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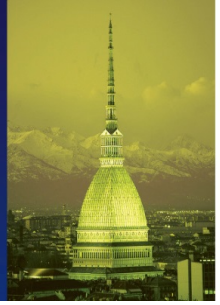

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Valve-in-Valve International Data VIVID

The Forgotten Valve

Redo Tricuspid Interventions: Insights from the Valve-in-Valve International Data Registry (VIVID)

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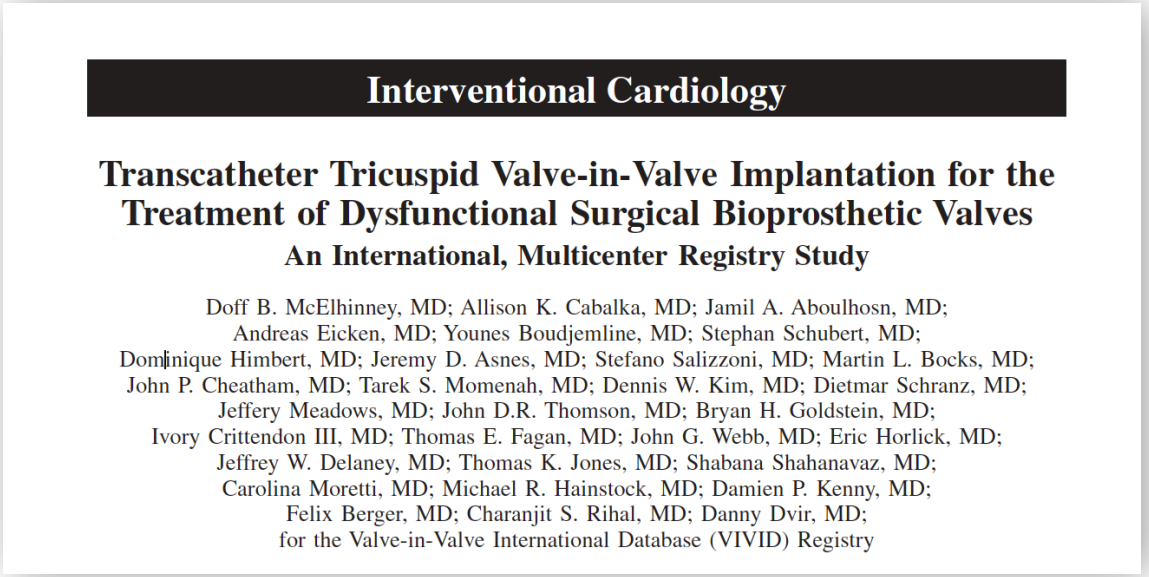
Disclosure Statement of Financial Interest

Within the past 12 months, I [Mohamed Abdel-Wahab] or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	• Boston Scientific, Medtronic

+ Personal experience in tricuspid VIV is limited to a few cases



Interventional Cardiology

Transcatheter Tricuspid Valve-in-Valve Implantation for the Treatment of Dysfunctional Surgical Bioprosthetic Valves

An International, Multicenter Registry Study

Doff B. McElhinney, MD; Allison K. Cabalka, MD; Jamil A. Aboulhosn, MD; Andreas Eicken, MD; Younes Boudjemline, MD; Stephan Schubert, MD; Dominique Himbert, MD; Jeremy D. Asnes, MD; Stefano Salizzoni, MD; Martin L. Bocks, MD; John P. Cheatham, MD; Tarek S. Momenah, MD; Dennis W. Kim, MD; Dietmar Schranz, MD; Jeffery Meadows, MD; John D.R. Thomson, MD; Bryan H. Goldstein, MD; Ivory Crittendon III, MD; Thomas E. Fagan, MD; John G. Webb, MD; Eric Horlick, MD; Jeffrey W. Delaney, MD; Thomas K. Jones, MD; Shabana Shahanavaz, MD; Carolina Moretti, MD; Michael R. Hainstock, MD; Damien P. Kenny, MD; Felix Berger, MD; Charanjit S. Rihal, MD; Danny Dvir, MD; for the Valve-in-Valve International Database (VIVID) Registry

McElhinney, Dvir et al. Circulation 2016;133:1582-1593

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STRUCTURAL

Transcatheter Valve-in-Ring Implantation for the Treatment of Residual or Recurrent Tricuspid Valve Dysfunction After Prior Surgical Repair

Jamil Aboulhosn, MD,[a] Allison K. Cabalka, MD,[b] Daniel S. Levi, MD,[a] Dominique Himbert, MD,[c] Luca Testa, MD,[d] Azeem Latib, MD,[e] Raj R. Makkar, MD,[f] Younes Boudjemline, MD,[g] Dennis W. Kim, MD,[h] Joelle Kefer, MD,[i] Sabine Bleiziffer, MD,[j] Gunter Kerst, MD,[k] Danny Dvir, MD,[l] Doff B. McElhinney, MD[m]

Aboulhosn et al. Circulation 2017;10:53-63

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The need for a percutaneous option for redo tricuspid procedures is obvious

- Patients who undergo surgical tricuspid valve replacement or repair are often complex and debilitated
  - Polyvalvular involvement
  - Rheumatic or infectious processes, congenital anomalies, or recurrent TV dysfunction
- TVR longevity may be shorter than with bioprosthetic valves in the systemic circulation
- Surgical mortality as high as 37% in studies of patients undergoing TVR after prior TV repair

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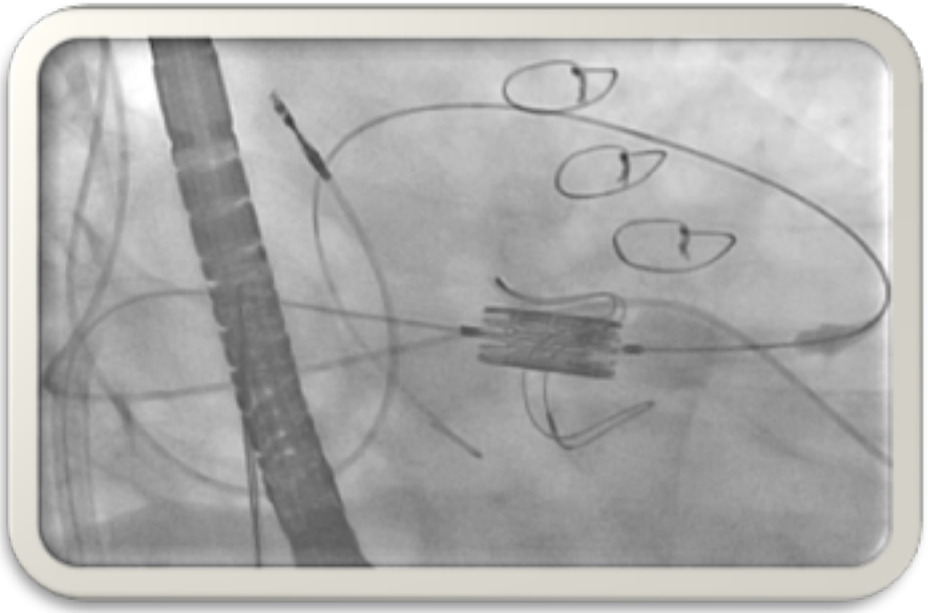
Tricuspid Valve-in-Valve

Off-label use of Sapien and Melody aortic and pulmonic valves for dysfunctional tricuspid biological valves



156 patients included in VIVID
Treated between 2008 and 2015 (8 years)
53 centers
Median per center =2
5 centers with ≥ 5 cases

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Baseline characteristics

Variable	All Patients N=156	Melody Patients N=94	Sapien Patients N=58	P Value
Patient age (yrs)	40 (5-84)	27 (5-84)	53 (8-81)	<0.001
Pediatric (<21 yrs)	45 (29%)	36 (38%)	9 (16%)	0.003
Etiology of Original TV Disease (prior to TVR)				<0.001
Congenital	87 (56%)	63 (67%)	21 (36%)	
Acquired	69 (44%)	31 (33%)	37 (64%)	
Atrial fibrillation or flutter	60 (38%)	36 (38%)	24 (41%)	0.7
Acute/chronic renal insufficiency	20 (13%)	9 (10%)	10 (17%)	0.17
COPD/Lung disease	10 (6%)	6 (6%)	4 (7%)	0.8
Prior history of endocarditis	31 (20%)	14 (15%)	16 (30%)	0.03
Existing permanent pacemaker	62 (39%)	37 (39%)	22 (38%)	0.9
Epicardial	38 (24%)	23 (25%)	14 (24%)	
Transvenous	24 (15%)	14 (15%)	8 (14%)	

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Bioprosthesis-related data

Variable	All Patients N=156	Melody Patients N=94	Sapien Patients N=58	P Value
Age of TV bioprosthesis (yrs) (N=146)	7.4 (1-38)	7.2 (1.2-34)	8.0 (1-38)	0.4
Labeled size of TV bioprosthesis (mm) (N=146)	28 (18-35)	27 (18-35)	31 (24-33)	<0.001
29mm or larger	74 (51)	33 (38%)	39 (68%)	<0.001
TR severity				0.06
None/trivial	19 (12%)	7 (8%)	12 (20%)	
Mild	24 (15%)	14 (15%)	9 (16%)	
Moderate	45 (29%)	26 (28%)	16 (28%)	
Severe	68 (44%)	47 (50%)	21 (36%)	
Mean Doppler TV inflow gradient (mmHg)	9 (2-29)	9 (2-29)	9 (2-24)	0.8
11-14	46 (30%)	31 (33%)	15 (26%)	
≥15	15 (10%)	9 (10%)	6 (10%)	

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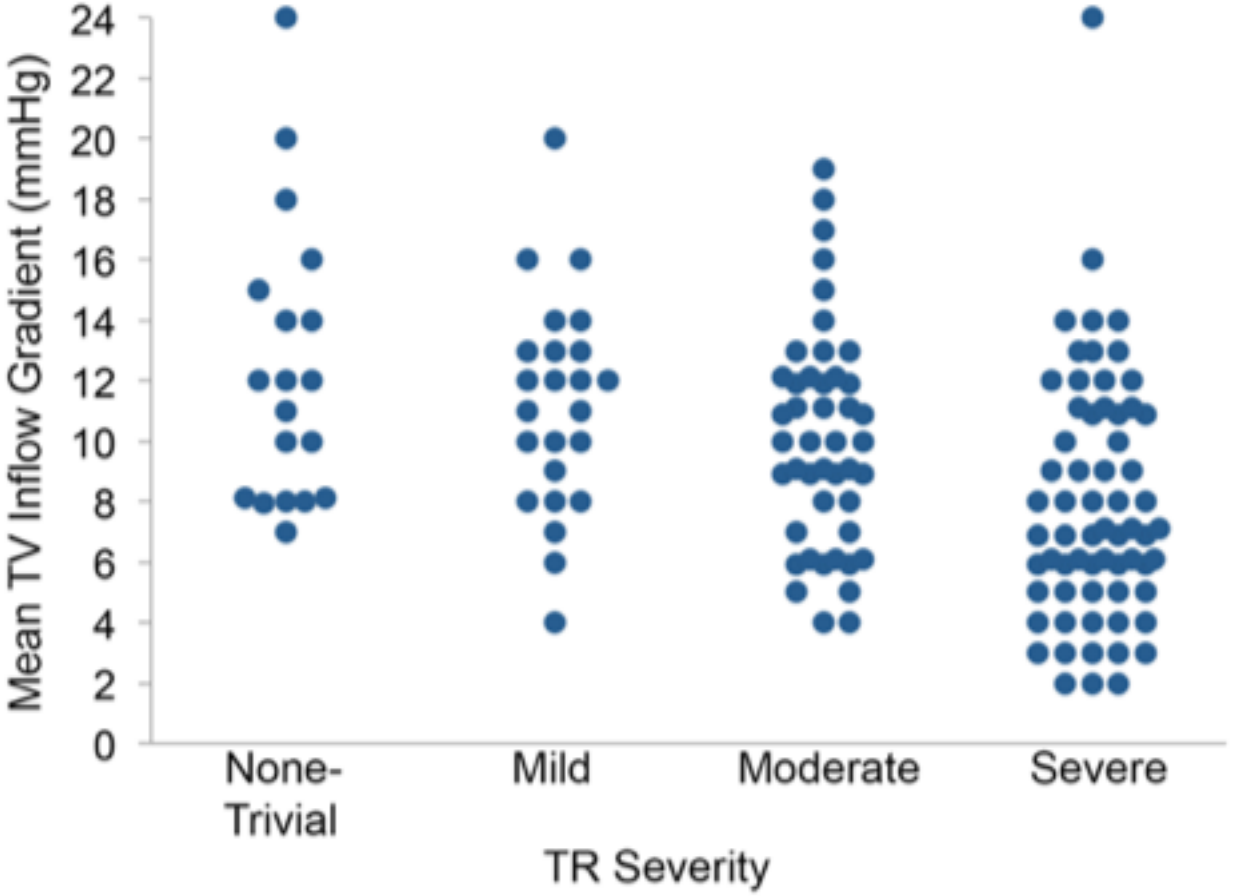
Bioprosthesis-related data



Dominant TR in 24%, dominant TS in 29%, mixed TR and TS in 47%

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Functional class

Variable	All Patients N=156	Melody Patients N=94	Sapien Patients N=58	P Value
NYHA class				0.1
I	3 (2%)	2 (2%)	1 (2%)	
II	40 (26%)	28 (30%)	12 (21%)	
III	76 (50%)	46 (51%)	29 (51%)	
IV	32 (21%)	15 (16%)	15 (26%)	

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Functional class

Variable	NYHA Class IV (N=32)	NYHA Class I-III (N=119)	P Value
Demographics and History			
Patient age (yrs)	61 (7-81)	34 (5-84)	<0.001
Underlying Congenital Heart Disease	11 (34%)	71 (60%)	0.01
Atrial fibrillation or flutter	18 (56%)	42 (35%)	0.03
Acute/chronic renal insufficiency	12 (38%)	9 (8%)	<0.001
Hemodynamics			
Moderate or severe TR	18 (56%)	90 (76%)	0.03
Mean Doppler TV inflow gradient (mmHg)	11 (3-29)	9 (2-21)	0.06
Right atrial mean pressure (mmHg) (N=134)	19 (2-37)	16 (6-27)	0.009
Right ventricular end-diastolic pressure (mmHg) (N=123)	11 (3-17)	8 (1-12)	0.16
Right ventricular systolic pressure (mmHg) (N=132)	36 (12-92)	29 (14-63)	0.006

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Procedural characteristics

Variable	All Patients N=152	Melody Patients N=94	Sapien Patients N=58	P Value
Vascular access				0.01
Femoral vein	105 (69%)	65 (69%)	40 (69%)	
Jugular vein	42 (28%)	29 (31%)	13 (22%)	
Surgical via right atrium	5 (3%)	0 (0%)	5 (9%)	
General anesthesia	137 (90%)	87 (93%)	50 (88%)	0.3
Intraprocedural echocardiography performed	125 (82%)	77 (82%)	48 (83%)	0.9
Transthoracic	10 (7%)	8 (9%)	2 (4%)	
Transesophageal	77 (51%)	37 (39%)	42 (72%)	<0.001
Intracardiac	32 (21%)	29 (31%)	3 (5%)	<0.001

Rapid Pacing almost exclusively with Sapien
Pacing either through permanent implant or temporary LV/coronary sinus wire

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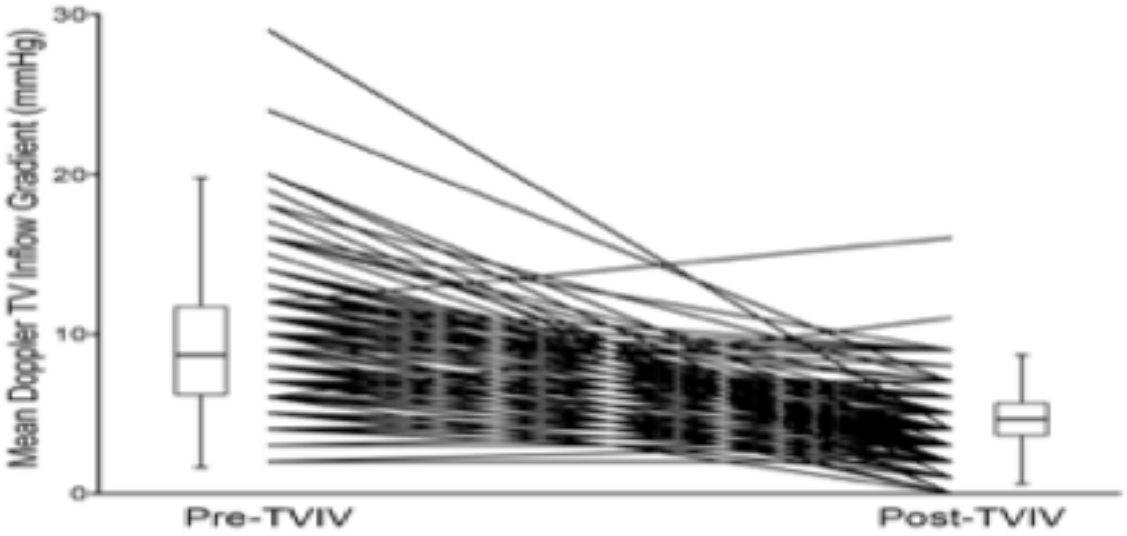
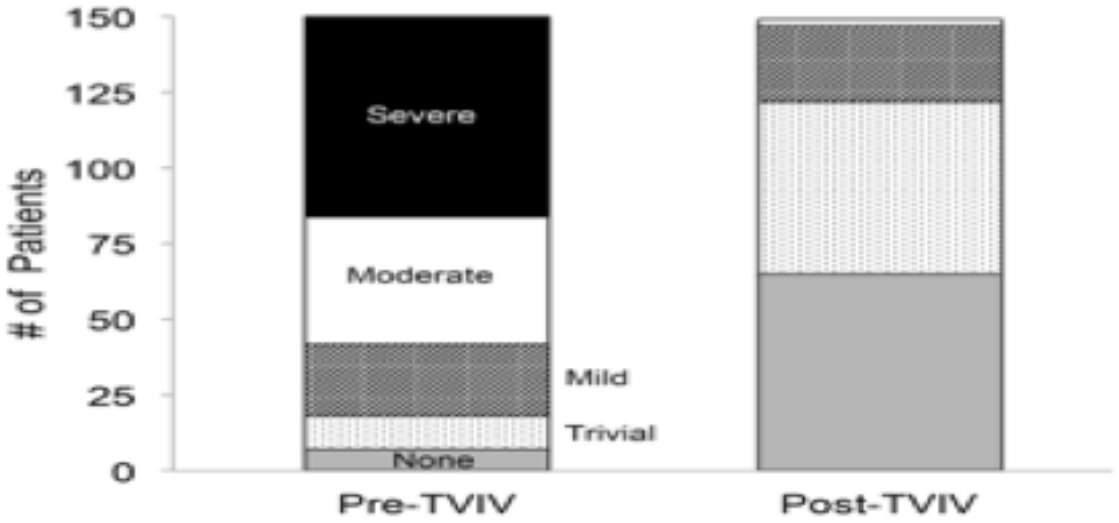
Hemodynamics after VIV





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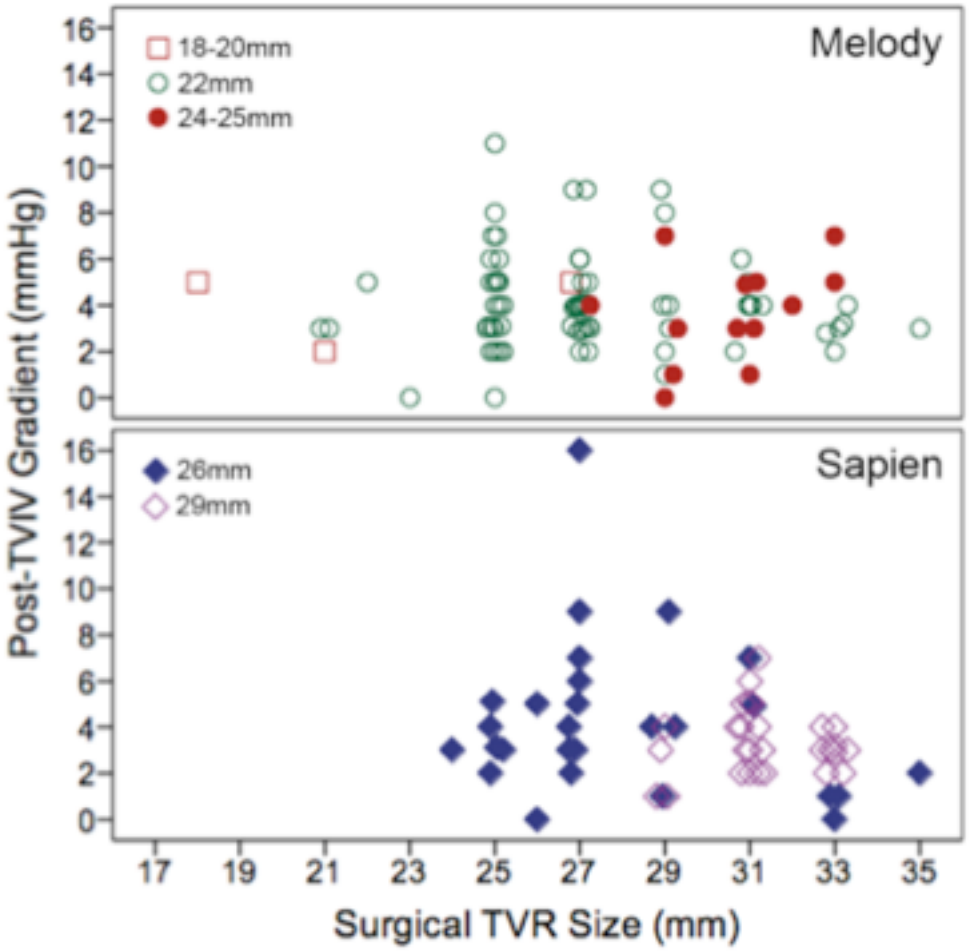
Hemodynamics after VIV



The majority of patients were discharged on antiplatelets (n=105)

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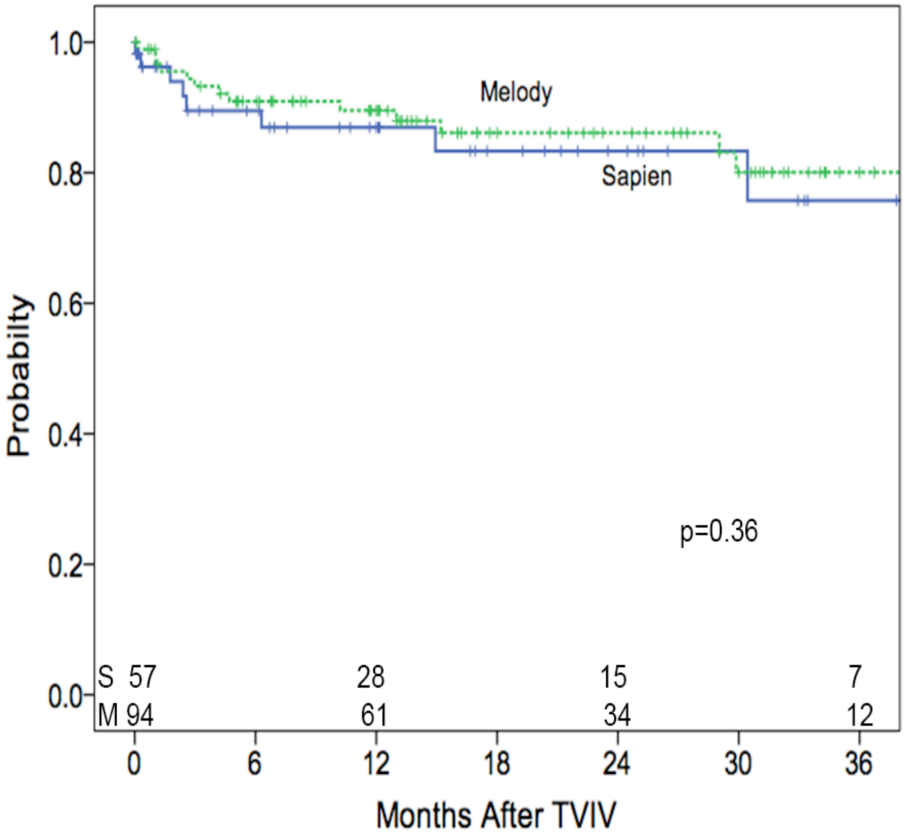
Survival after Tricuspid ViV



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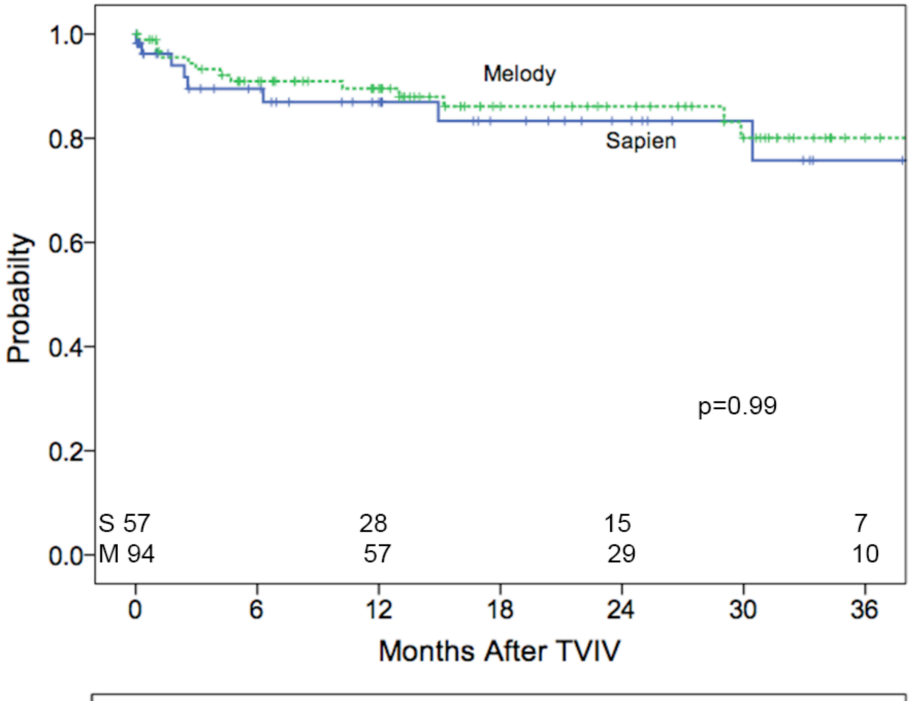
Survival free from TVIV reintervention



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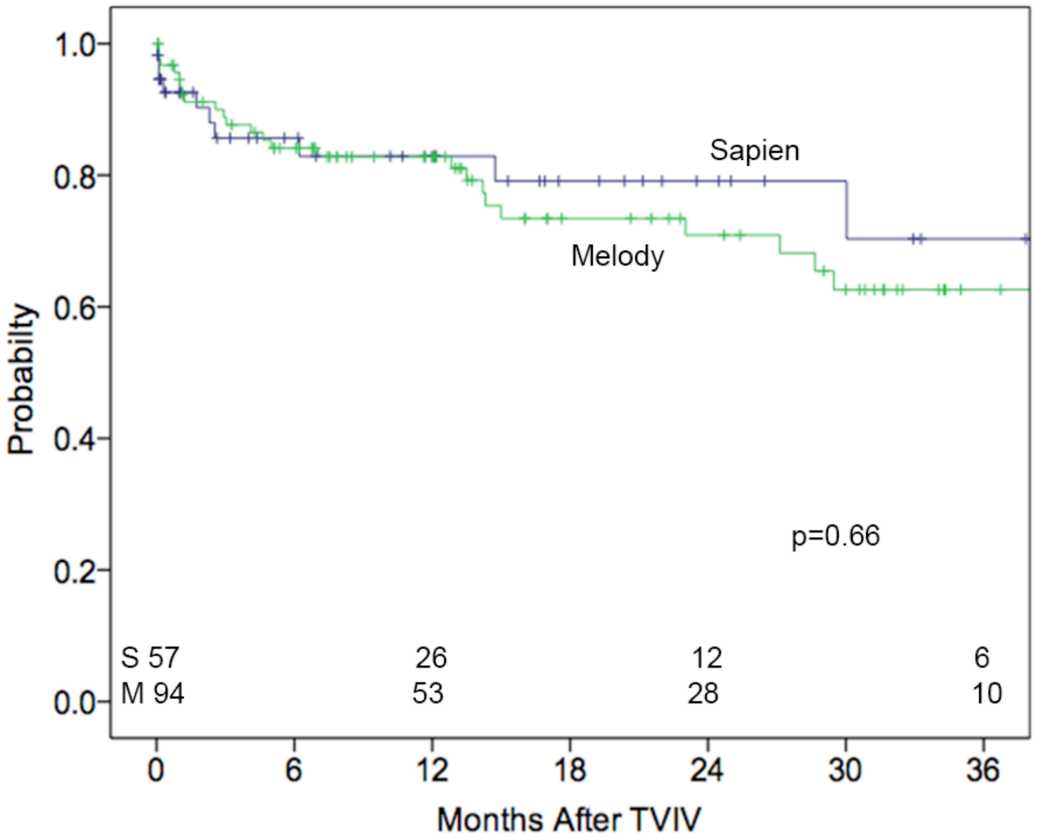
Survival free from TVIV reintervention or significant TS (mean gradient ≥10) or TR



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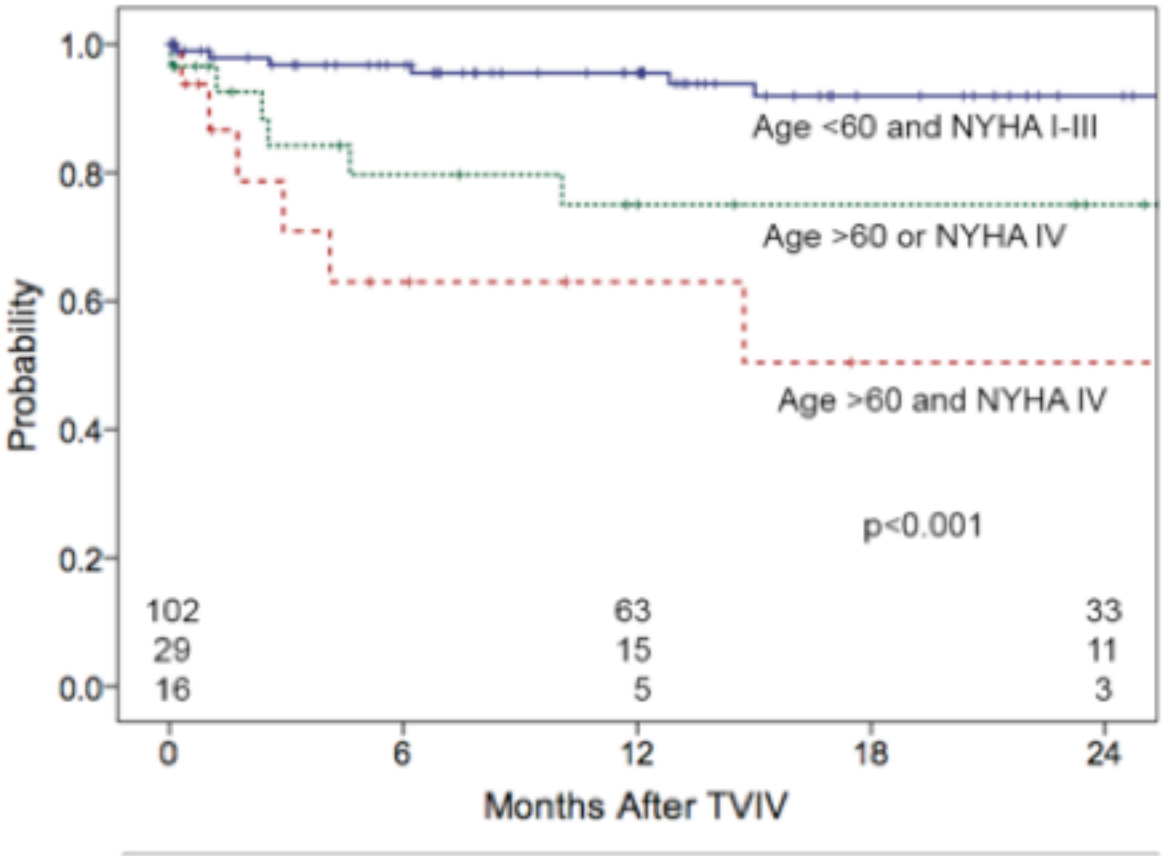
Survival free from TVIV reintervention or significant TS (mean gradient ≥10) or TR



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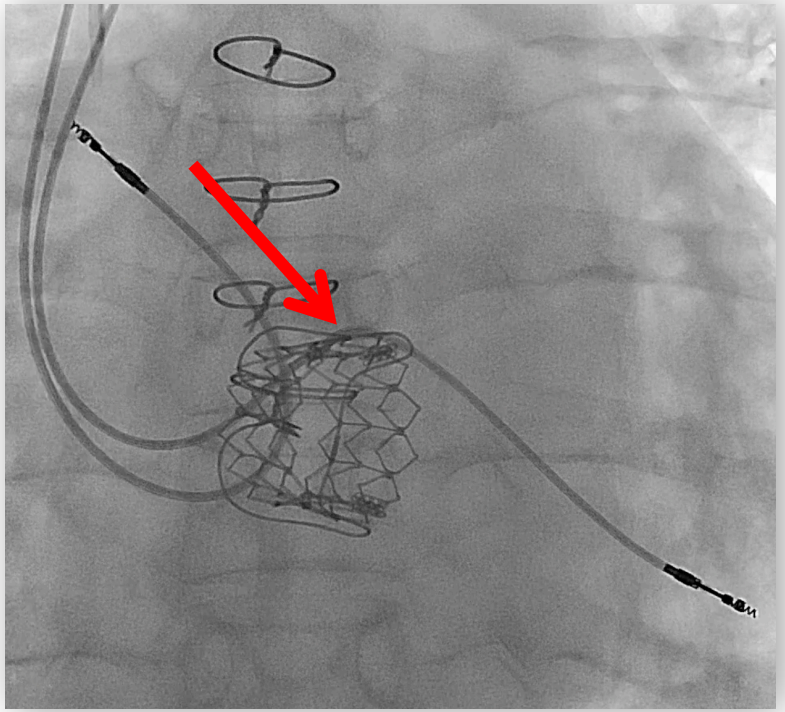
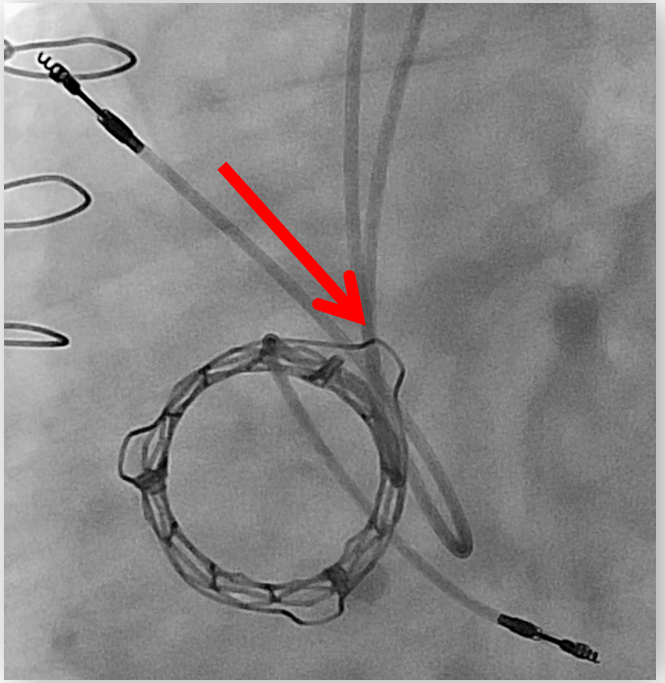
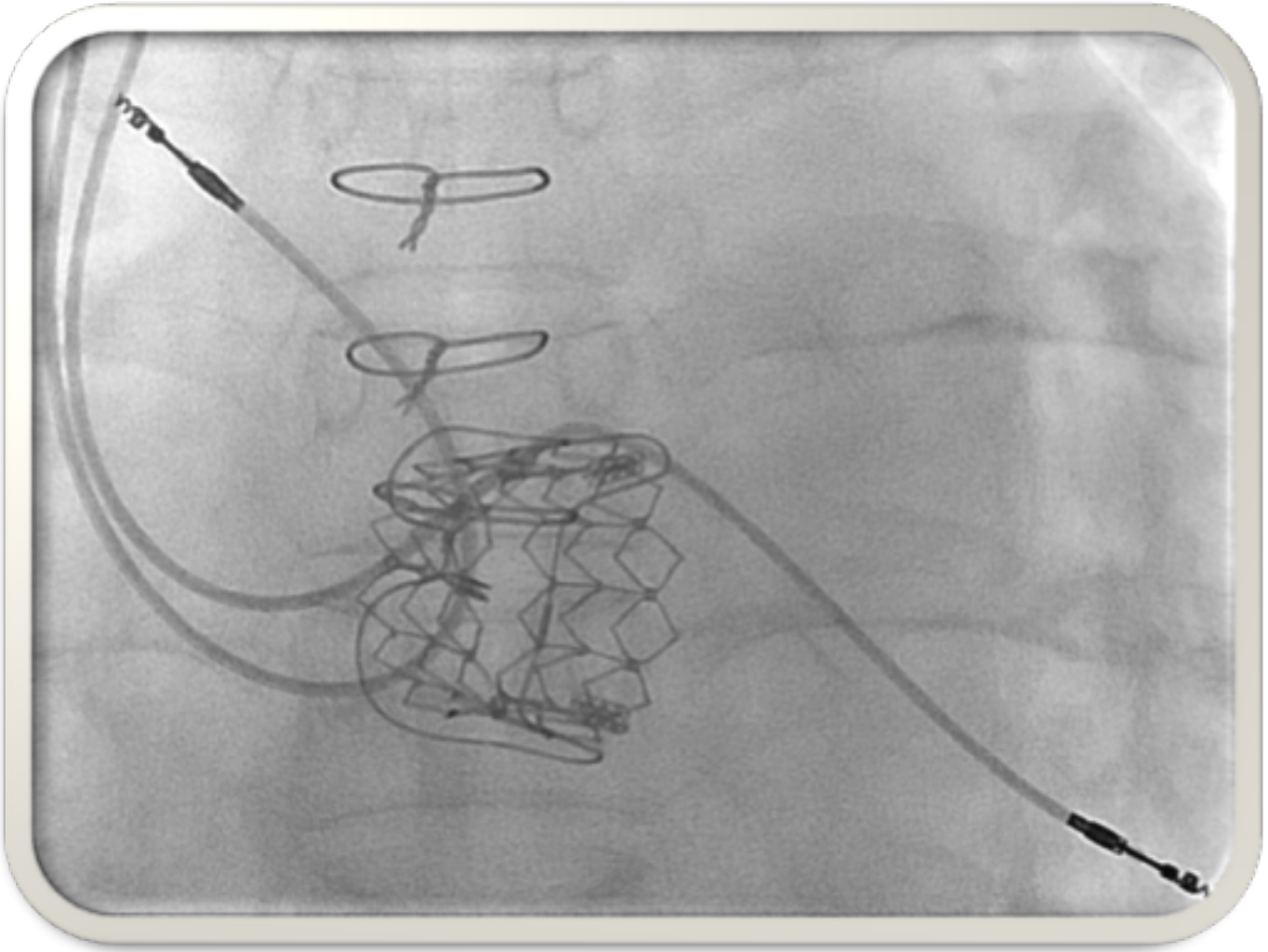
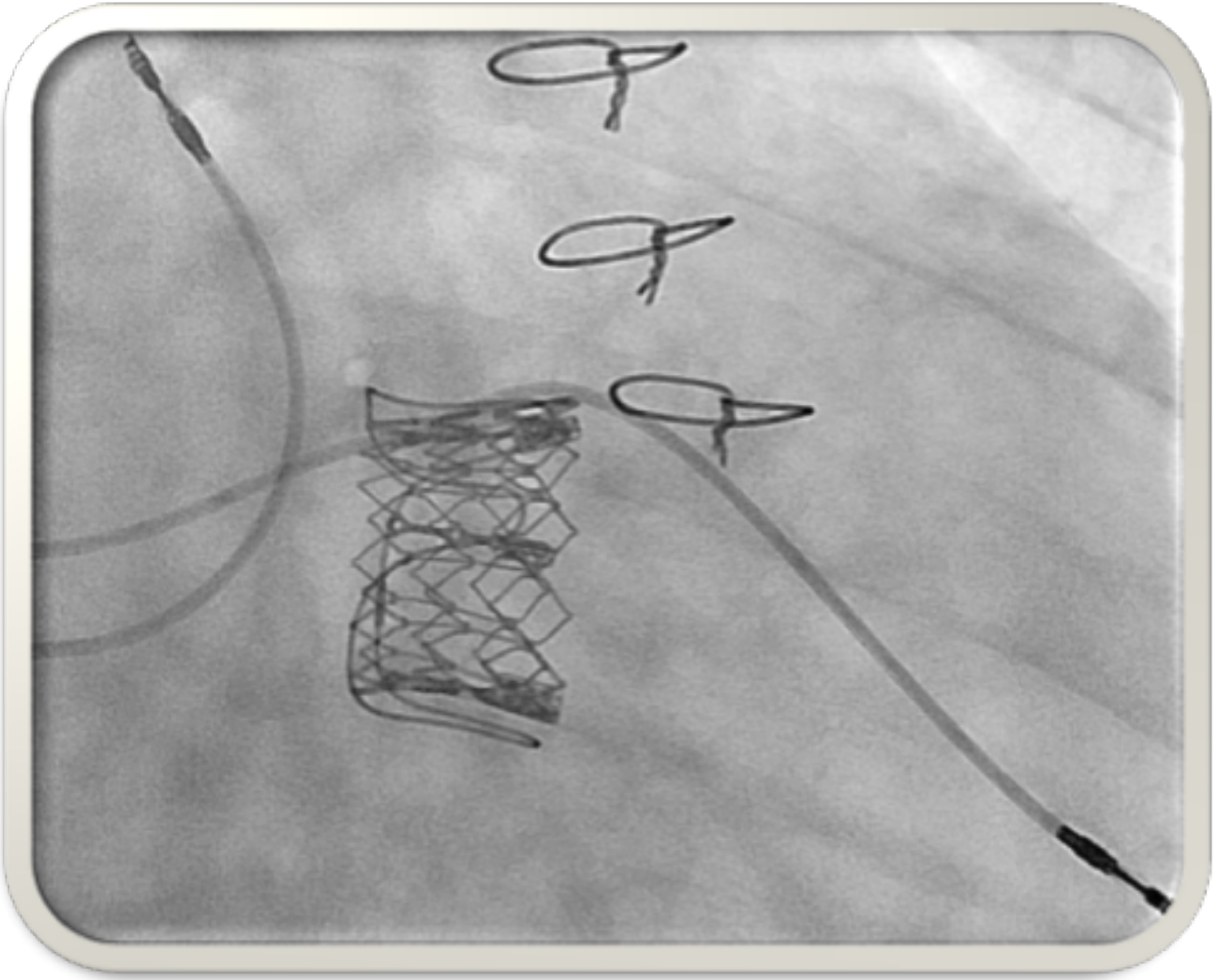
RV pacemaker lead jailed with no acute issues

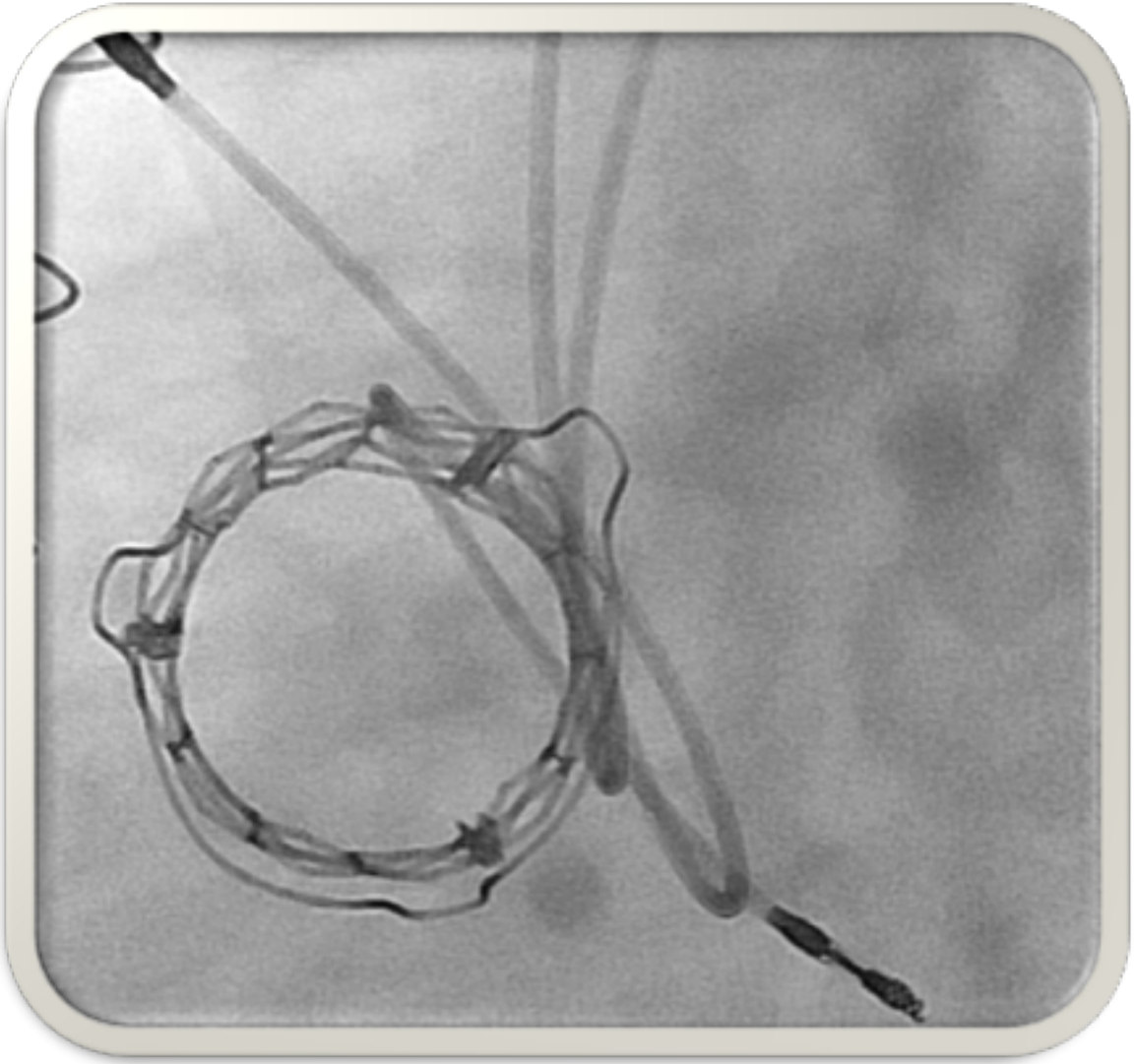
No tricuspid regurgitation, Conduction of pacemaker did not change











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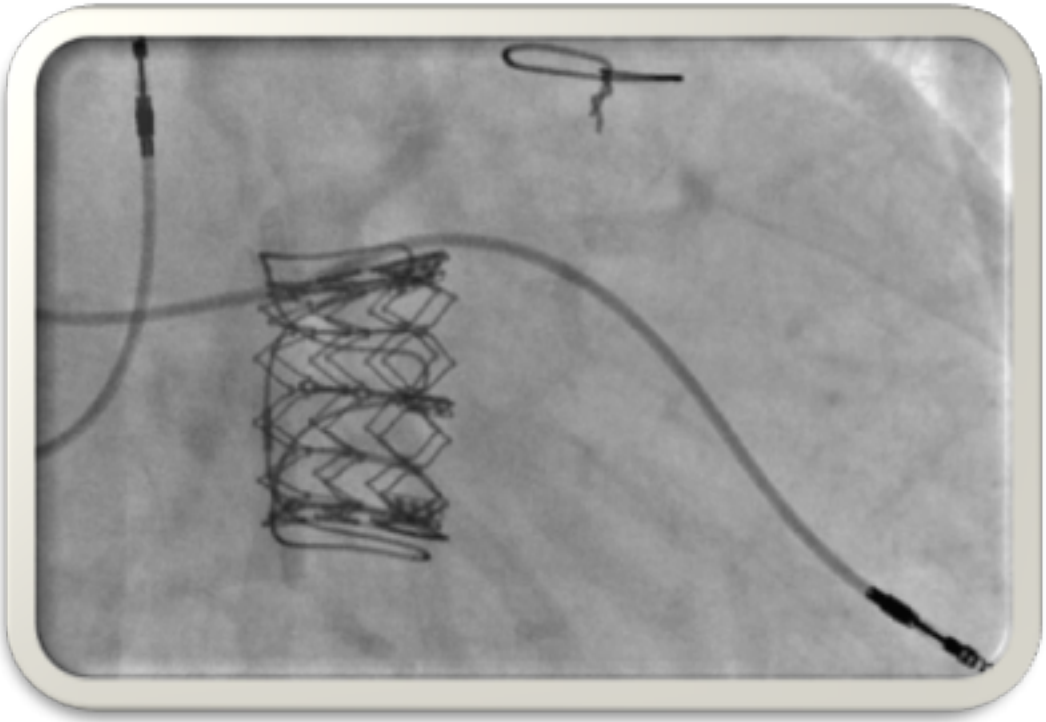
1-month follow up



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Pacemaker Performance

	Pre procedure	Immediately after deployment	6 h post procedure	6 weeks post implantation	6 months post implantation
Lead impedances, Ω					
Atrial	418	361	380	456	456
Ventricular	418	361	380	418	399
Sensing, mV					
P-waves	1.6	2.8	3.3	2.8	2.4
R-waves	17.4	9.9	13.5	15.3	18.3 mV
Pacing threshold, V/ms					
Atrial	0.75/0.4	0.50/0.4	0.50/0.4	1.0/0.4	0.75/0.4
Ventricular	1.25/0.4	1.0/0.4	0.75/0.4	1.25/0.4	2.0/0.4

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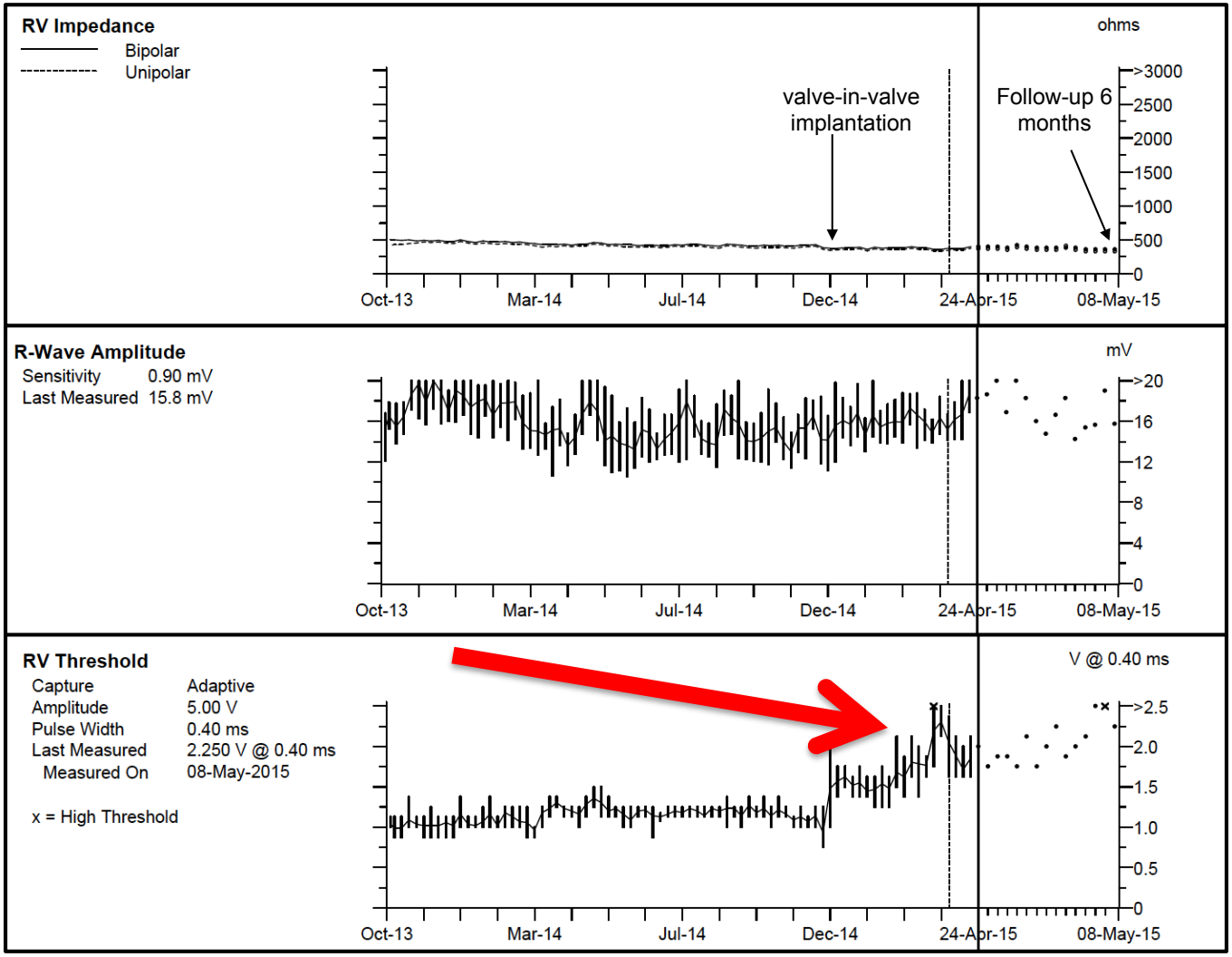
Pacemaker Performance



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STRUCTURAL

Transcatheter Valve-in-Ring Implantation for the Treatment of Residual or Recurrent Tricuspid Valve Dysfunction After Prior Surgical Repair

Jamil Aboulhosn, MD,[a] Allison K. Cabalka, MD,[b] Daniel S. Levi, MD,[a] Dominique Himbert, MD,[c] Luca Testa, MD,[d] Azeem Latib, MD,[e] Raj R. Makkar, MD,[f] Younes Boudjemline, MD,[g] Dennis W. Kim, MD,[h] Joelle Kefer, MD,[i] Sabine Bleiziffer, MD,[j] Gunter Kerst, MD,[k] Danny Dvir, MD,[l] Doff B. McElhinney, MD[m]

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Patients Catheterized With Intent to Perform TVIR
N=22

Excluded due to inadequate landing zone (N=2)
-1 No ring present
-1 CE MC 3 ring

TVIR Performed
N=20

No ring present (1)
-Severe PVL (1)

Ring unspecified (3)
-Moderate PVL (1)
-Mild PVL (2)

CE Classic (10)
-Severe PVL (3)
-Moderate PVL (2)
-Mild PVL (3)
-No PVL (2)

CE MC3 (3)
-Trivial PVL (3)

Medtronic Contour (2)
-Moderate PVL (1)
-Mild PVL (1)

Medtronic Sculptor (1)
-Severe PVL (1)

TABLE 1 Demographic and Diagnostic Data Among 22 Patients Catheterized for Intended TVIR Implant

Age, yrs	49 (5–69)
Etiology of original TV disease (prior to TV repair)	
Congenital	10 (45)
Ebstein's anomaly	4 (18)
Other CHD, abnormal TV or secondary TR	6 (27)
Acquired	12 (55)
Rheumatic heart disease	4 (18)
Left heart disease	3 (13)
Endocarditis	2 (9)
Pulmonary arterial hypertension	2 (9)
TV injury	1 (4)
Number of prior cardiac surgeries	2 (1–10)
Other prosthetic valves	13 (60)
Aortic	5 (24)
Mitral	9 (43)
Pulmonary	3 (10)
Comorbidities	
Acutely ill, hospitalized prior to procedure	6 (27)
Atrial fibrillation or flutter	16 (73)
Acute/chronic renal insufficiency	2 (19)
Chronic lung disease	3 (13)
Prior history of endocarditis	2 (9)
Existing permanent pacemaker	11 (50)
Epicardial	1 (4)
Transvenous	10 (45)
NYHA functional class	
I	0 (0)
II	3 (14)
III	11 (50)
IV	8 (36)

TABLE 2 TV Function and Annuloplasty Related Data Among 22 Patients Catheterized for Intended TVIR Implant

Age of TV repair, yrs	7 (0.1-25)
≤5	11 (50)
≥10	6 (27)
Type of surgical implant	
Ring only	19 (86)
Ring with homograft/autograft	2 (9)
No ring/repaired valve	1 (5)
Ring size, mm	
<30	7 (32)
30-32	11 (50)
>32	2 (9)
TR severity	
None/trivial	0 (0)
Mild	0 (0)
Moderate	3 (14)
Severe	19 (86)
Mean Doppler TV inflow gradient, mm Hg	3 (2-8)
≤5	17 (77)
6-9	4 (18)
≥10	1 (5)
Invasive pressure measurements, mm Hg	
Right atrial mean pressure	19 (7-25)
Right ventricular end-diastolic pressure	14 (6-21)
Right ventricular systolic pressure	36 (25-124)

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TABLE 3 Procedural Variables for 22 Patients Who Underwent Attempted TVIR Implant

Transcatheter valve implanted	20 (91)
Transcatheter valve type	
Sapien	17 (85)
Sapien XT	13 (76)
Sapien 3	3 (18)
Sapien	1 (6)
Melody	3 (15)
Implant balloon diameter, mm	
<26	3 (15)
26	6 (30)
29	10 (50)
>29	1 (5)
Vascular access	
Femoral vein	16 (73)
Jugular vein	1 (5)
Surgical via right atrial access	2 (9)
Hybrid via right ventricular access	1 (5)
General anesthesia	22 (100)
Intraprocedural transesophageal echocardiography	22 (100)
Rapid pacing used during implant	11 (50)
Permanent pacing system	9 (41)
Temporary pacing catheter/wire	2 (9)
Pre-dilation/balloon sizing before implant	10 (45)
Ring pre-stented before TVIR	3 (15)
Valve post-dilated	5 (25)
Second valve implanted	2 (10)
Additional procedures performed at same catheterization	8 (40)
Tricuspid paravalvular leak occlusion	4 (20)
Other transcatheter valve replacement	2 (11)
Other intervention	2 (11)
Procedural complications	3 (14)

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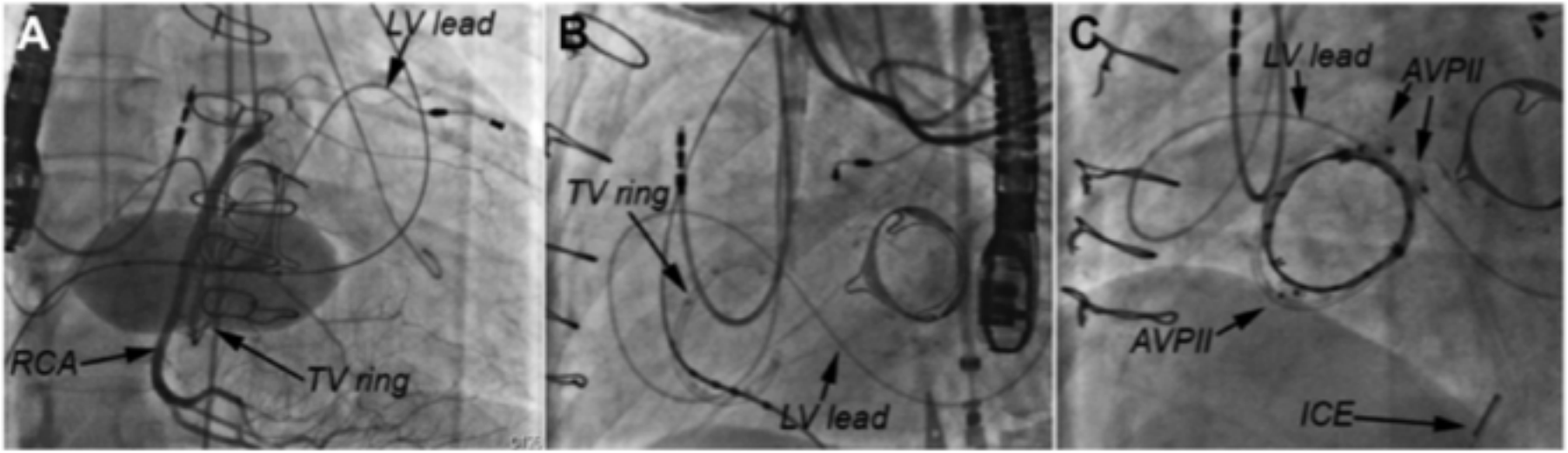
Significant PVL- the Achilles' Heel of tricuspid valve in ring procedures?



Clinically significant PVL in 25% of cases post tricuspid valve in ring

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Summary

- Tricuspid valve-in-valve procedures are increasingly performed using Melody and SAPIEN THV devices.
- Although half the patients had etiology of congenital heart disease, most of them were adults at the time of VinV.
- Specific considerations in these cases include treatment of large surgical valves, coaxilaity issues and transvalvular pacemaker leads.
- SAPIEN and Melody implantation for this indication show similar clinical outcomes.
- Tricuspid valve-in-ring is feasible but associated with an increased risk of significant PVL.

Thank you!

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