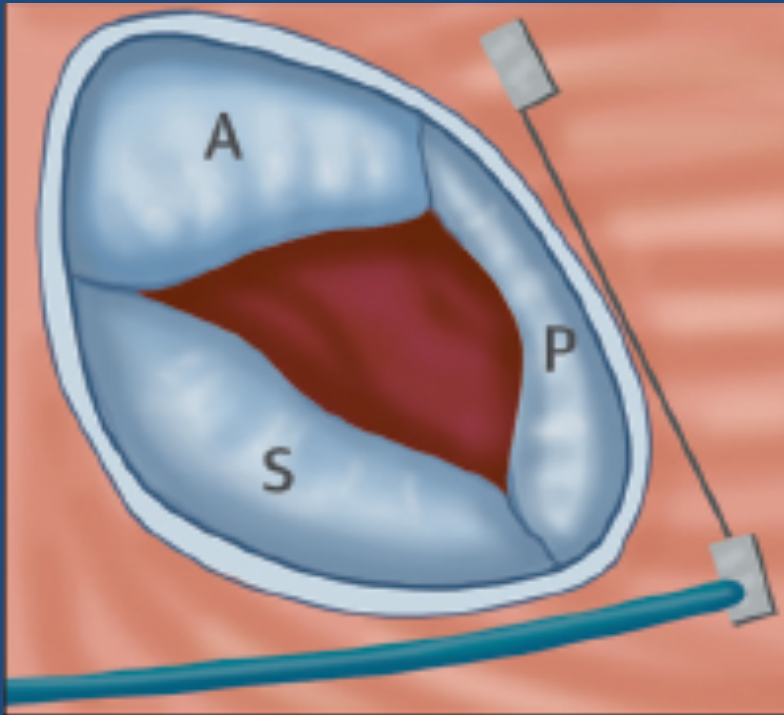
Transcatheter interventions for tricuspid regurgitation: TriCinch (4Tech)



Transcatheter interventions for tricuspid regurgitation: TriCinch (4Tech)

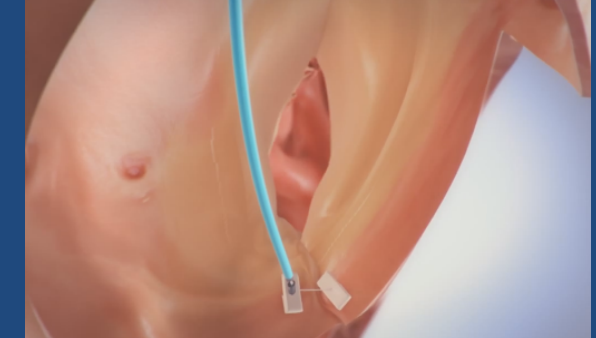
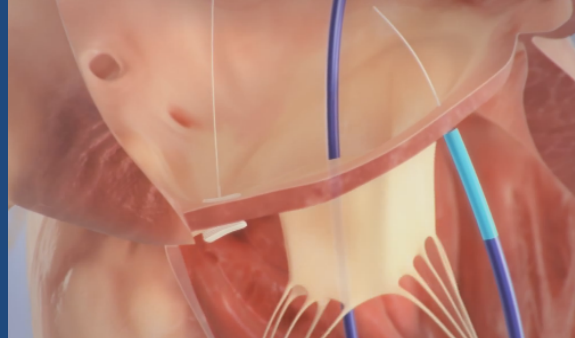
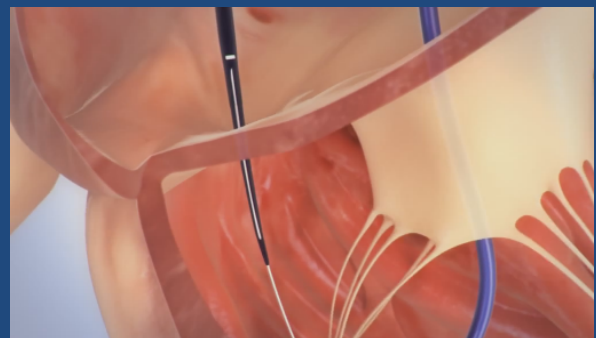
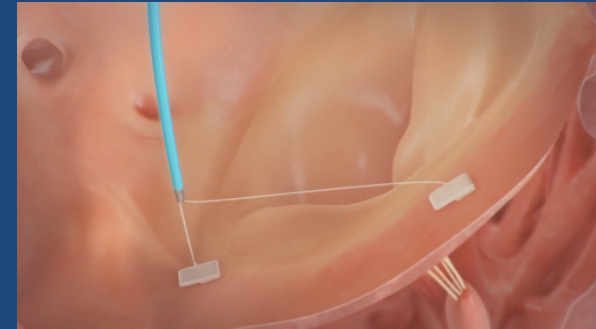
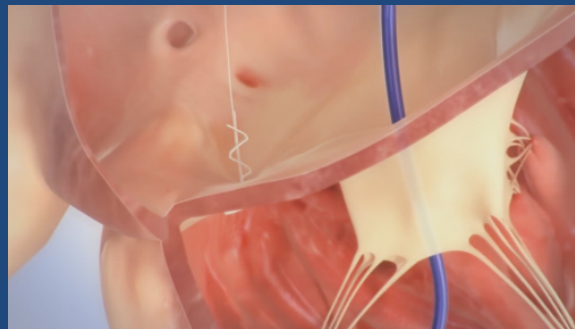
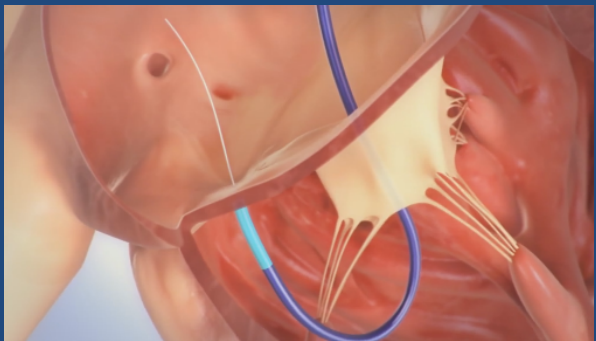
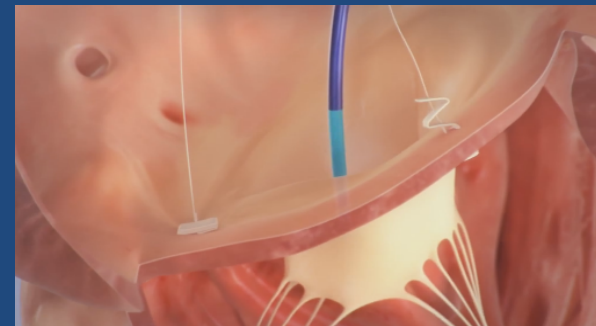
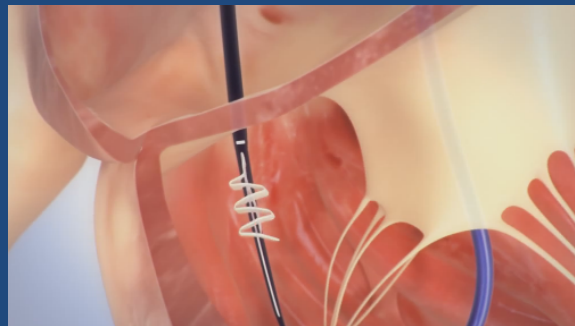
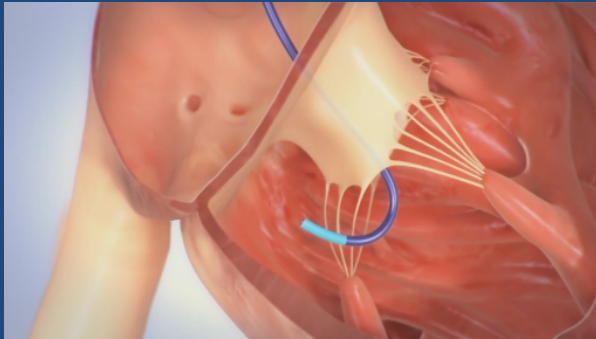
- The targeted population includes:
 - Patients with isolated **severe functional TR** due to **annular dilatation** (>40 mm at echocardiography), **symptomatic** despite maximal medical therapy, who are deemed to be **inoperable or at high risk** for open heart surgery.
 - Patients **undergoing transcatheter mitral valve treatment** with concomitant **severe functional TR** or with **less than severe TR** in the presence of **annular dilatation**.

First-in-Human Transcatheter Tricuspid Valve Repair in a Patient With Severely Regurgitant Tricuspid Valve



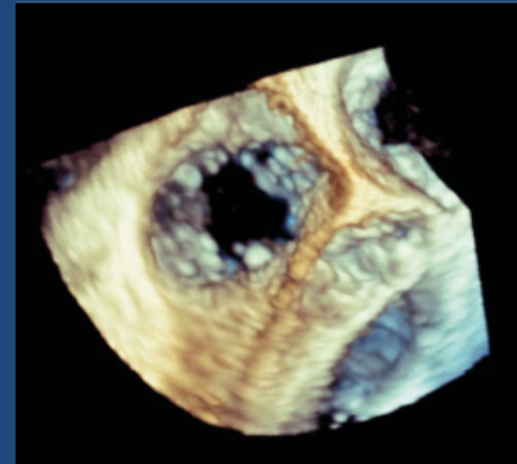
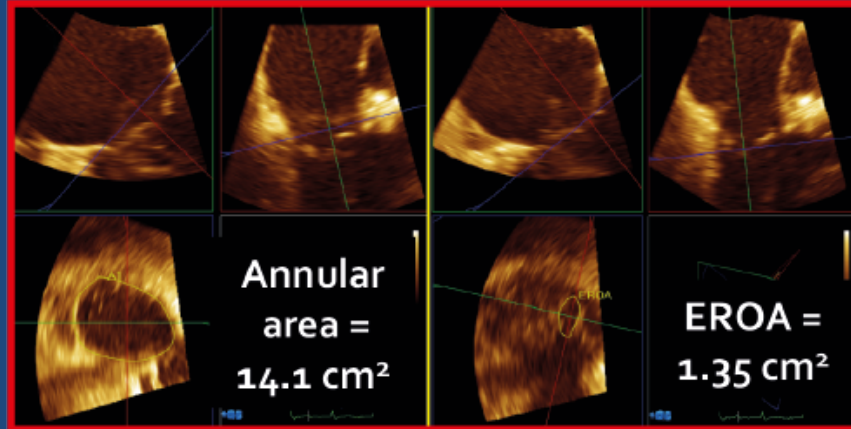
Trialalign

Transcatheter interventions for tricuspid regurgitation: Trialalign and Mitralign

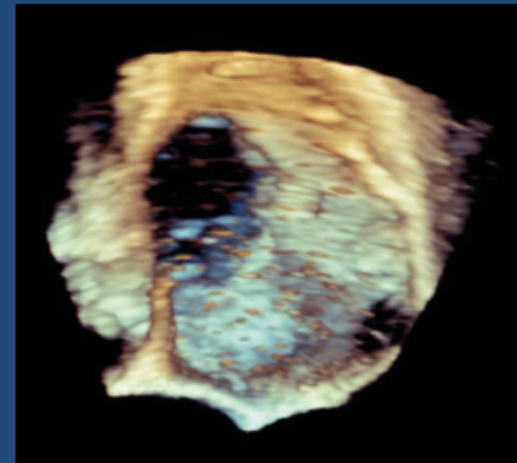
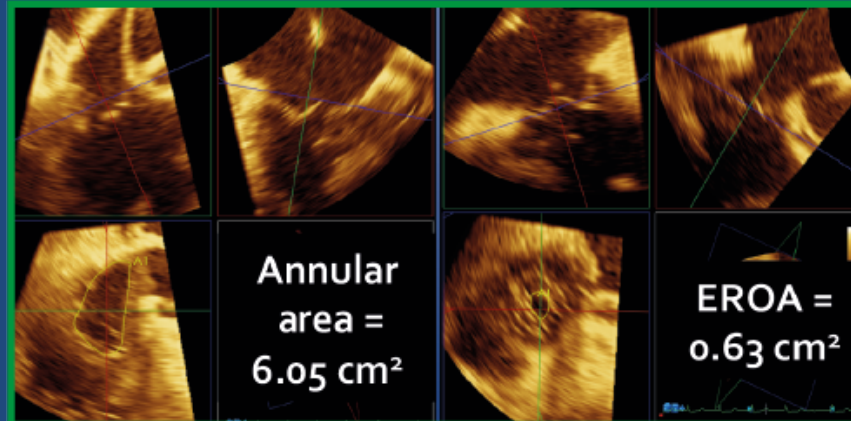


Transcatheter interventions for tricuspid regurgitation: Trialalign and Mitralign

A Baseline



B Post-transcatheter tricuspid annuloplasty



Transcatheter interventions for tricuspid regurgitation: Trialalign and Mitralign

- **Procedural details**
 - General anaesthesia, transjugular access (two 14 Fr sheaths)
 - 6 Fr guiding catheter in the RCA and a soft PTCA wire is introduced into the artery as a fluoroscopic marker
 - TEE guidance (2D and 3D)
- **Clinical data**
 - First-in-man in September 2014
 - Meanwhile, 16 patients have been treated in different centres in Europe and the USA with a good safety profile
 - No procedural death, no myocardial infarction, no stroke or TIA, no acute kidney injury or conduction disturbance, no perforation, and
 - Only one bleeding complication at the venous puncture site with no consequences
- **A feasibility trial (SCOUT) was started in the USA in November 2015**
- **CE-mark trial in Europe may start in the third quarter of 2016**

Transcatheter interventions for tricuspid regurgitation: the FORMA Repair System

- **Device concept and design**
 - ✓ **Spacer** (foam-filled polymer balloon)
(occupies the regurgitant space)
 - ✓ Six-pronged nitinol **anchor**
- **Patient selection**
 - ✓ Severe TR
 - ✓ Symptomatic right heart failure
 - ✓ High or prohibitive surgical risk
- **Pre-procedure TTE, TEE, CT scan**
 - ✓ Severity and mechanism of TR
 - ✓ Annular dimensions, right ventricular geometry
 - ✓ Subclavian venous access

Transcatheter interventions for tricuspid regurgitation: the FORMA Repair System

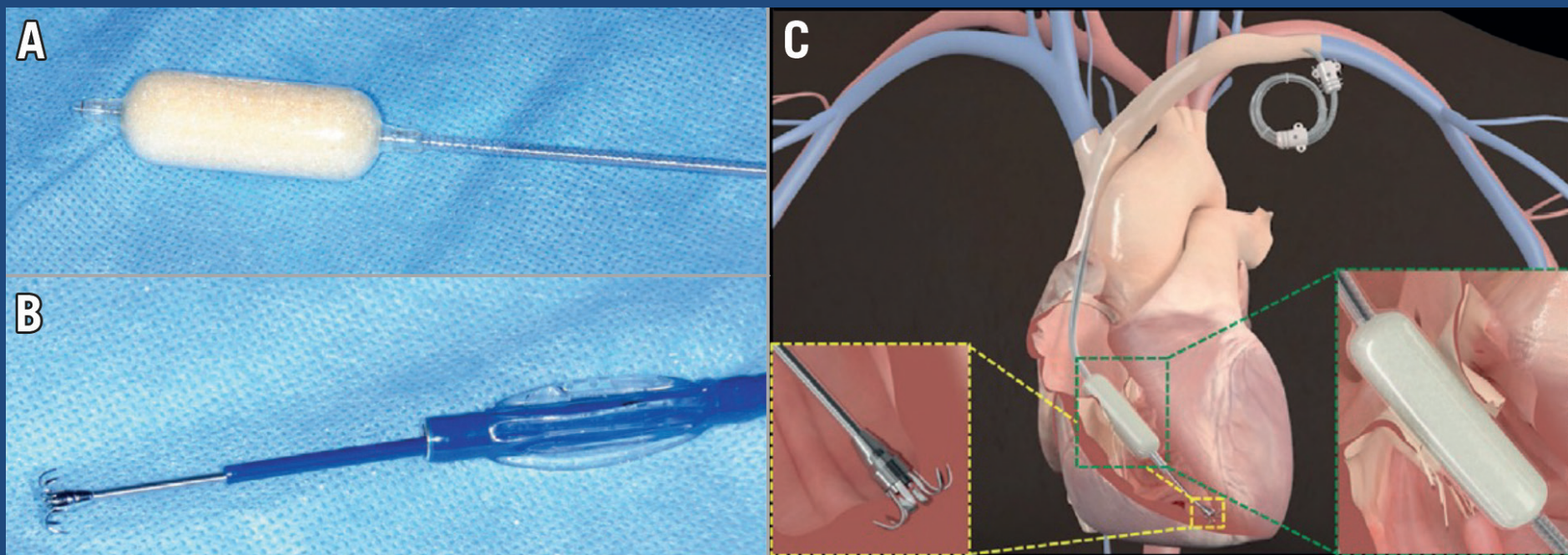
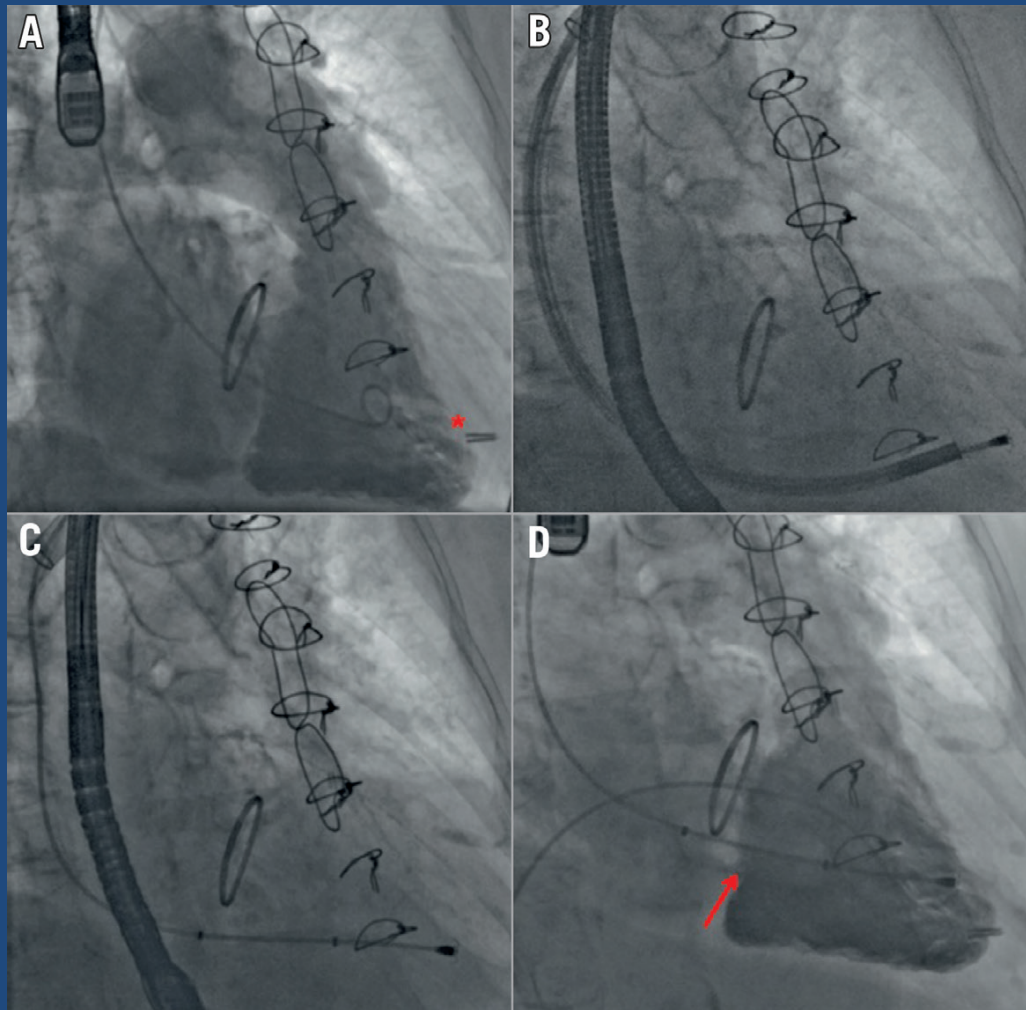


Figure 1. The FORMA Repair System. A) Spacer. B) Steerable delivery catheter and anchoring system. C) Device at the tricuspid valve annulus, anchoring system at the right ventricular apex, and excess device length coiled into a subcutaneous pocket. Reproduced with permission from Campelo-Parada et al, J Am Coll Cardiol. 2015;66:2475-83.

Transcatheter interventions for tricuspid regurgitation: the FORMA Repair System



Transcatheter interventions for tricuspid regurgitation: the FORMA Repair System

Table 1. Baseline patient and echocardiographic characteristics of the FIM population.

Variable		N=7
Age (yrs)		76±13
Male		4 (57)
NYHA functional Class ≥III		6 (86)
Prior open heart surgery		5 (71)
COPD		1 (14)
Permanent atrial fibrillation		5 (71)
Pulmonary hypertension		5 (71)
Creatinine clearance <60 ml/min		6 (86)
Logistic EuroSCORE (%)		25.7±17.4
6MWT (m)		297±66
KCCQ		59.6±14.1
Daily furosemide dose (mg)		80±61
LVEF (%)		56±5
sPAP (mmHg)		69.7±6
MR grade	Mild	3 (43)
	Mild-to-moderate	3 (43)
	Moderate	1 (14)
TR vena contracta (mm)		15.5±5.1
RV diameter (mm)		47±7

Values are mean±SD or n (%). COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MR: mitral regurgitation; NYHA: New York Heart Association; sPAP: systolic pulmonary artery pressure; RV: right ventricle; 6MWT: six-minute walk test; KCCQ: Kansas City Cardiomyopathy Questionnaire

Table 2. Post-procedural and in-hospital outcomes.

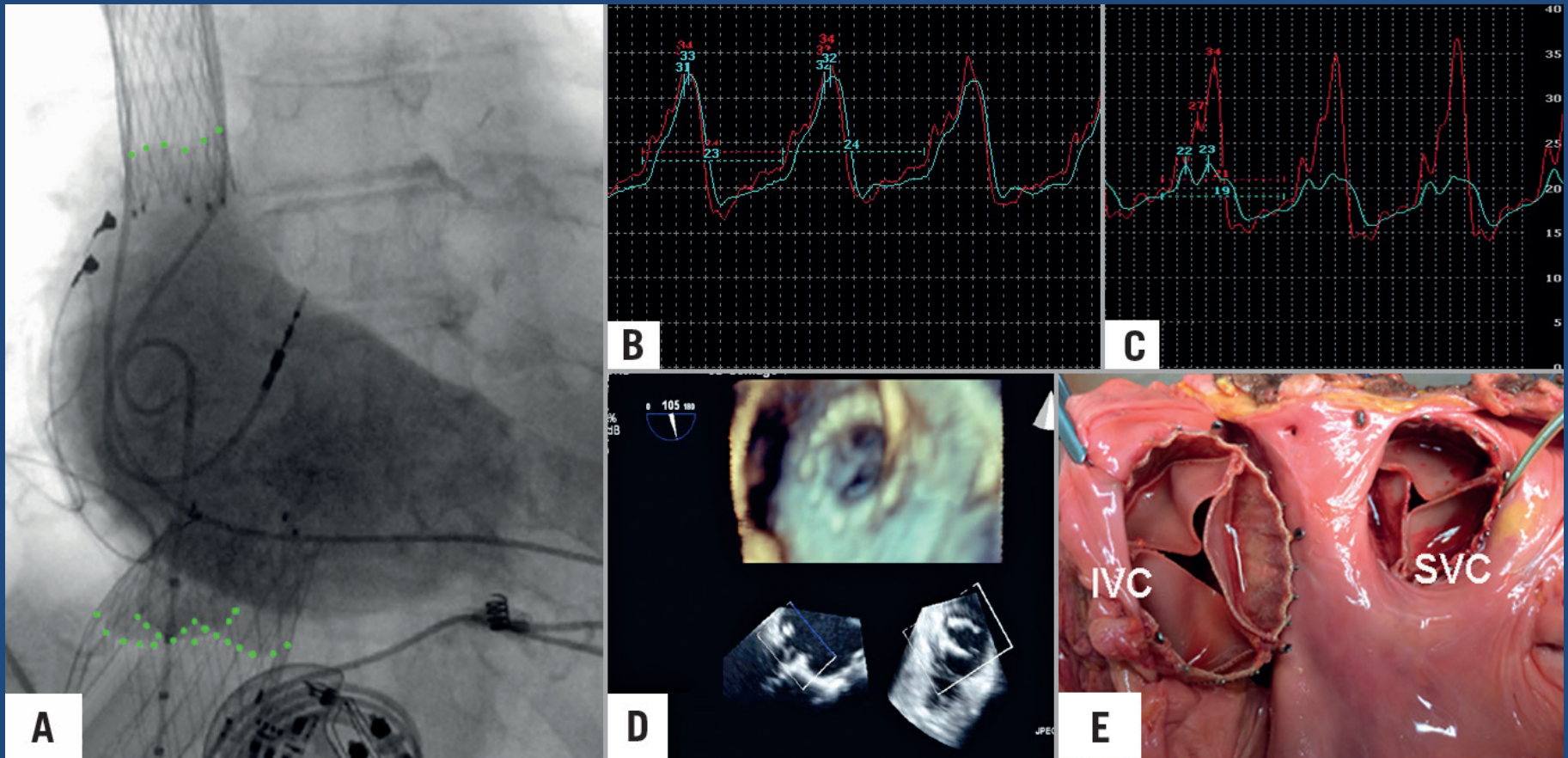
Procedural results		N=7
Successful device implantation		7 (100)
Conversion to open heart surgery		0 (0)
Cardiac tamponade		0 (0)
Access-site complication		1 (14)
Skin-to-skin procedural time (min)		122±34
Contrast volume (ml)		71±32
Venous closure	Surgical closure	5 (71)
	Percutaneous*	2 (29)
Intraprocedural TEE TR reduction >1 grade		7 (100)
Hospital outcomes		
Renal failure		1 (14)
Arrhythmia		2 (29)
Bleeding (VARC-2 criteria)	Minor	1 (14)
	Major	0 (0)
Vascular access-site complication	Minor	1 (14)
	Major	0 (0)
In-hospital mortality		0 (0)
Hospital length (days)		4 (3-6)

Values are n (%), mean±SD, or median (interquartile range). *With the Perclose ProGlide closure system (Abbott Vascular, Santa Clara, CA, USA). TEE: transoesophageal echocardiography; TR: tricuspid regurgitation; VARC-2: Valve Academic Research Consortium-2

Transcatheter interventions for tricuspid regurgitation - heterotopic technology: TricValve



Transcatheter interventions for tricuspid regurgitation - heterotopic technology: TricValve



Transfemoral Caval Valve Implantation (Edwards Sapien XT) for Severe Tricuspid Regurgitation

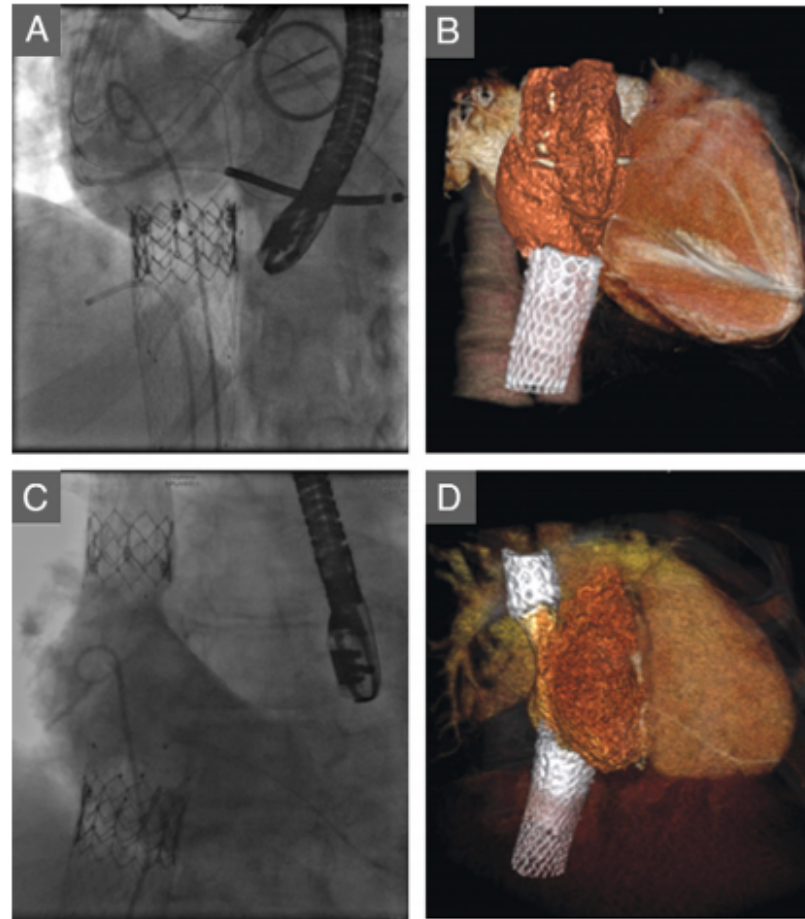


Figure 1 Transfemoral Caval Valve Implantation (Edwards Sapien XT) for Severe Tricuspid Regurgitation

Fluoroscopy (A) and multislice computed tomography (B) show single-valve approach with Edwards Sapien XT in the inferior vena cava. (C and D) Dual valve approach with a second valve in the superior vena cava.

Ongoing TR Device Trials

TABLE 1 Ongoing TR Device Trials

Trial Acronym	Trial Name and Device	Inclusion	Exclusion	Principal Investigator
PREVENT (NCT02098200)	Percutaneous Treatment of Tricuspid Valve Regurgitation With the TriCinch System	Functional symptomatic TR 2 ⁺ to 4 ⁺ on a scale of 4 ⁺ (moderate to severe), with annular dilation >40 mm	At the heart team's judgment, patient IVC dimension not adequate for device implantation	Antonio Colombo, MD
HOVER (NCT02339974)	Heterotopic Implantation of the Edwards-Sapien XT Transcatheter Valve in the Inferior Vena Cava for the Treatment of Severe Tricuspid Regurgitation	TR should be functional in nature, without anatomical abnormalities of the tricuspid valve leaflets themselves	Mean pulmonary artery pressures $\geq$ 40 mm Hg and PVR >4 Wood units as assessed by right heart catheterization	Brian P. O'Neill, MD
TRICAVAL (NCT02387697)	Treatment of Severe Secondary Tricuspid Regurgitation in Patients With Advance Heart Failure With CAval Vein Implantation of the Edwards Sapien XT VALve	Severe symptomatic TR with a significant regurgitation jet into the caval and hepatic veins	IVC diameter >32 mm, severe left ventricular dysfunction with LVEF <30%	Karl Stangl, MD
SPACER (NCT02787408)	Repair of Tricuspid Valve Regurgitation Using the Edwards Tricuspid REpair System	Clinically significant, symptomatic (NYHA functional class II or greater); TR (per applicable guidelines) requiring tricuspid valve repair or replacement as assessed by the heart team; functional TR as the primary etiology	Tricuspid valve/right heart anatomy not suitable for the study device	Not announced
SCOUT (NCT02574650)	Early Feasibility of the Mitralign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS)	Chronic functional TR with a minimum of moderate TR	Tricuspid valve annular diameter $\geq$ 40 mm (or 21 mm/m ²) and $\leq$ 55 mm (or 29 mm/m ²)	Rebecca Hahn, MD

IVC = inferior vena cava; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PVR = pulmonary vascular resistance; TR = tricuspid regurgitation.

Conclusões

- Functional TR is a common condition in patients with left heart valve or myocardial disease and has a significant impact on functional status and longterm survival
- Interventional strategies for TV disease are still in the early stages
- The challenges of the TV apparatus are mainly related to the large TA dimensions, lack of valve/annulus calcification, close proximity of the right coronary artery, and fragility of the TA tissue
- Such therapies should be limited to those patients with severe comorbidities leading to an extreme or prohibitive surgical risk.

Obrigado pela atenção