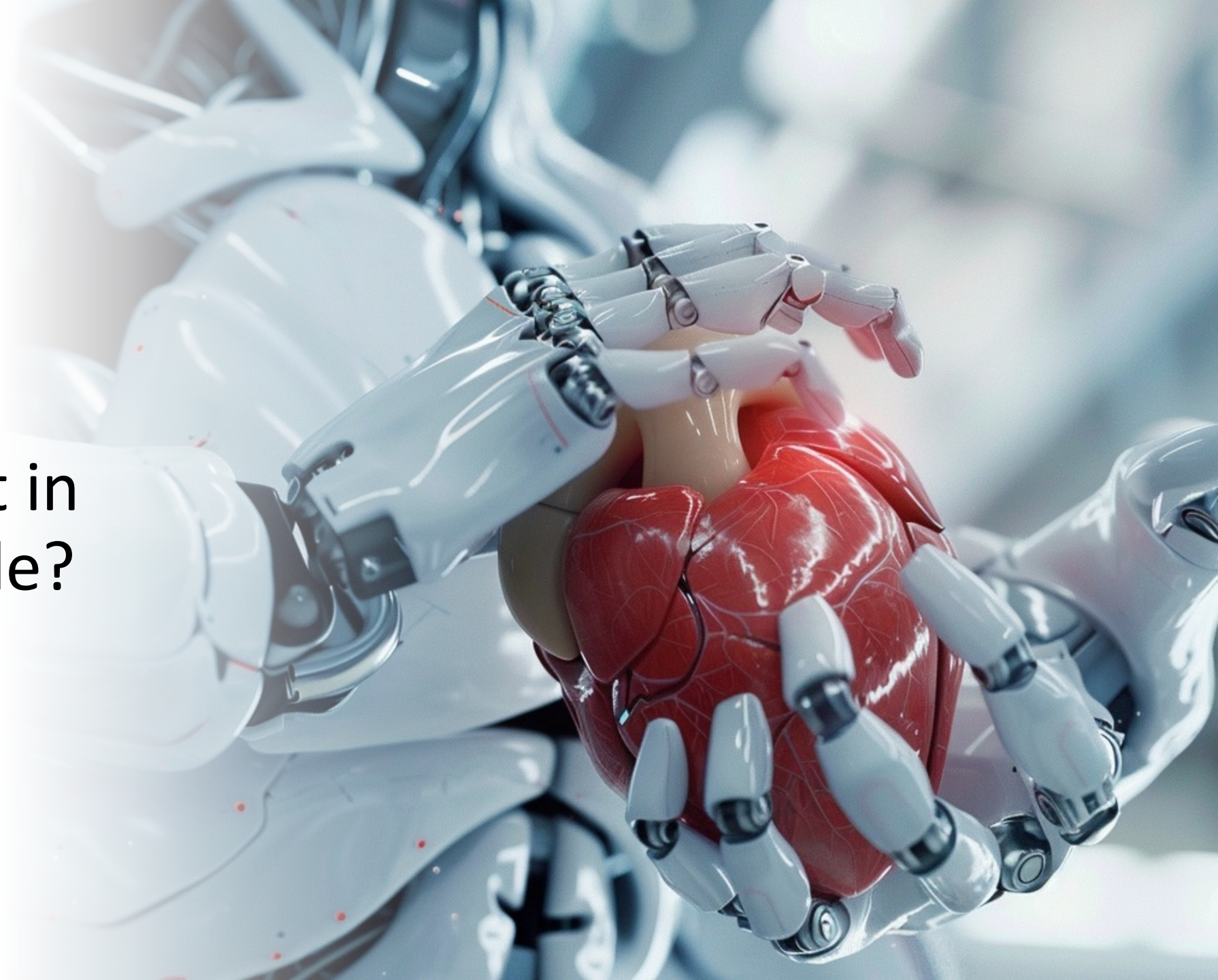
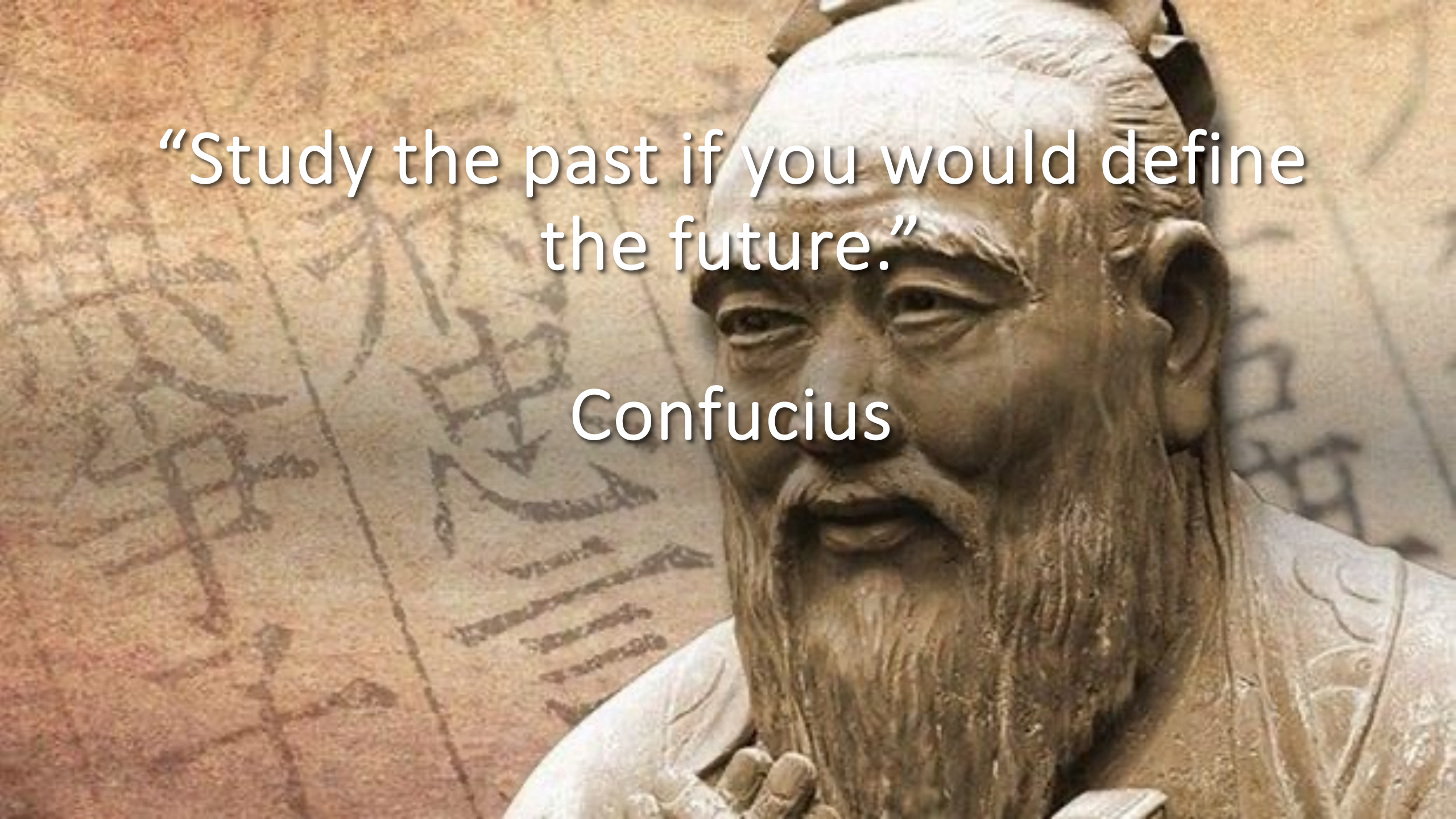
Innovations in Transcatheter Valvular Interventions – **What** to Expect in the Next Decade?

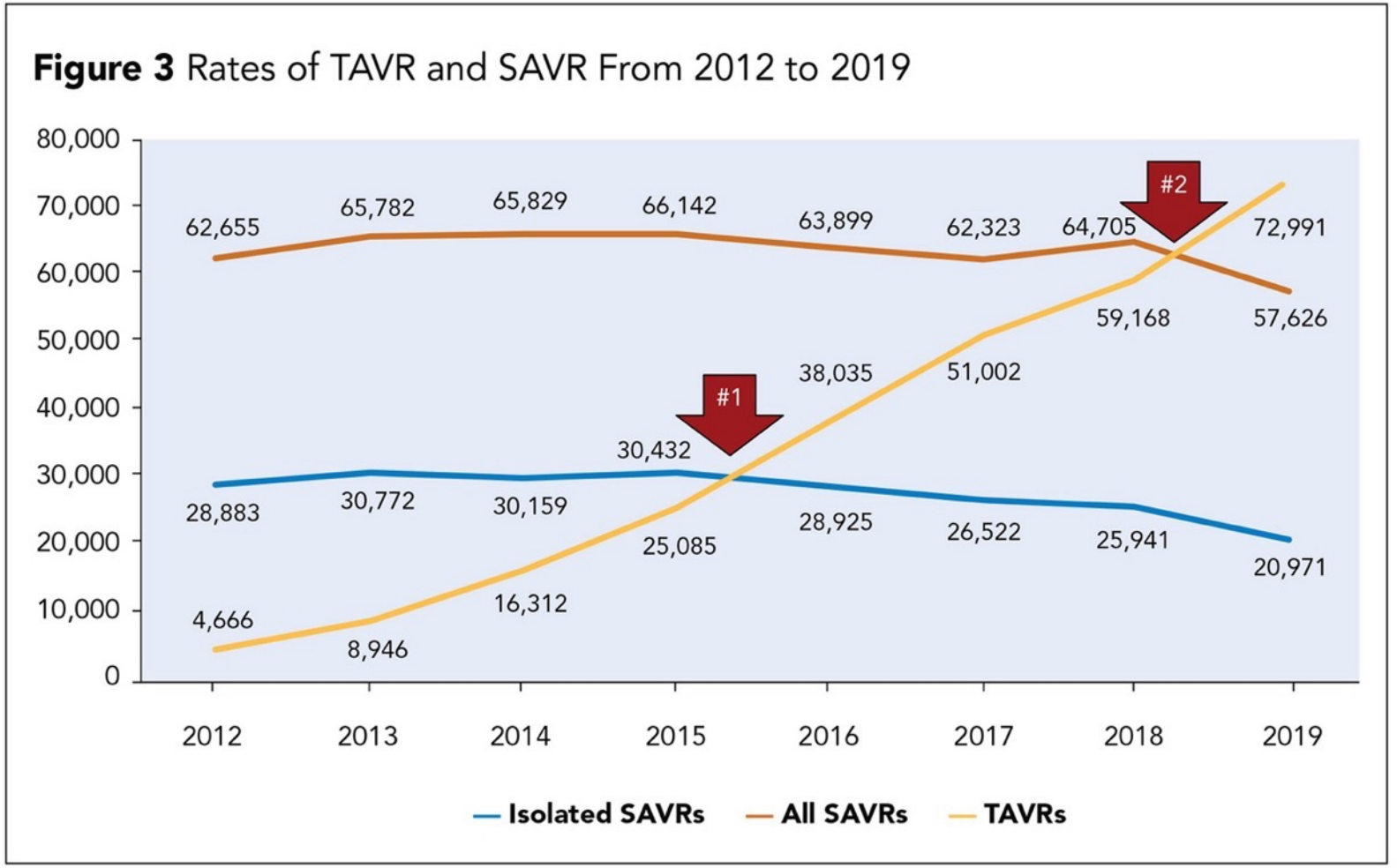
Leor Perl, MD

Rabin Medical Center



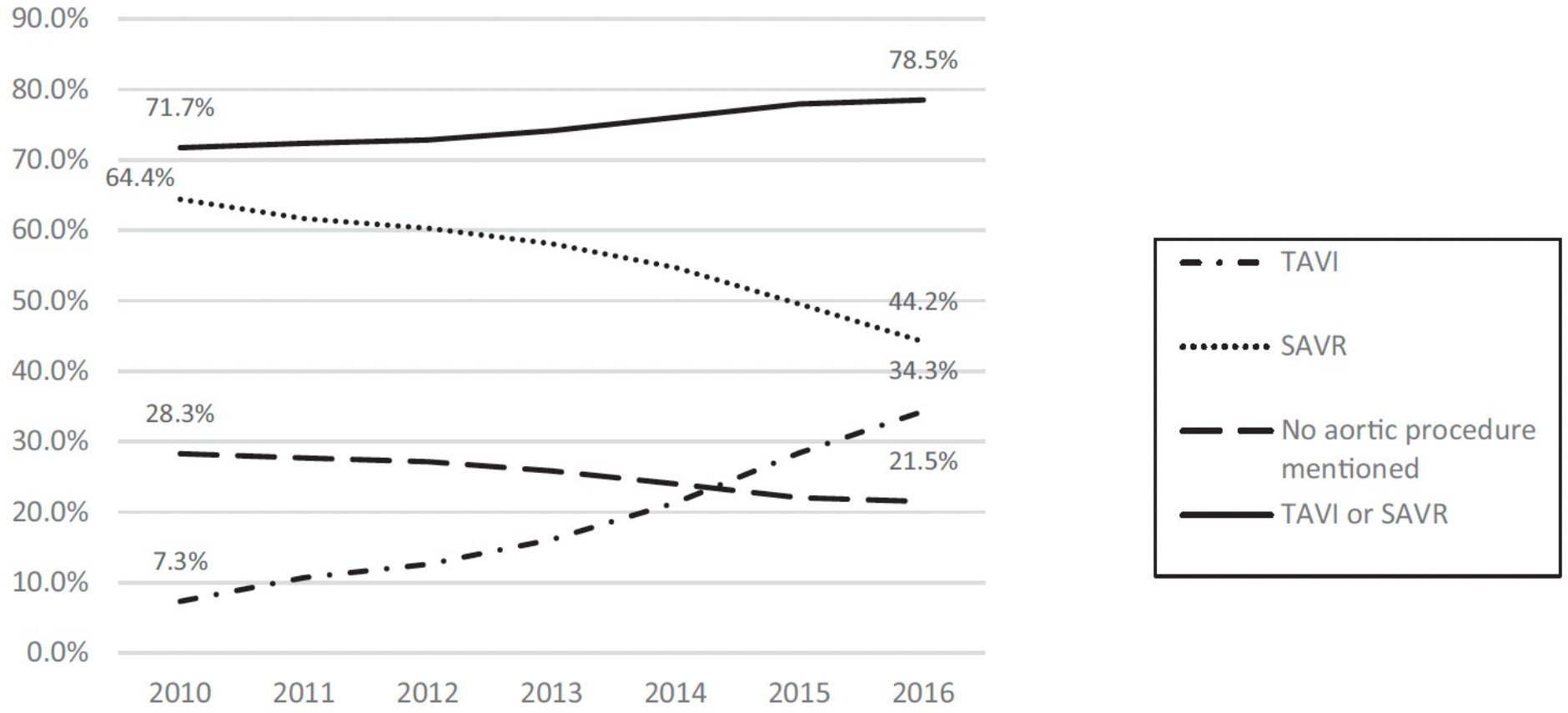

“Study the past if you would define the future.”
Confucius

Epidemiological Features of Aortic Stenosis in USA



Mack MJ, Jan 22, 2021; Cardiology Magazine, ACC Website

Epidemiological Features of Aortic Stenosis in France



J Am Heart Assoc. 2020;9:e017588.

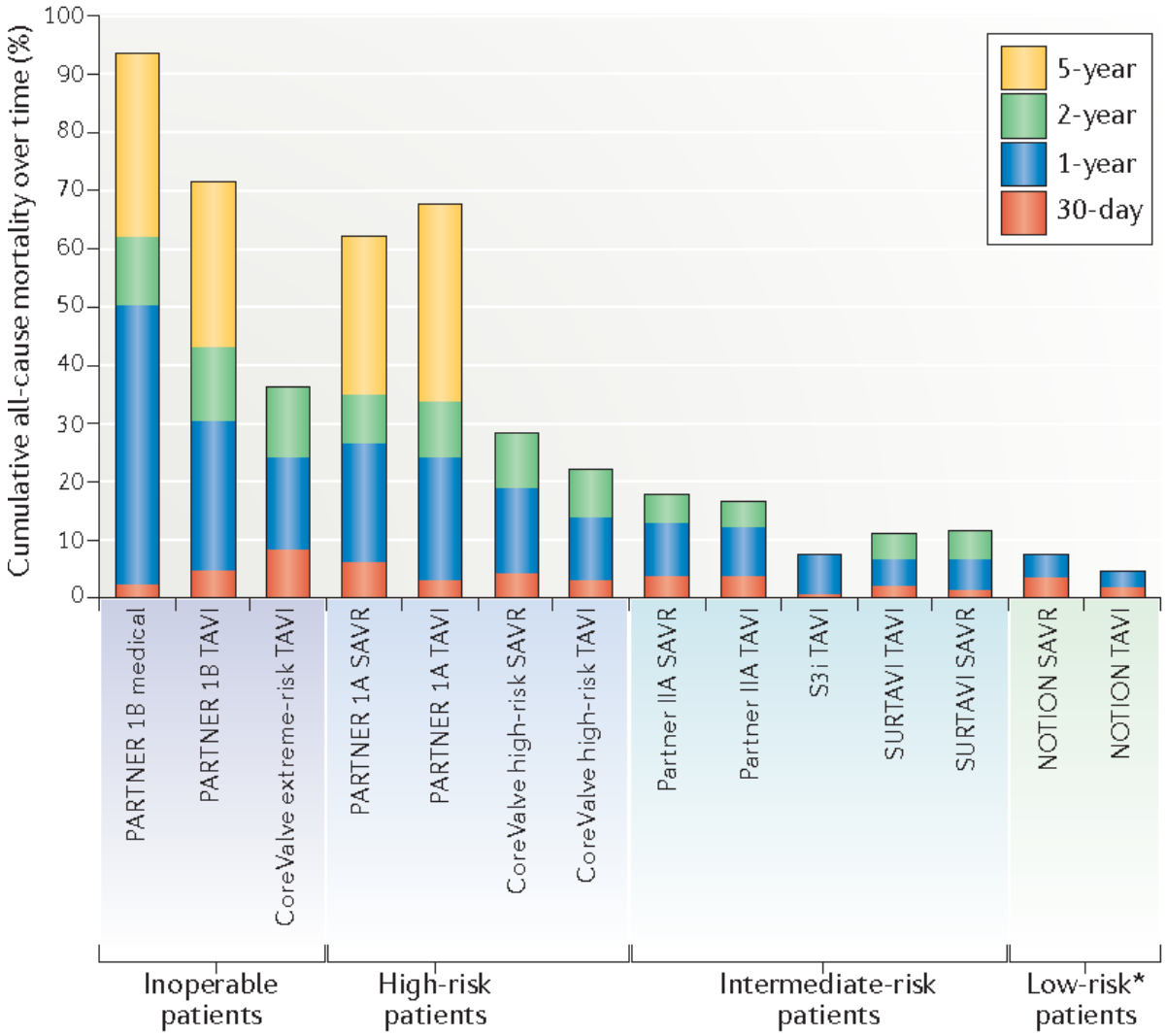
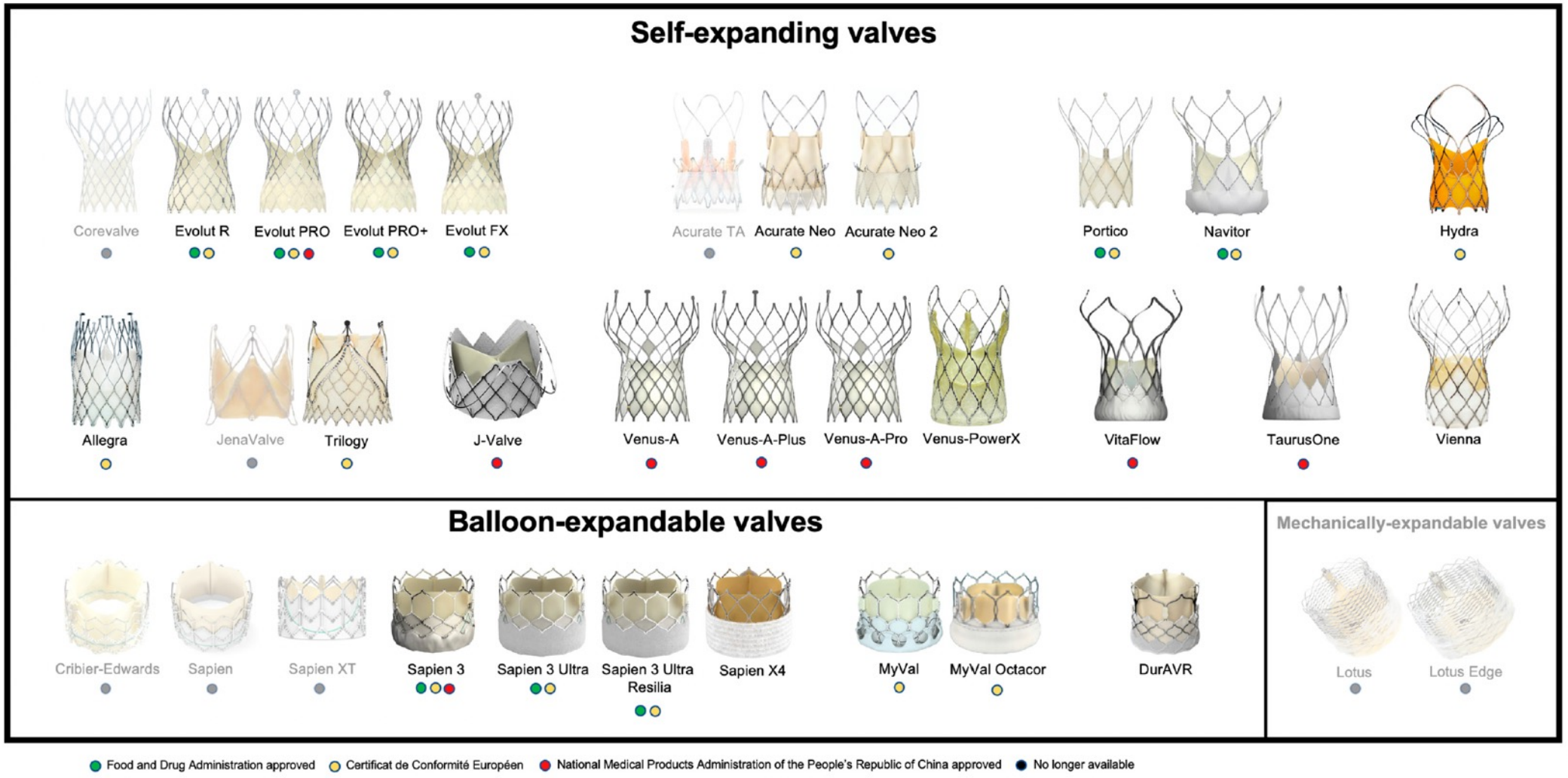
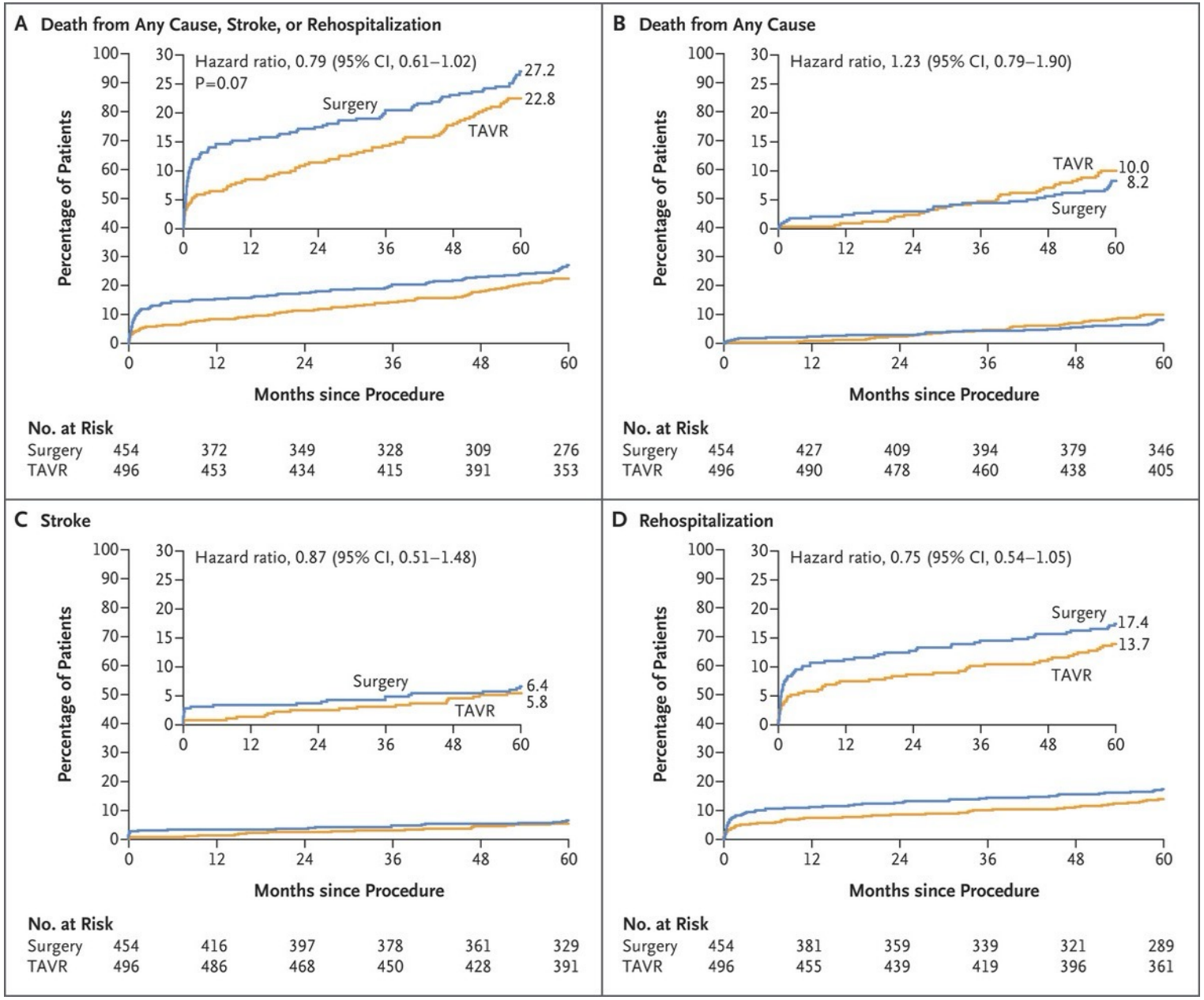


Figure 2 | **All-cause mortality in pivotal TAVI/SAVR studies grouped by risk category.**

Nat Rev Cardiol. 2017 Oct;14(10):615-626



J. Clin. Med. 2024, 13, 373

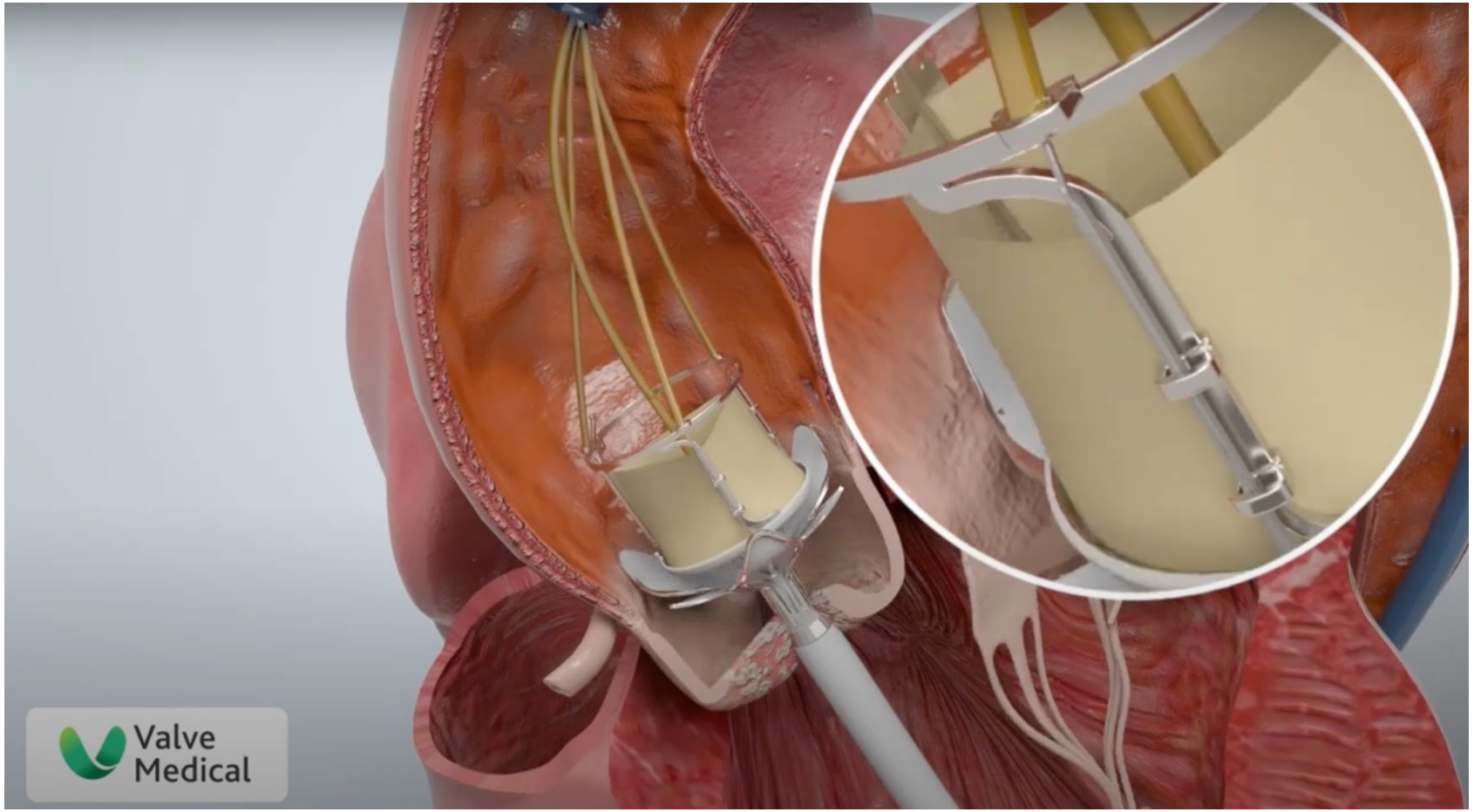


MJ Mack et al. N Engl J Med 2023;389:1949-1960.

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

The Xemed Valve



Medinol
Ingenuity for life

TEL AVIV UNIVERSITY

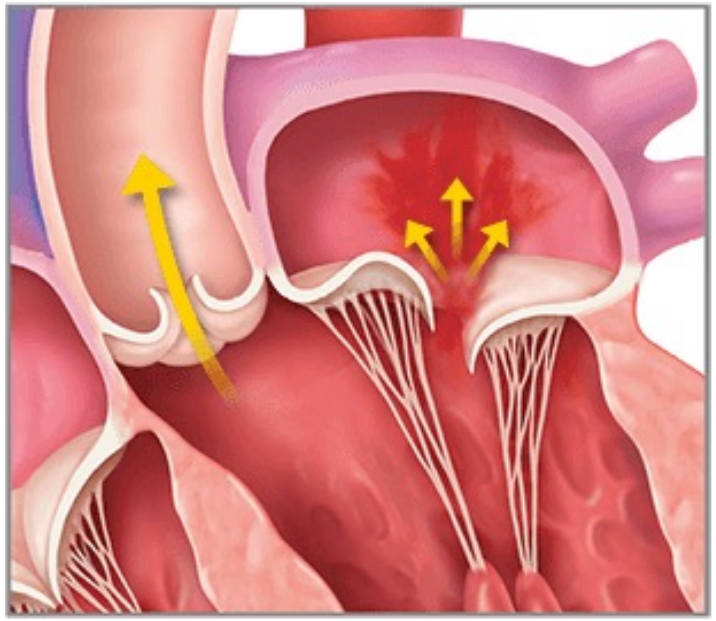
RABIN MEDICAL CENTER
BEILINSON • HASHARON

Remaining Questions for TAVR

- Very long-term durability
- Valve in valve
- HALT
- Coronary access
- How much more can we reduce side effects?

Undertreatment of Severe Mitral Regurgitation

- Mitral surgery is performed in only 15% of severe MR patients.
- 5% of secondary MR versus 29% of primary MR.



Lancet. 2018 March 10; 391(10124): 960–969.

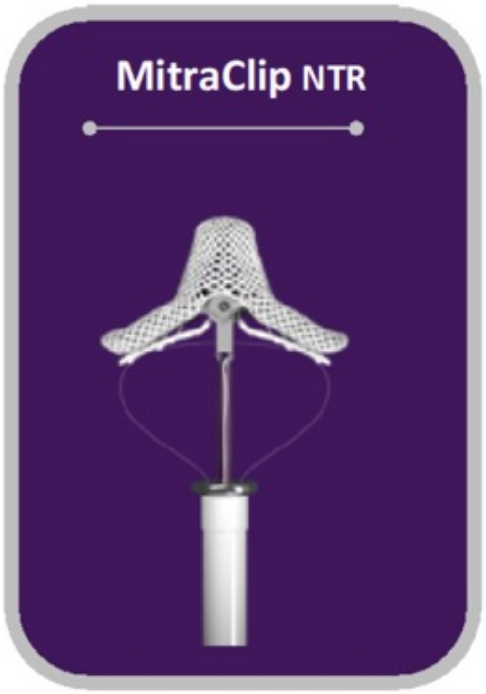
Octalina Mendoza

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

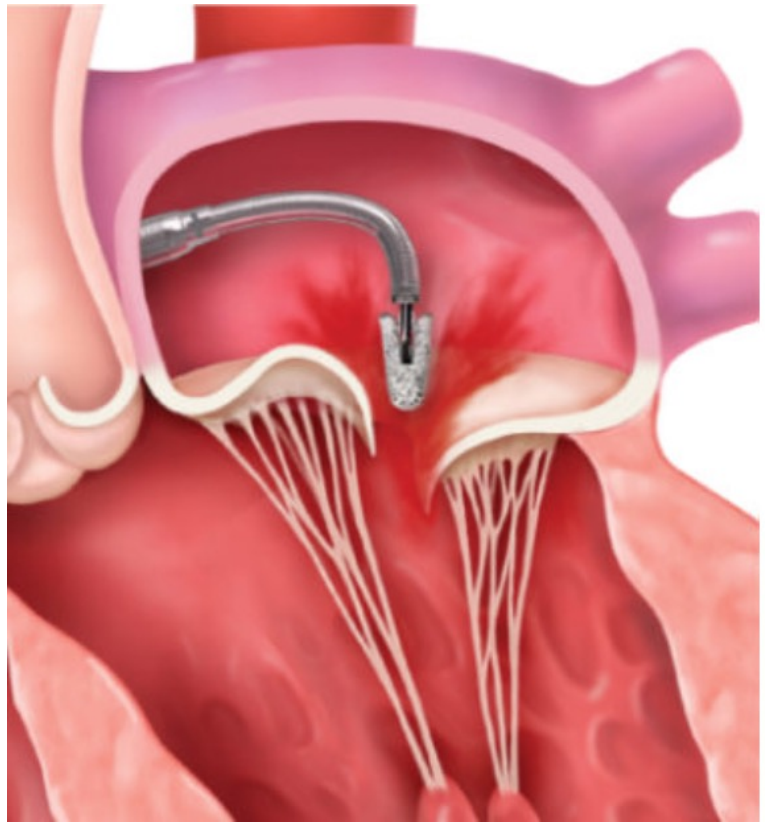
Mitral Transcatheter Edge-to-edge Repair

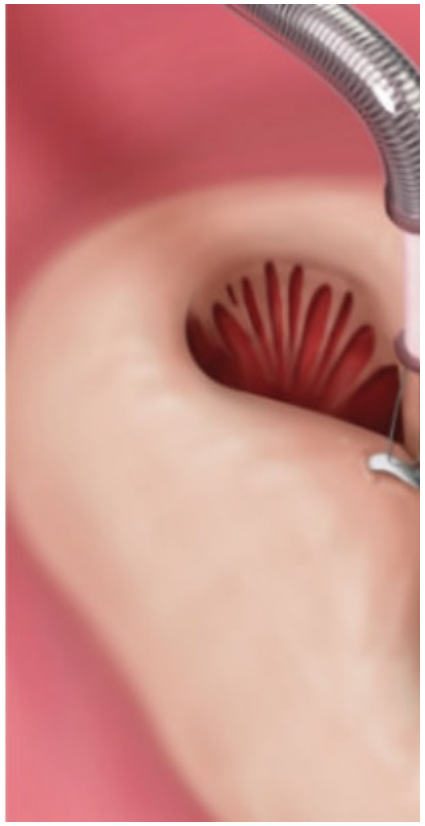
Over 100,000 procedures performed since first patient



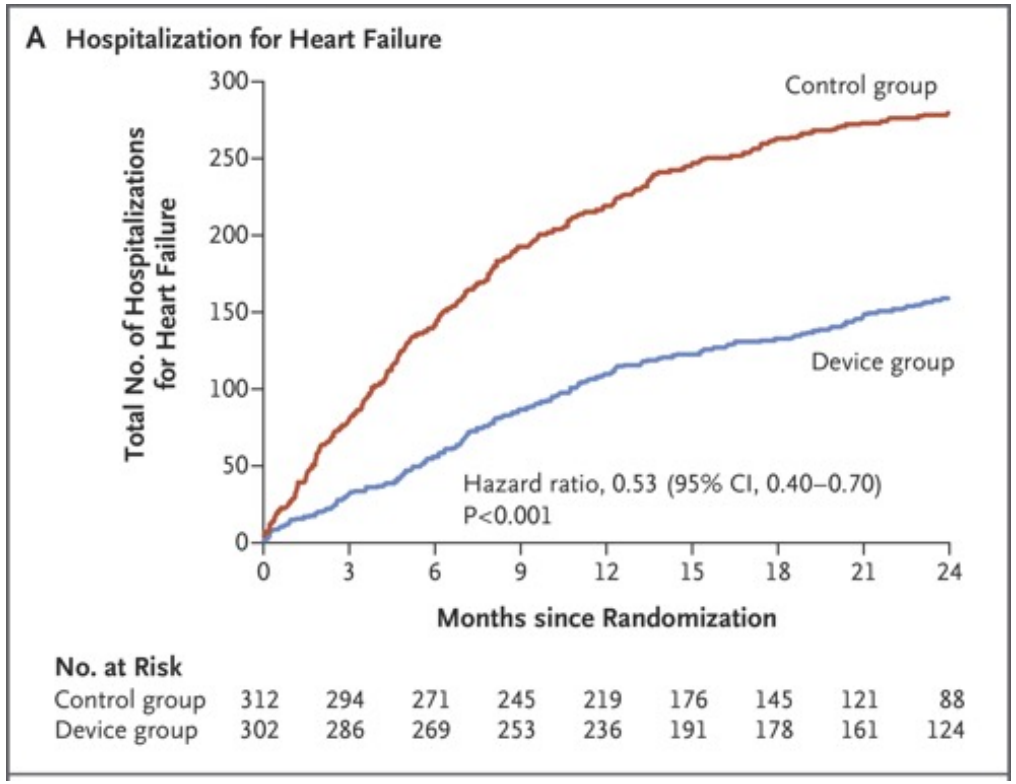
MitraClip NTR
The original MitraClip NT size,

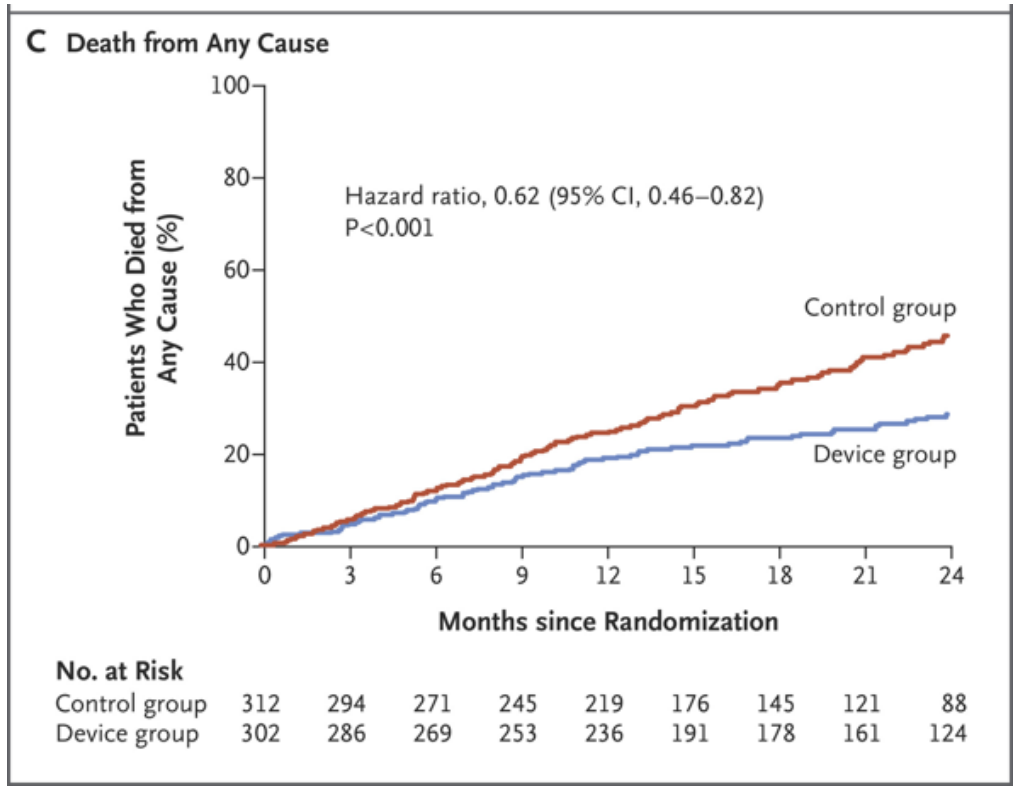
MitraClip XTR
Longer arms for easier grasping





Transcatheter Mitral-Valve Repair in Patients with Heart Failure





N Engl J Med 2018; 379:2307-2318

Comparison of TEER with Mitral Surgery

Population of interest

- Patients with severe mitral regurgitation seen in French hospitals 2012–2022
- Propensity matching

Intervention

Mitral transcatheter edge-to-edge repair

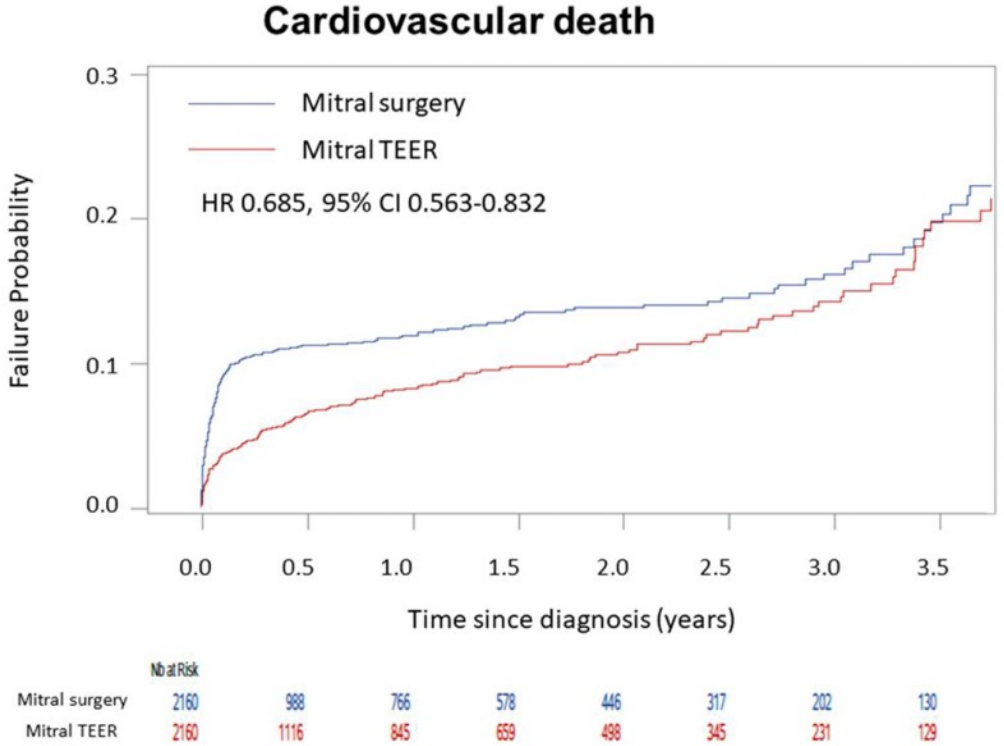
2160 patients

VS

Comparison

Isolated mitral surgery

2160 patients

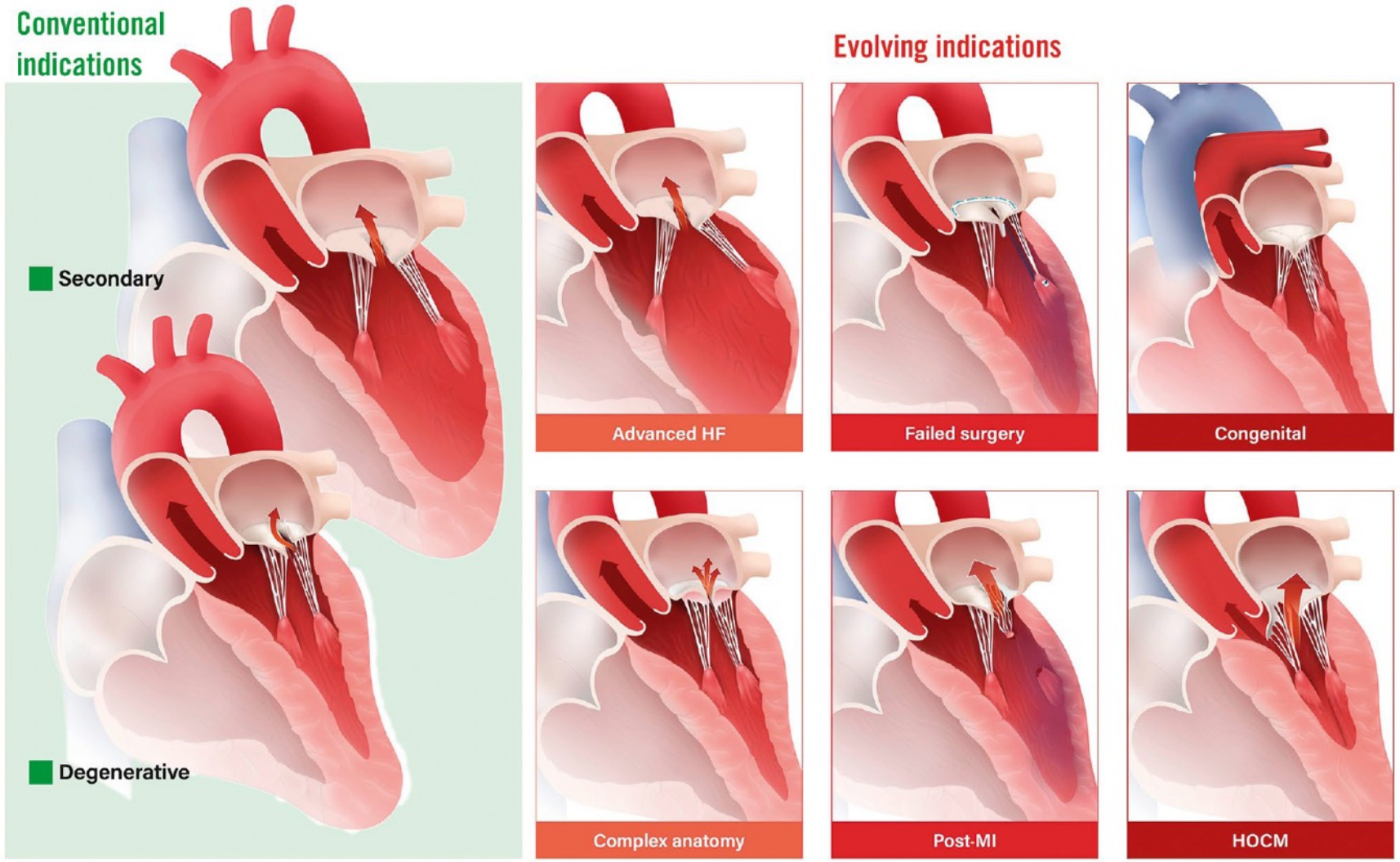


European Heart Journal (2024) 45, 940–949

TEL AVIV UNIVERSITY

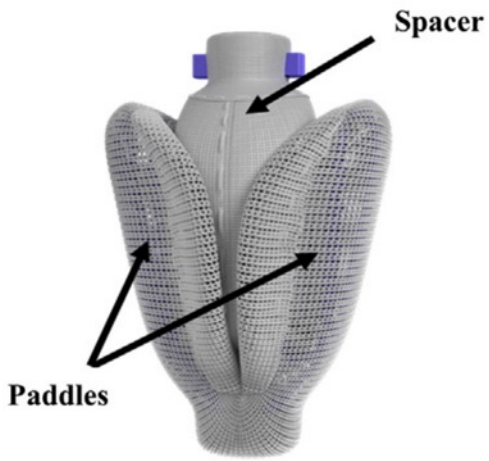
RABIN MEDICAL CENTER
BEILINSON • HASHARON

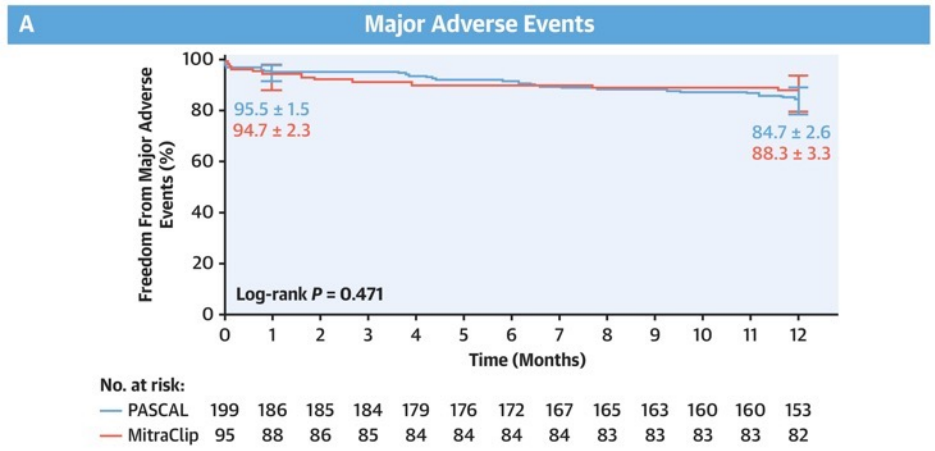
Clinical indications for mitral TEER.

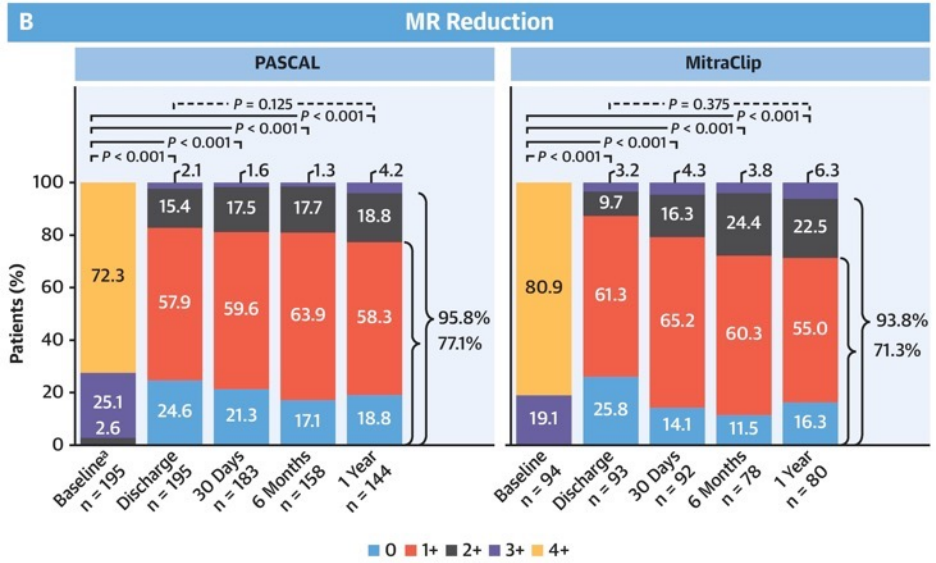


Mony Shuvy *et al.* • *EuroIntervention* 2024;20:e230-e238 • DOI: 10.4244/EIJ-D-23-00700

One-Year Outcomes From the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation



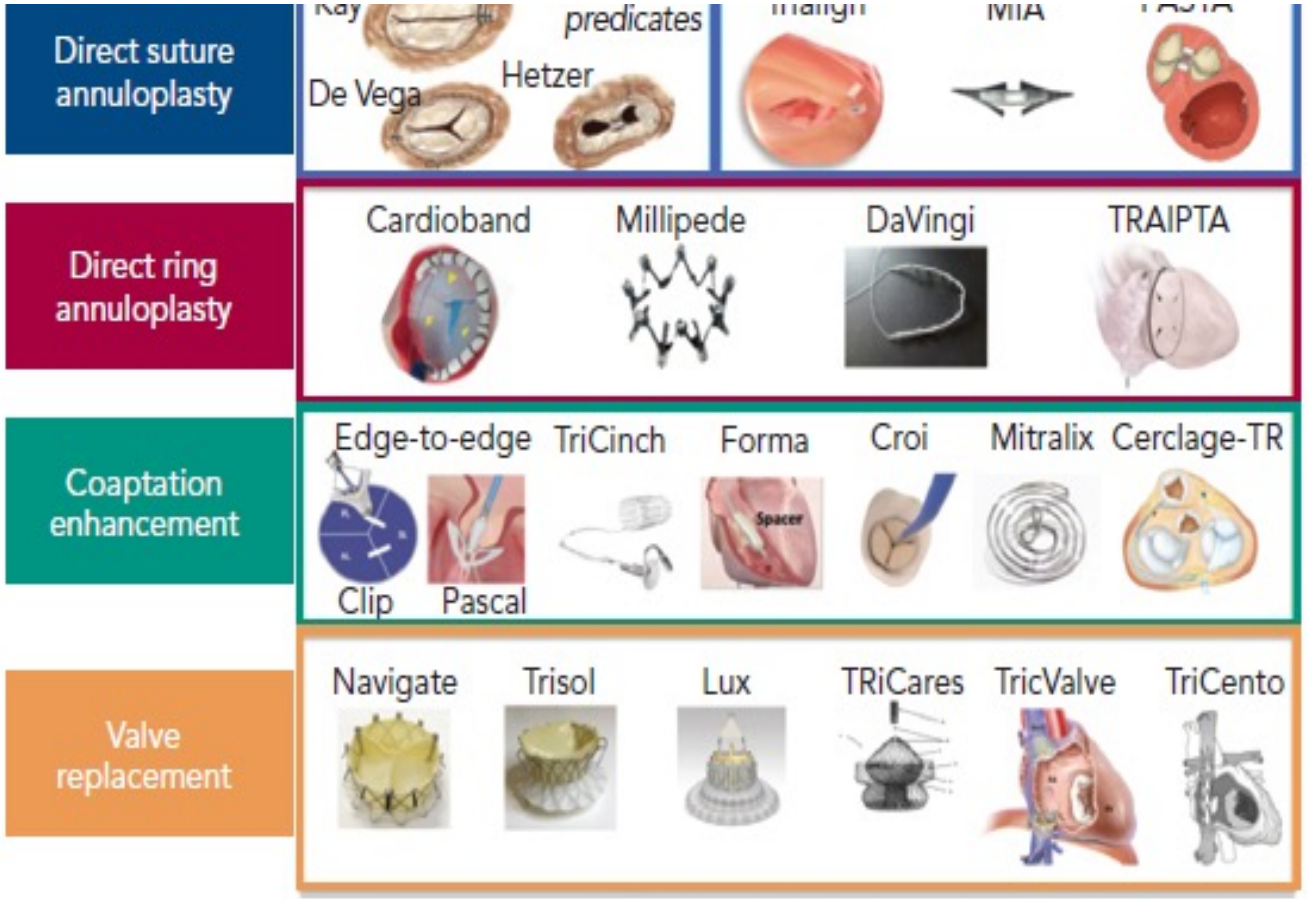




- PASCAL system is noninferior to the MitraClip system for DMR
- PASCAL system provides significant and durable MR reduction
- Marked improvements in functional class and QoL observed in both device groups

Zahr F, et al. J Am Coll Cardiol Intv. 2023;16(23):2803-2816.

Percutaneous Mitral Valve Therapies



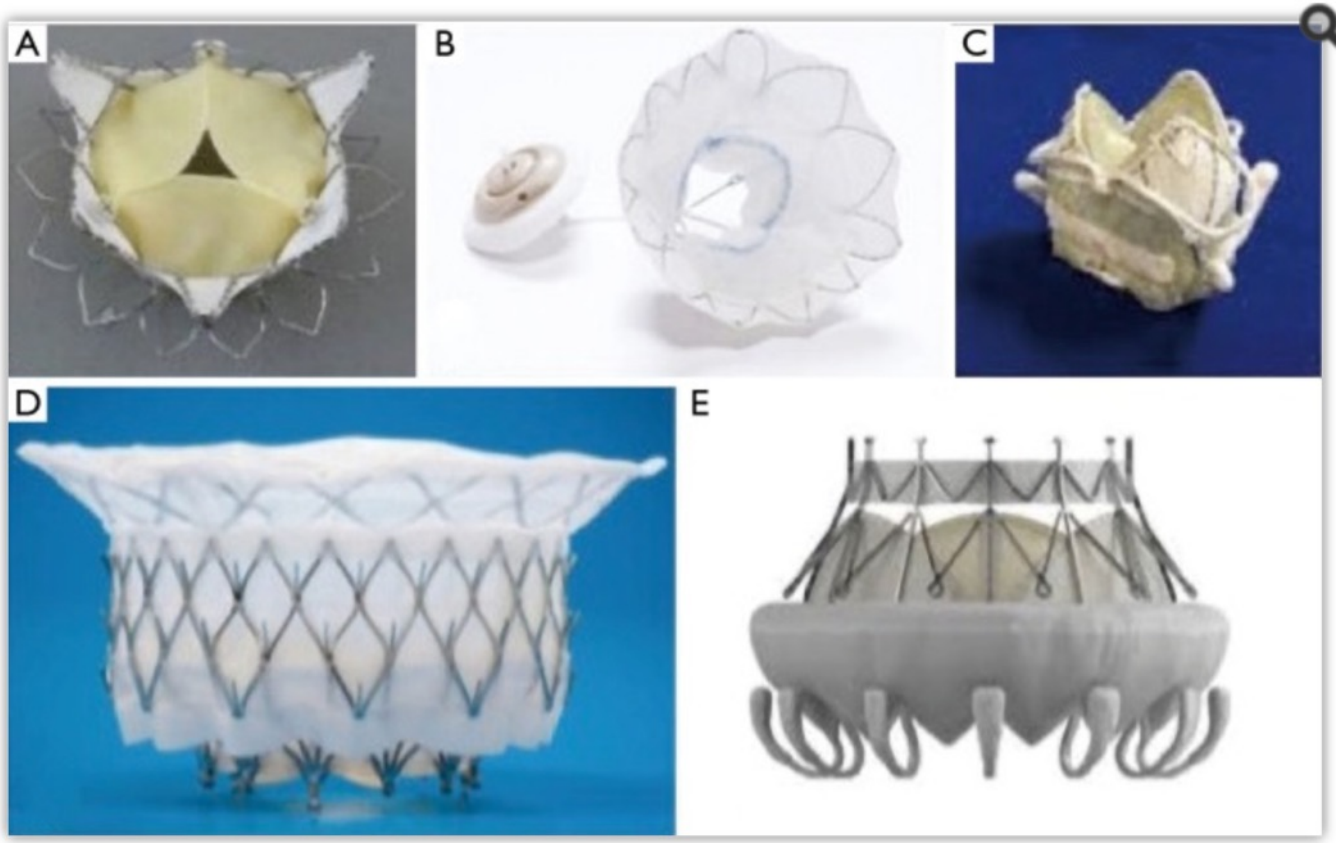
MIA = minimally invasive annuloplasty; PASTA = pledget-assisted suture tricuspid annuloplasty; TRAIPTA = transatrial intrapericardial tricuspid annuloplasty.

Interventional Cardiology Review 2019;14(2):54–61.

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Transcatheter Mitral Valve Replacement Systems



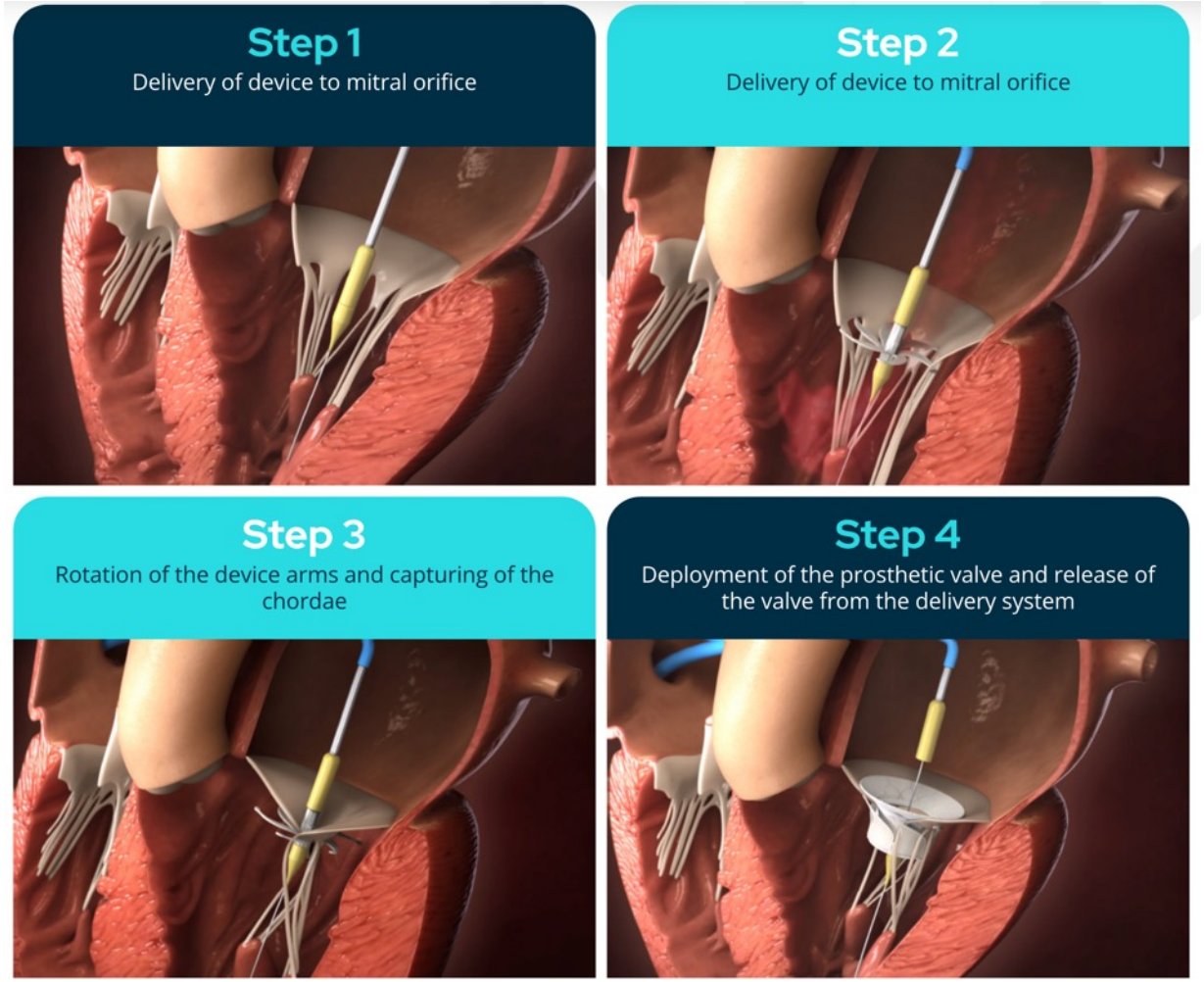
Transcatheter mitral valve replacement systems. (A) Tiara (Neovasc Inc.); (B) Tendyne (Abbott Vascular); (C) Caisson (LivaNova); (D) Intrepid (Medtronic); (E) CardiAQ (Edwards Lifesciences).

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Transcatheter Mitral Valve Replacement Systems

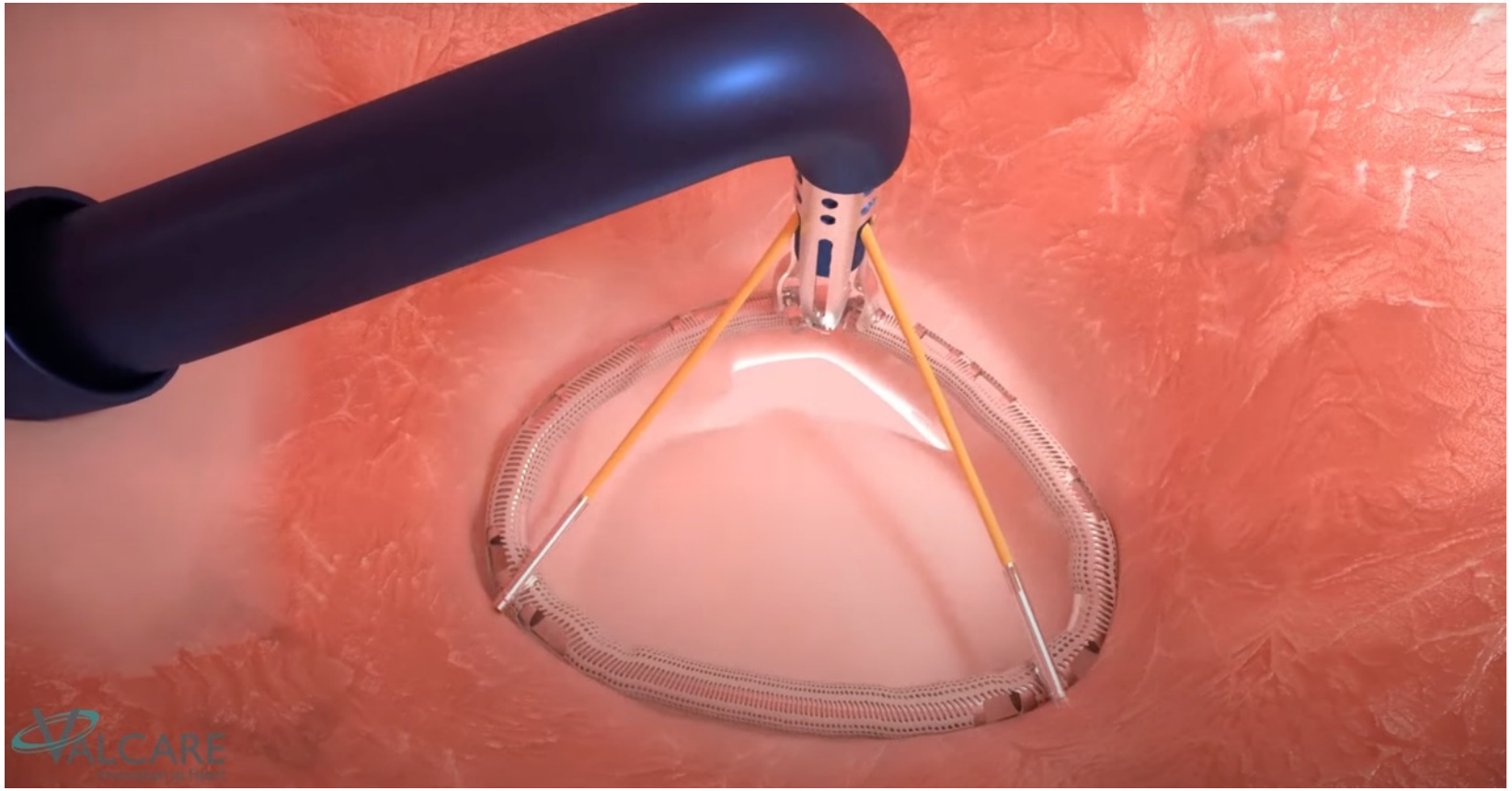
innovalve



TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Amend Valve Repair System

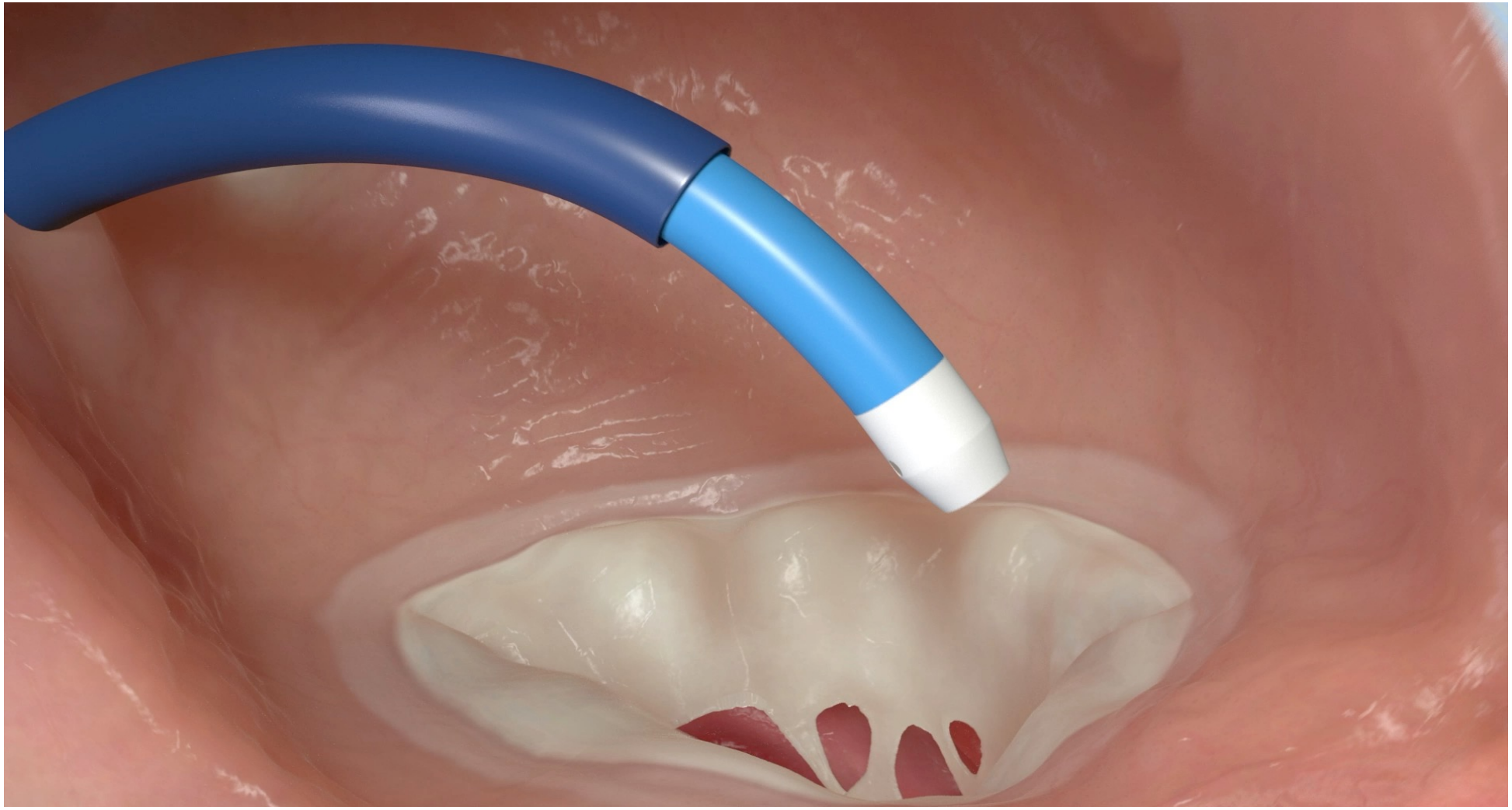


VALCARE
Innovation at Heart

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Coriofix



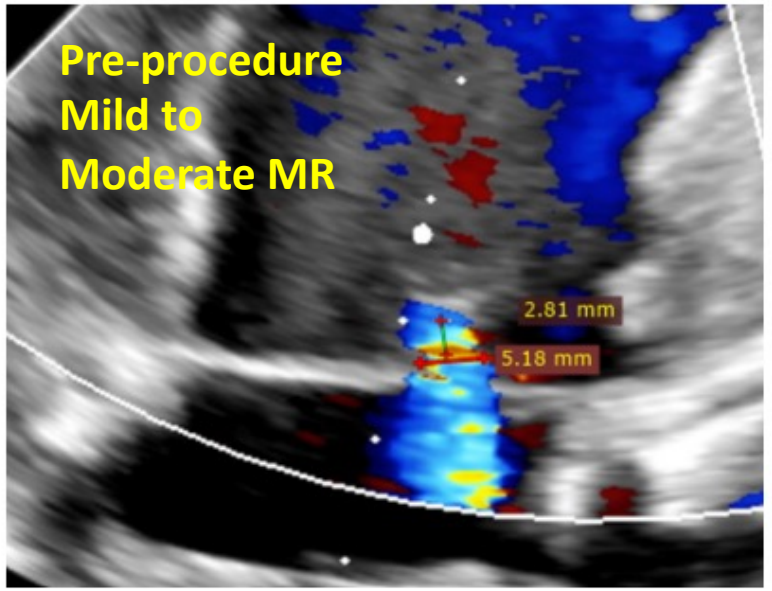
Bio ReFine

TEL AVIV UNIVERSITY

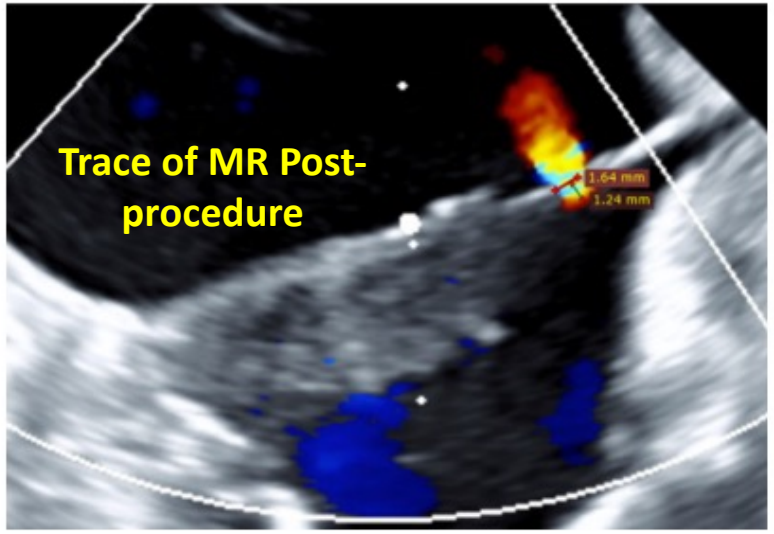
ANIMAL TRIAL RESULTS – ACUTE

	sheep AS22394 - Average measurement		
	Day 0		
Weight [kg]	81.4		
# of ablation points	12		
Dimensions / Average Measurements	**Before**	**After**	**% (-) reduction/ (+) Increase : Nominal**
C1 - C2 [cm]	4.08	3.67	**-10.11%**
A2-P2 [cm]	3.28	2.61	**-20.2%**
Annulus perimeter [cm]	12.08	10.38	**-14.1%**
Annulus Area [cm^2]	10.58	7.81	**-26.2%**
Coaptation Height [cm]	0.39	0.59	**50.0%**

MR PREPROCEDURE



MR POSTPROCEDURE



TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

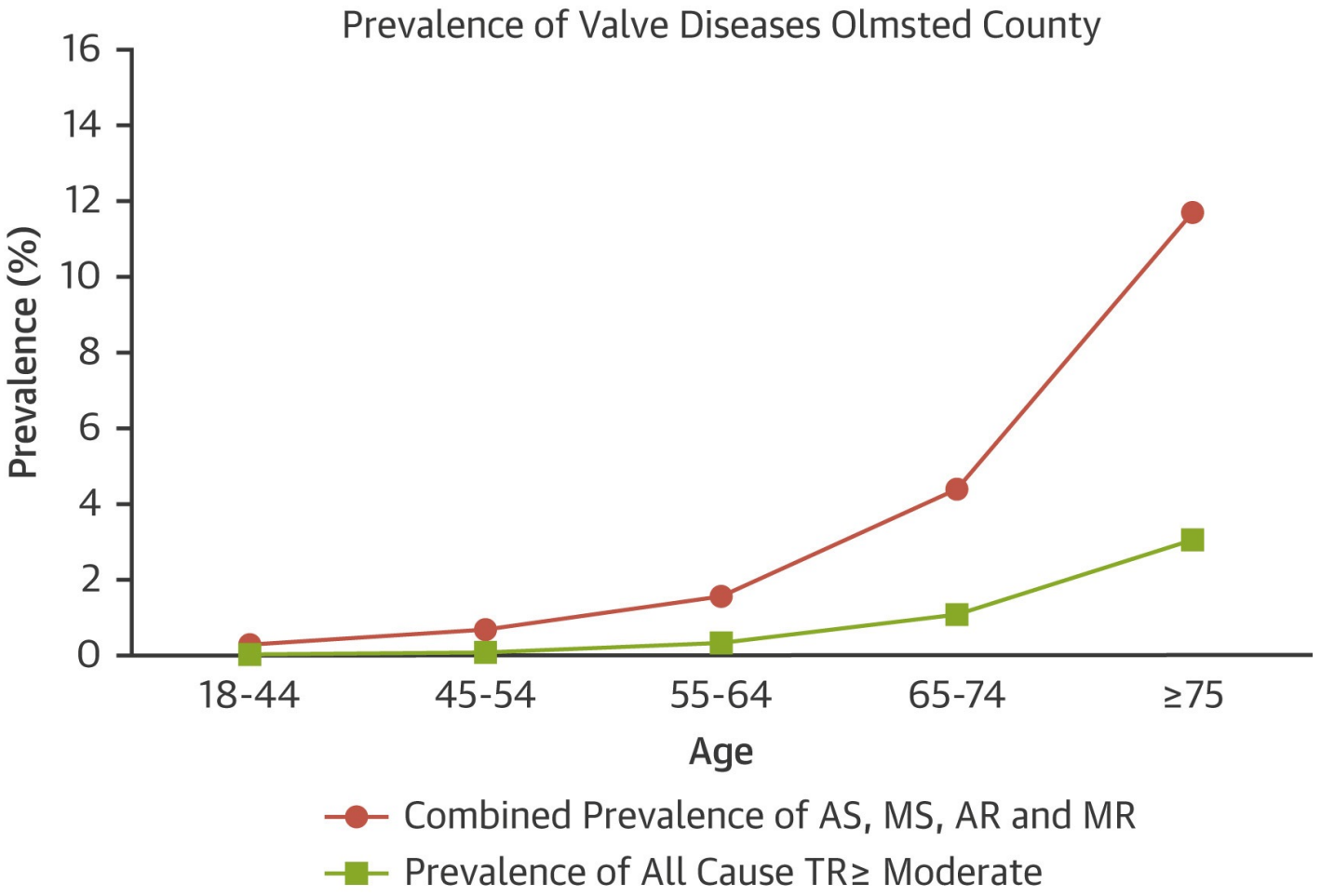
Remaining Questions for MR Therapy

- Competitors to TEER? TMVR Perhaps?
- Combination therapy? TEER + Annuloplasty?
- Clear clinical impact in degenerative MR vs surgery
- Optimal timing

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Burden of Tricuspid Regurgitation

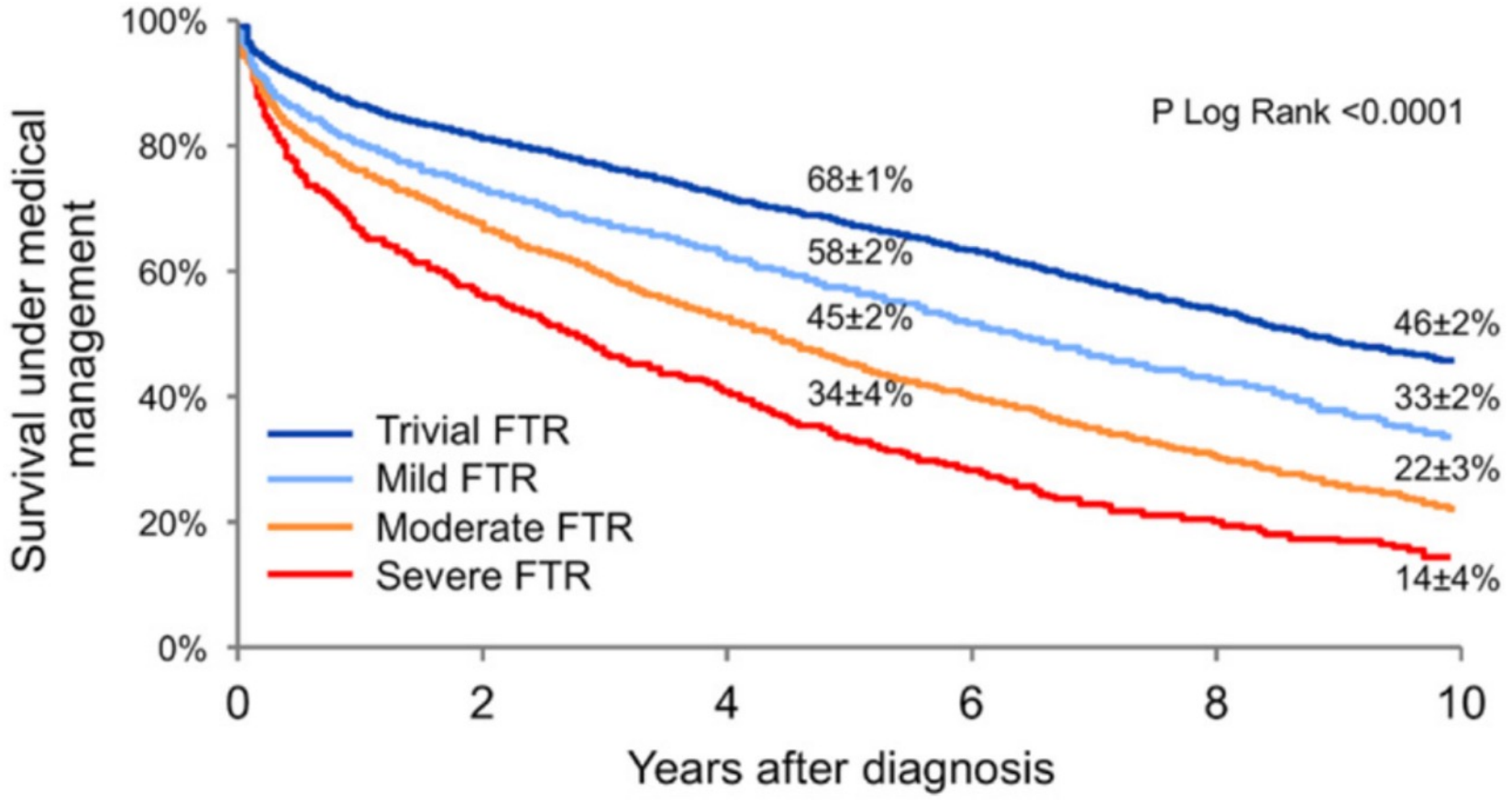


J Am Coll Cardiol Img 2019;12:433–42

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Tricuspid regurgitation is a public health crisis!



M. Enriquez-Sarano et al. Progress in Cardiovascular Diseases 62 (2019) 447–451

TEL AVIV UNIVERSITY

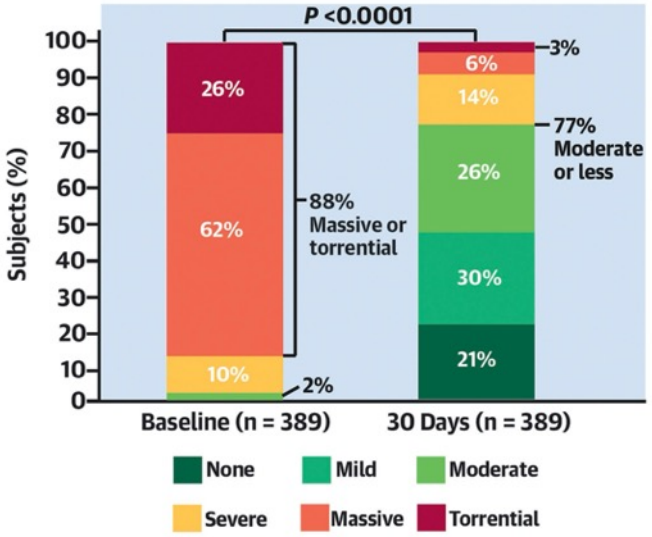
RABIN MEDICAL CENTER
BEILINSON • HASHARON

CENTRAL ILLUSTRATION: Transcatheter Tricuspid Valve Repair Safe and Effective in Real-World Population

Real-World Population

- Mean age: 78.9 years
- Mean LVEF 55.8%
- NYHA functional class III/IV: 88%
- Male: 44%
- Prior HF Hospitalization: 40.3%
- Baseline KCCQ score: 44.52

Reduction in TR at 30 Days



Safety Profile at 30 Days

Major Adverse Event	2.7%
• Cardiovascular mortality	0.8%
• Myocardial infarction	0.0%
• Stroke	0.4%
• New onset renal failure	1.4%
• Endocarditis requiring surgery	0.0%
• Nonelective CV surgery for device-related AE	0.2%

MAEs adjudicated by independent clinical events committee

Lurz P, et al. J Am Coll Cardiol. 2023;82(4):281-291.

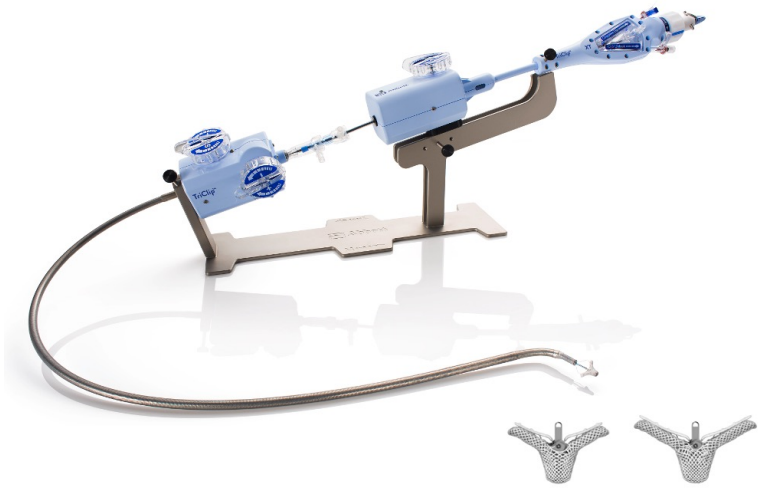
TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

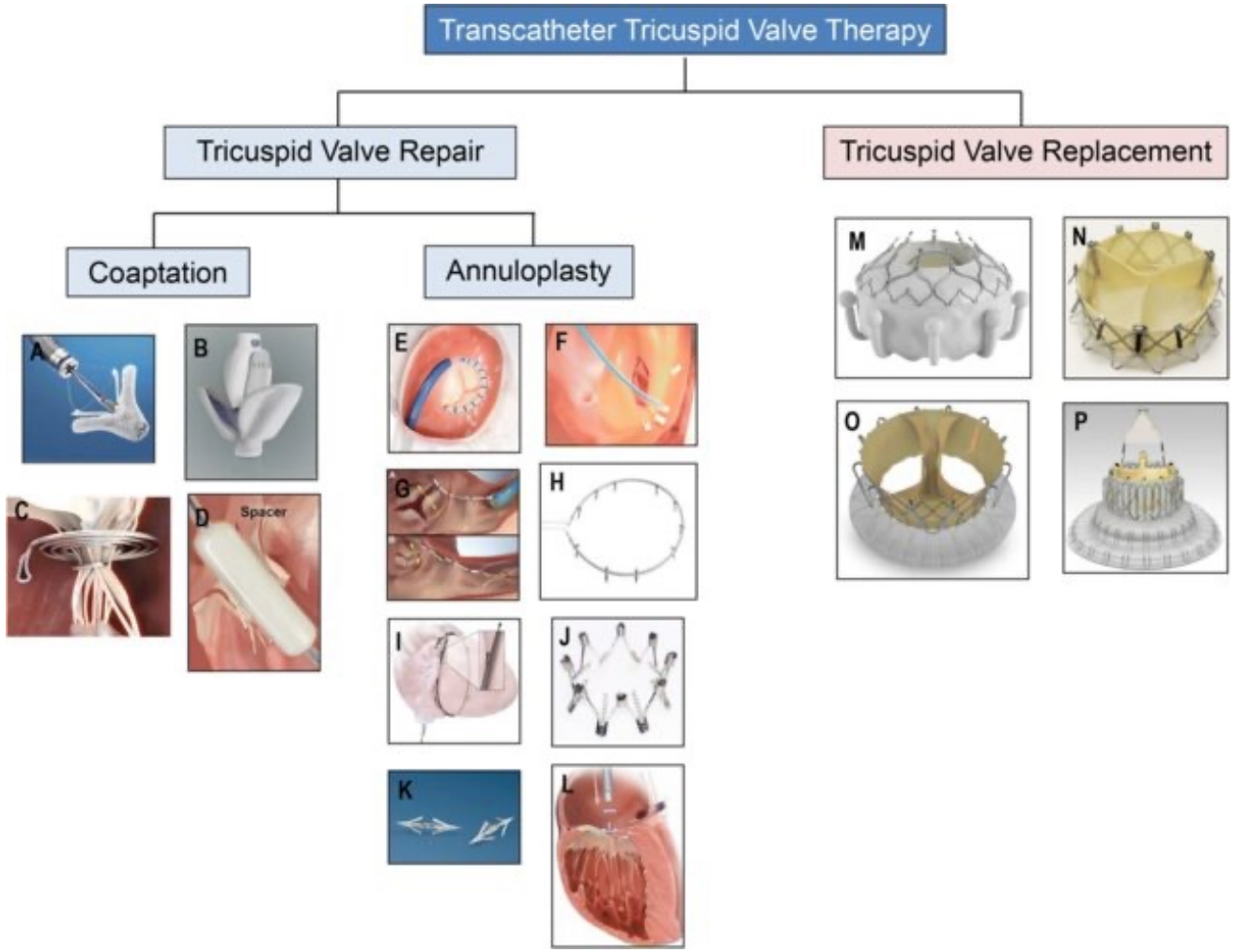
FDA Advisory Committee Votes in Favor of Abbott's First-of-Its-Kind TriClip™ System to Treat People With a Leaky Tricuspid Heart Valve

המלצות הועדה הציבורית להרחבת סל שירותי הבריאות - עדכון 2024

"תיקון דליפה טריקוספידלית קשה בחולים עם אי ספיקה לבבית ללא עדות למחלה מיטראלית משמעותית, למרות מיצוי הטיפול התרופתי המקסימלי, ואשר אינם מתאימים לניתוח וקיימת בהם אנטומיית מסתם מתאימה"



Transcatheter Tricuspid Valve Therapies

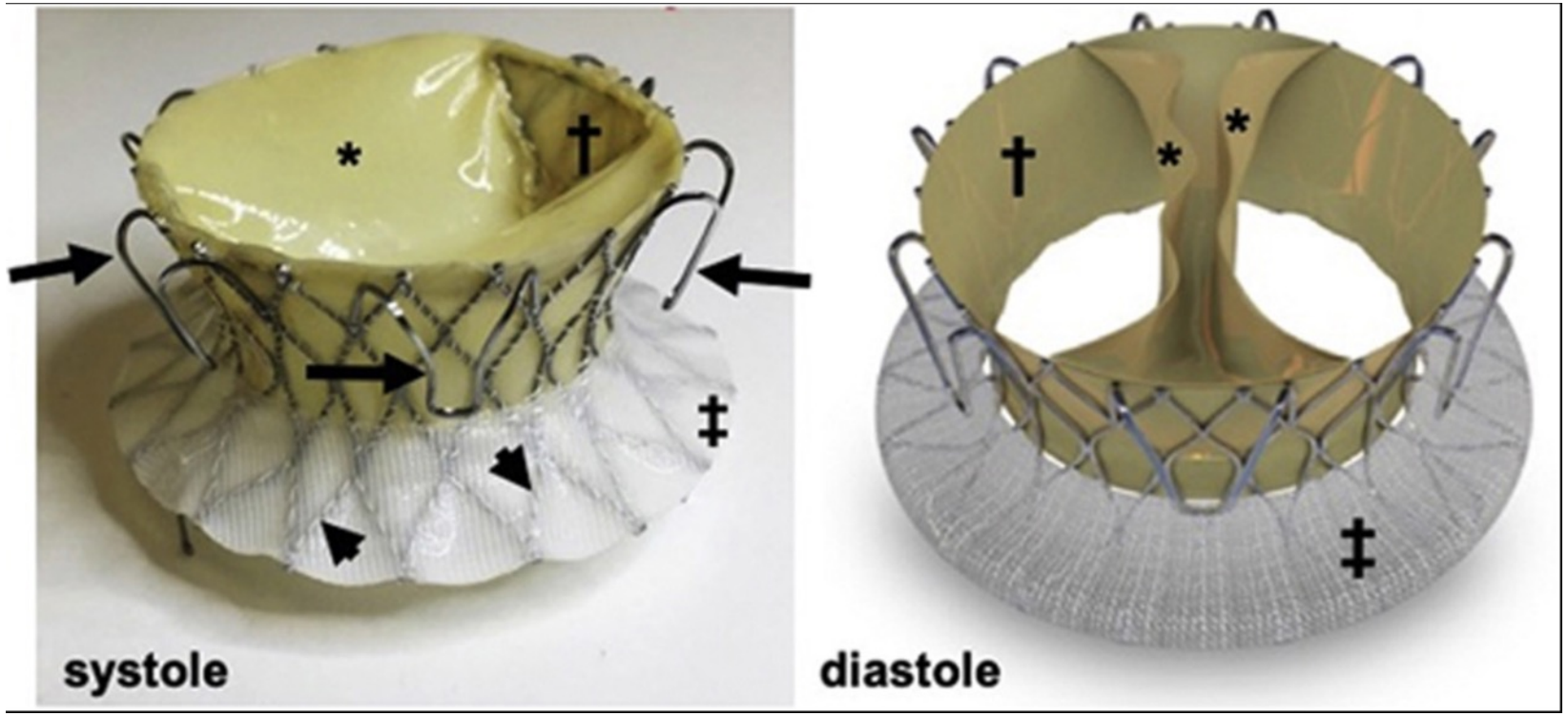


Curr Treat Options Cardio Med (2021) 23: 60

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

TRISOLMEDICAL
tricuspid valve replacement

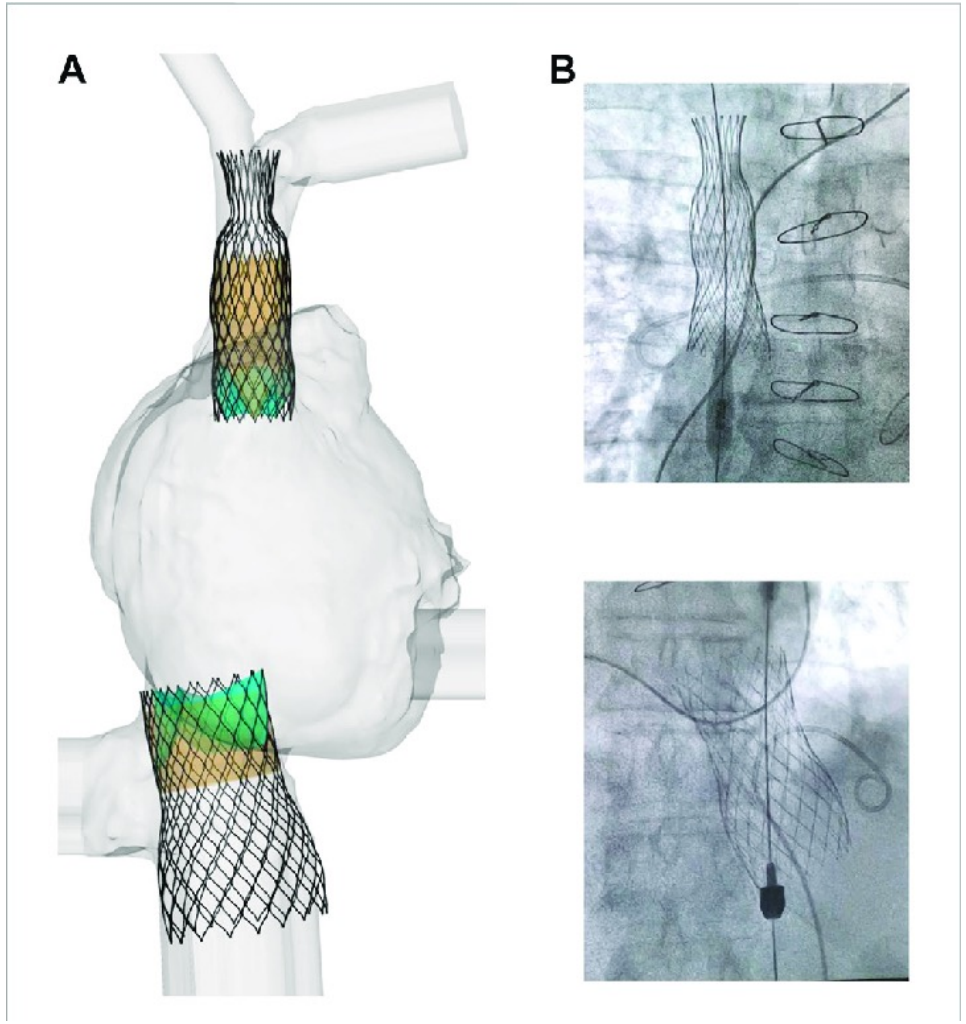


J Am Coll Cardiol Case Rep 2021;3:1281–1286

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

TRICVALVE®



CENTRAL ILLUSTRATION: Summary of Main Outcomes at 1 Year Following TricValve

Long-Term Follow-Up of Bicaval TricValve for Severe Symptomatic Tricuspid Regurgitation, N = 44

Findings	TRICUS Study N = 9	and	TRICUS EURO Study N = 35
Functional result	↑ KCCQ-12 $P < 0.001$	↑ NYHA $P < 0.001$	↑ 6MWT $P = 0.285$
Labs/Drugs	↓ Diuretic dose	↓ NTproBNP	= Kidney and liver function
Prognostic result	CV death 2.2%	HF readmission 29.5%	Stroke 9.0%
Safety outcomes	Major bleeding 20.0%	Right heart thrombi (normal leaflets) 13.6%	TV surgery 2.2%

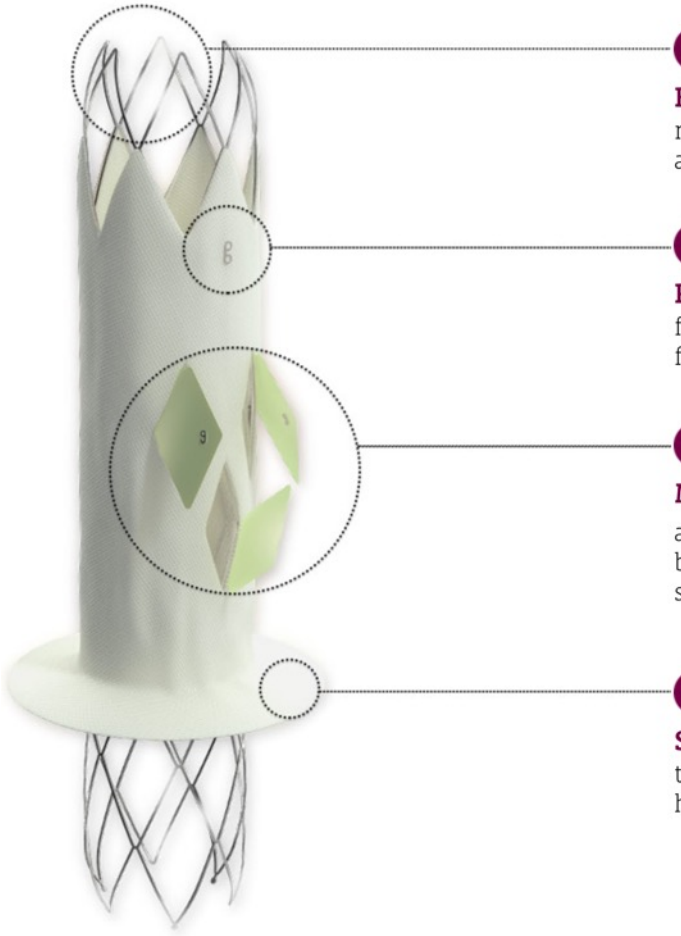
- TricValve CAVI associated with improved symptoms and QOL at 1 year
- Relatively low cardiac mortality

Blasco-Turrión S, et al. J Am Coll Cardiol Intv. 2024;17(1):60-72.

TEL AVIV UNIVERSITY

INNOVENTRIC
Simplicity at Heart

RABIN MEDICAL CENTER
BEILINSON • HASHARON



01
BARE METAL STENT
reliable A-traumatic anchoring
and bifurcation blood inflow

02
RADIO-OPAQUE MARKER
for accurate positioning in
fluoroscopy based procedures

03
MULTIPLE VALVES
allow the required
blood inflow and
simplify device positioning

04
SEALING SKIRT
tight seal while allowing
hepatic vein inflow

Rev Esp Cardiol. 2023 Sep;76(9):750

TEL AVIV UNIVERSITY

INNOVENTRIC
Simplicity at Heart

RABIN MEDICAL CENTER
BEILINSON • HASHARON

CONTACT

EMAIL: info@innoventric.com

ADDRESS: 3 Golda Meir, Ness-Ziona. Israel

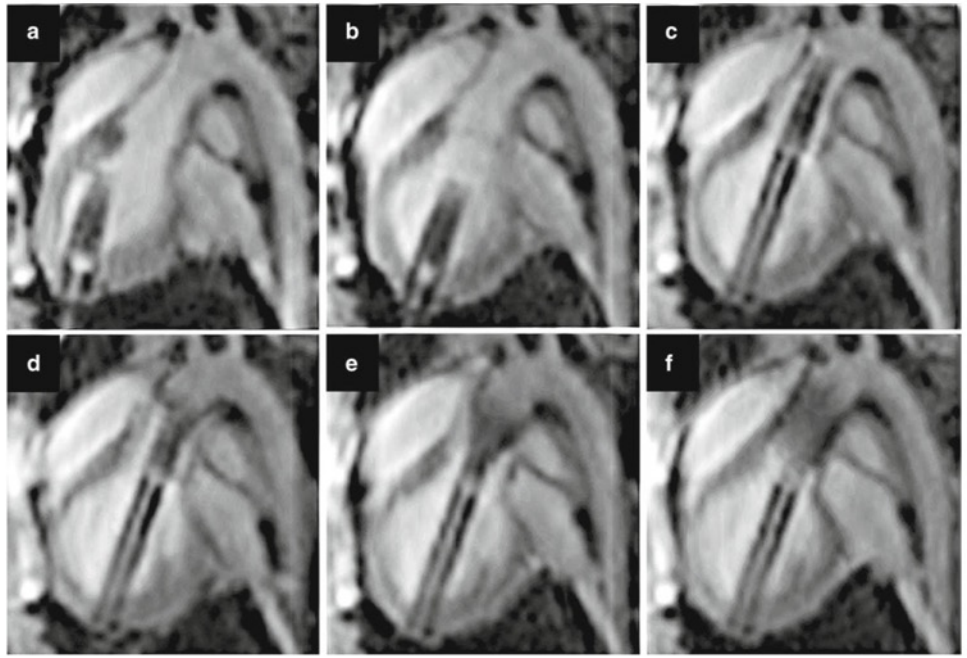
TEL AVIV UNIVERSITY

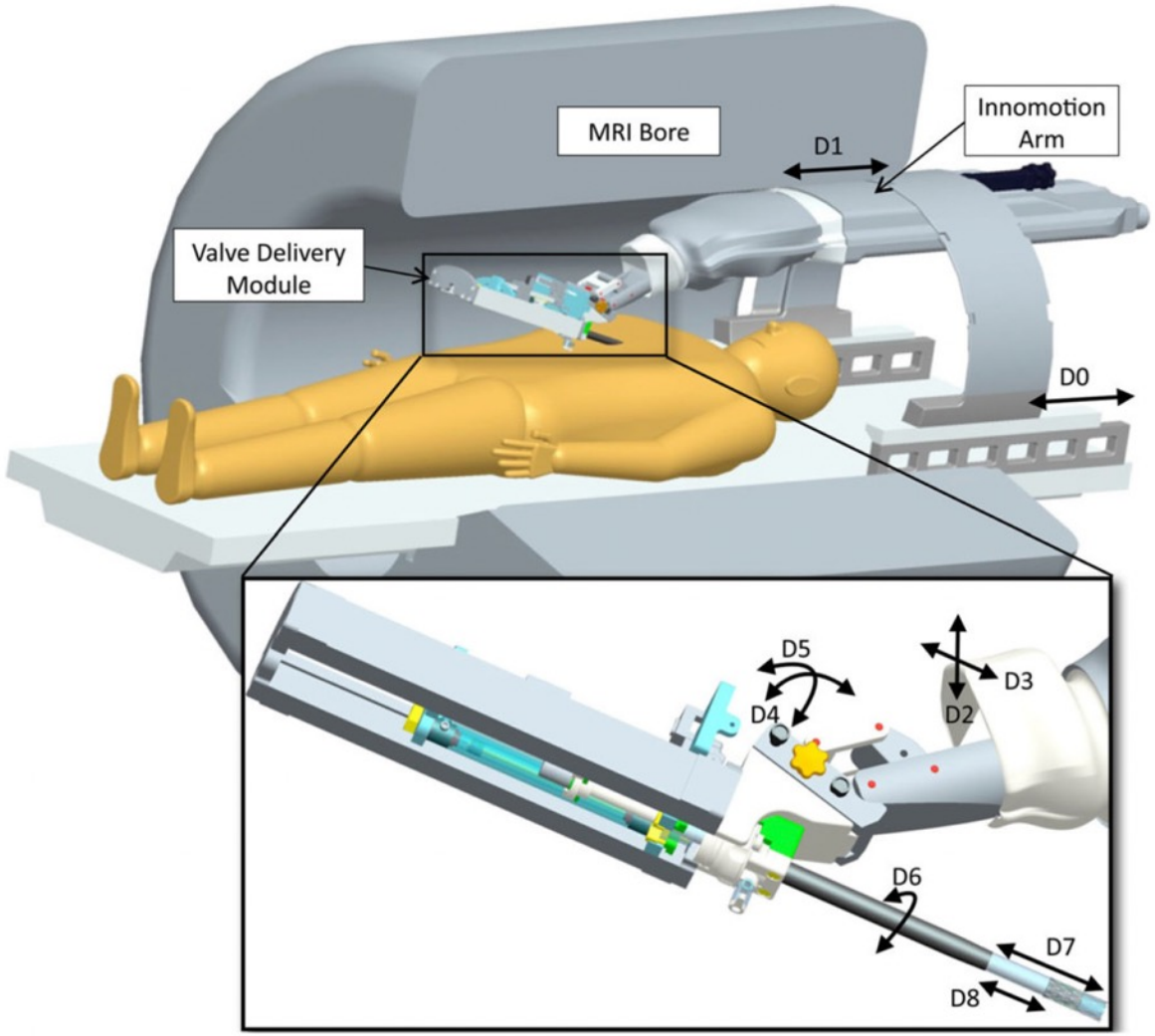
RABIN MEDICAL CENTER
BEILINSON • HASHARON

Remaining Questions for TR Therapy

- Optimal imaging for TV
- Is T-TEER comparable to M-TEER?
- TTVR? Orthotropic?
- Clinical impact beyond quality of life
- Optimal timing

Robotic-assisted real-time MRI-guided TAVR



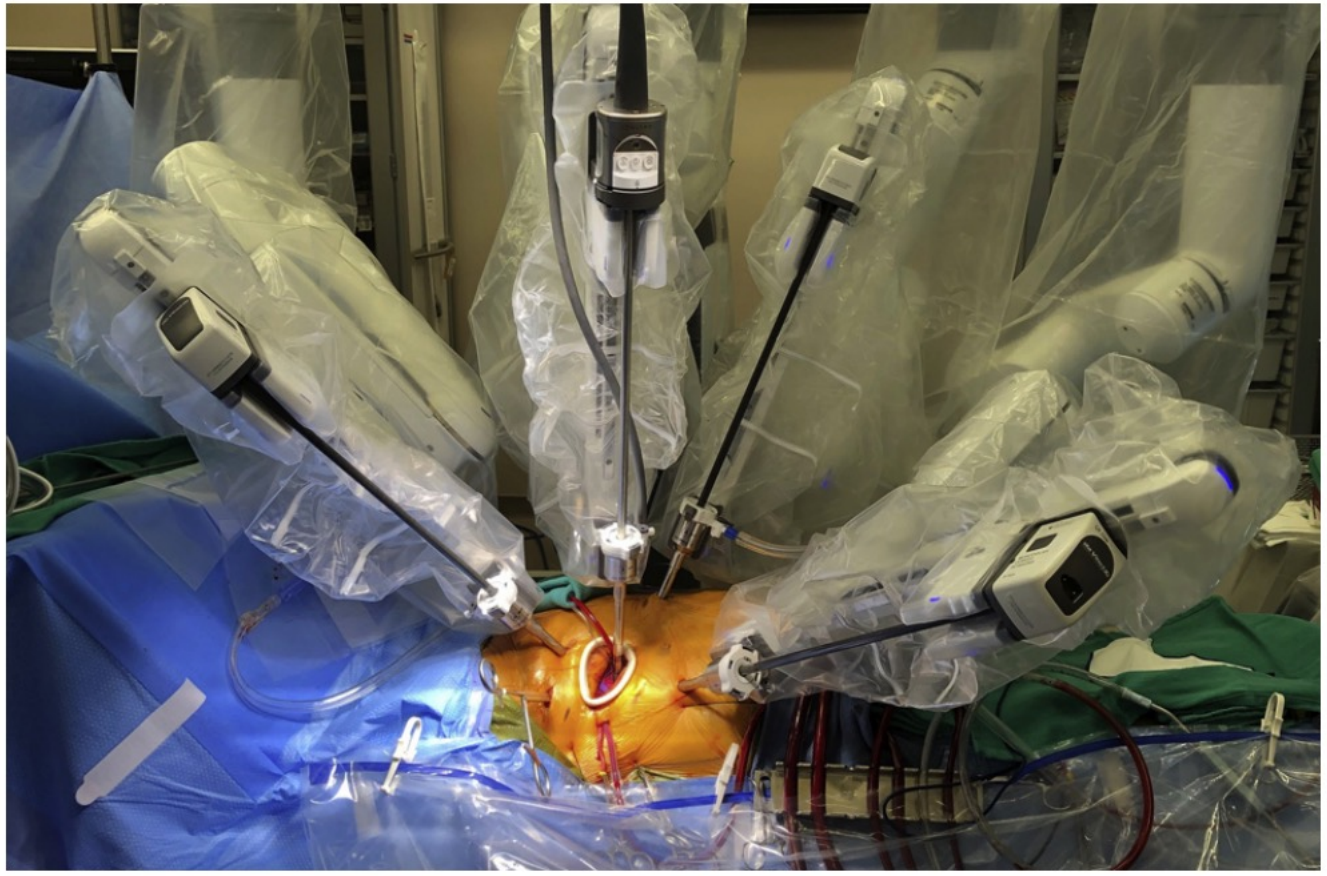


Int J Comput Assist Radiol Surg. 2016 October ; 11(10): 1905–1918

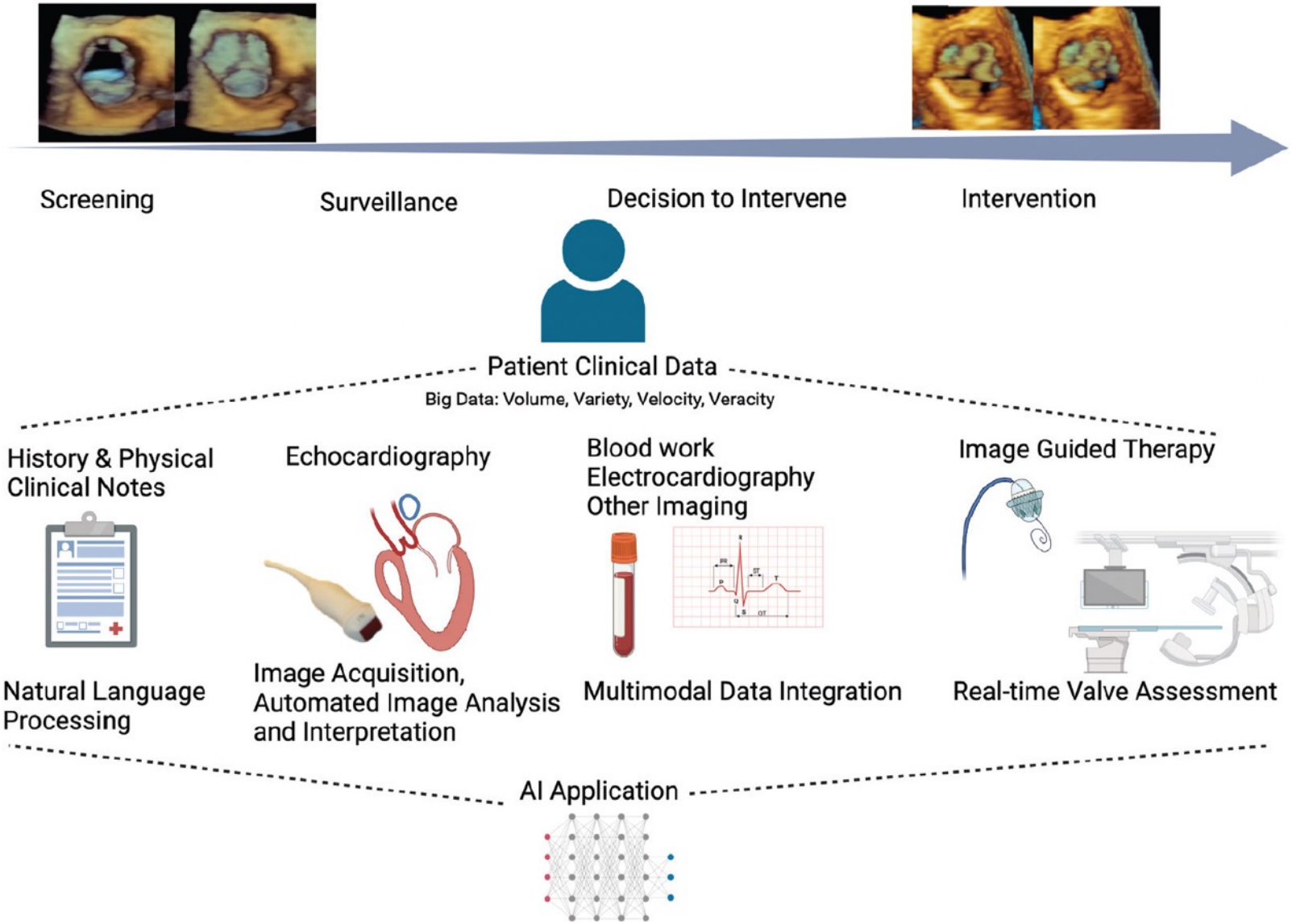
TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Robotic Aortic Valve Replacement

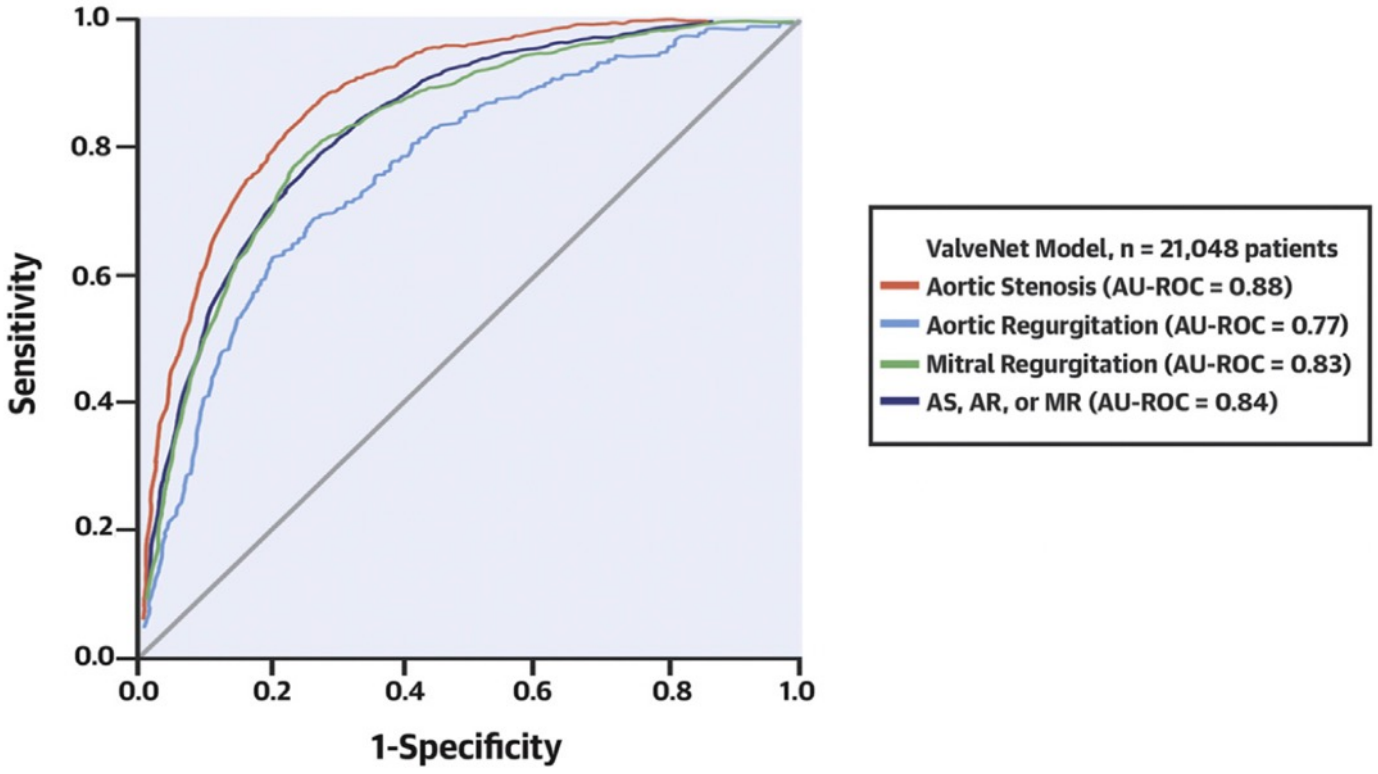


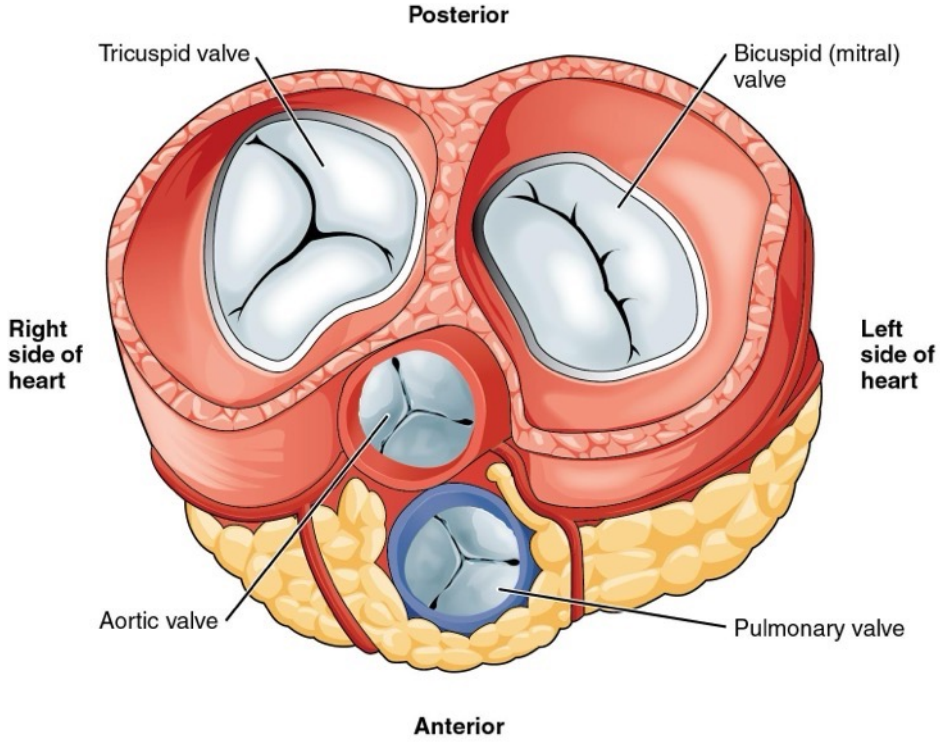
J Thorac Cardiovasc Surg 2020;-:1-7



Nedadur R, et al. Heart 2022;108:1592–1599

AI to Predict Valvular Disorders





Elias P, et al. J Am Coll Cardiol. 2022;80(6):613–626.

TEL AVIV UNIVERSITY

RABIN MEDICAL CENTER
BEILINSON • HASHARON

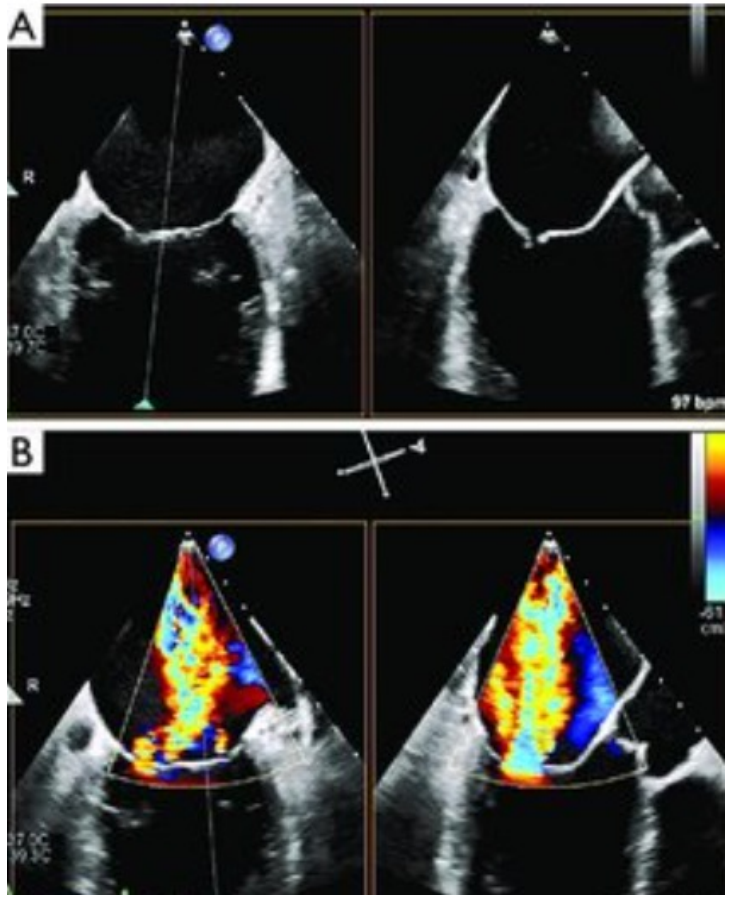
AI to Diagnose and Characterize Valvular Disease

a'sap

AI to Predict TEER Success and Guide Treatment

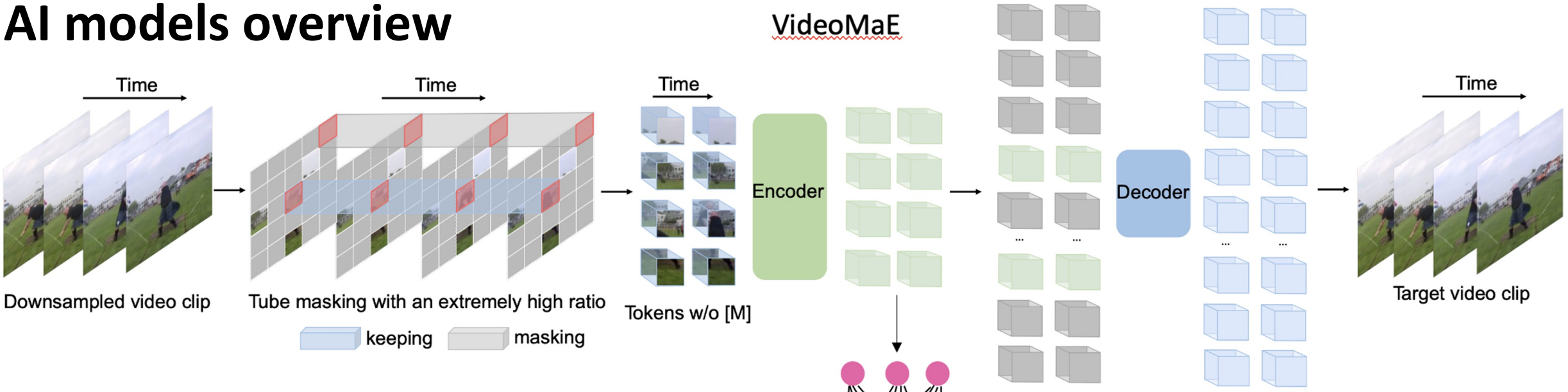
Severe MR patients from an international multi-center cohort:

- **TEE videos** standard views before and after procedure:
  3D, BIC, and LVOT
- **Tabular patient data** including, degree of MR before and after TEER, past medical history, valve measurements, etc.

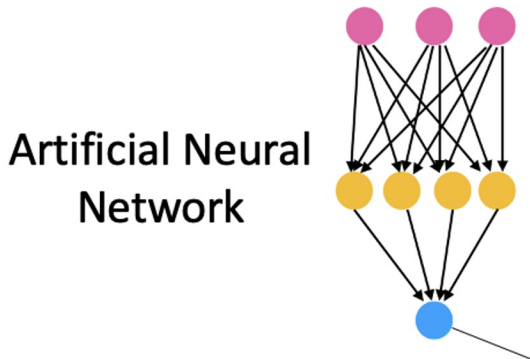


Bernal,Overview of Transesophageal Echocardiography for the Chest Physician,Chest, Volume 124, Issue 3, 2003, Pages 1081-1089,

AI models overview

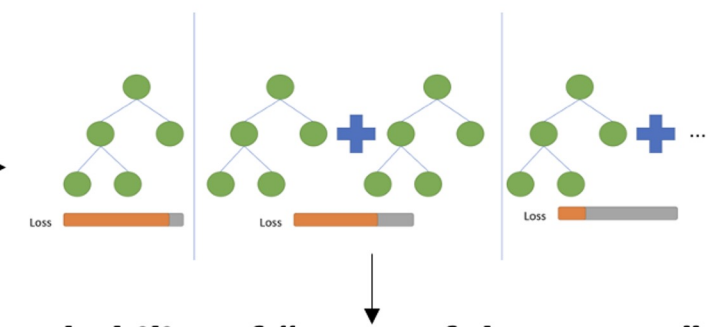


- VideoMAE
- Artificial Neural Network (NN)
- CatBoost



Tabular Data

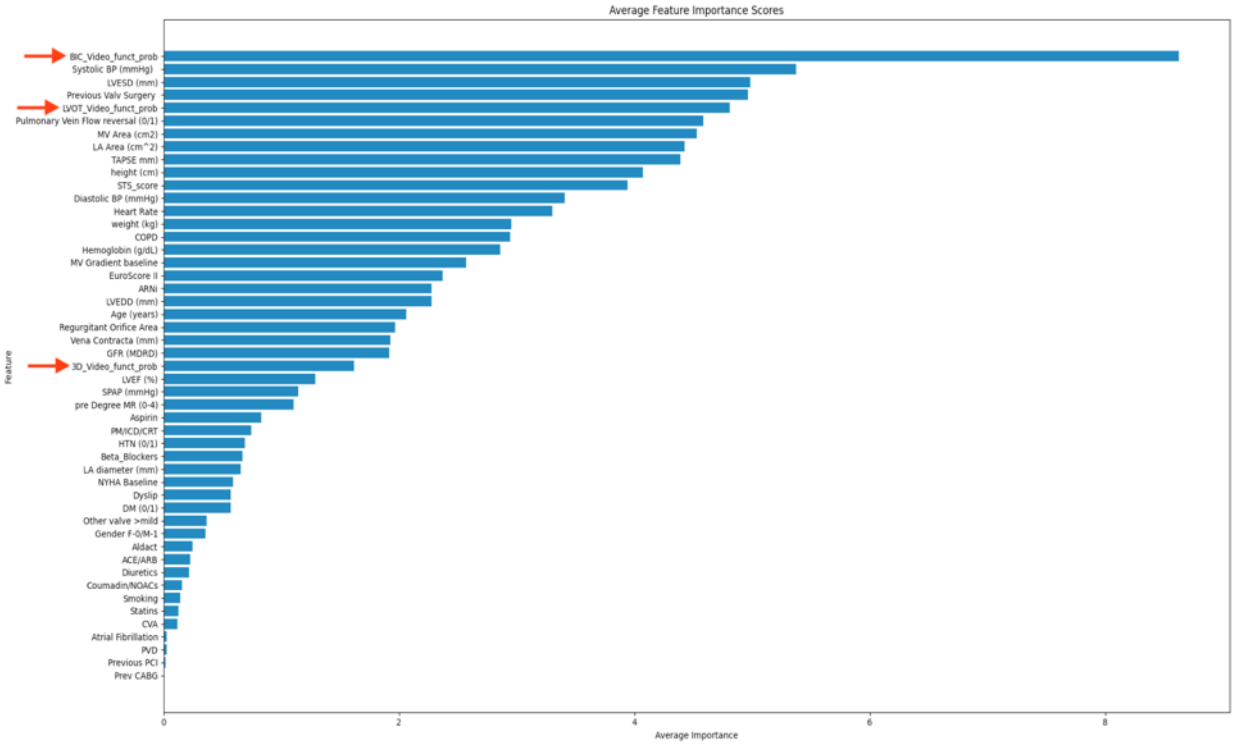
feature	feature	feature	feature	New
10	120	80	40	0:50:05
11	255	130	125	1:40:03
12	180	100	80	1:20:19
13	305	205	100	1:58:58
14	71	50	21	0:35:41
15	418	310	108	2:08:18
16	222	150	72	1:32:58



Credit to: Nadav Loebl

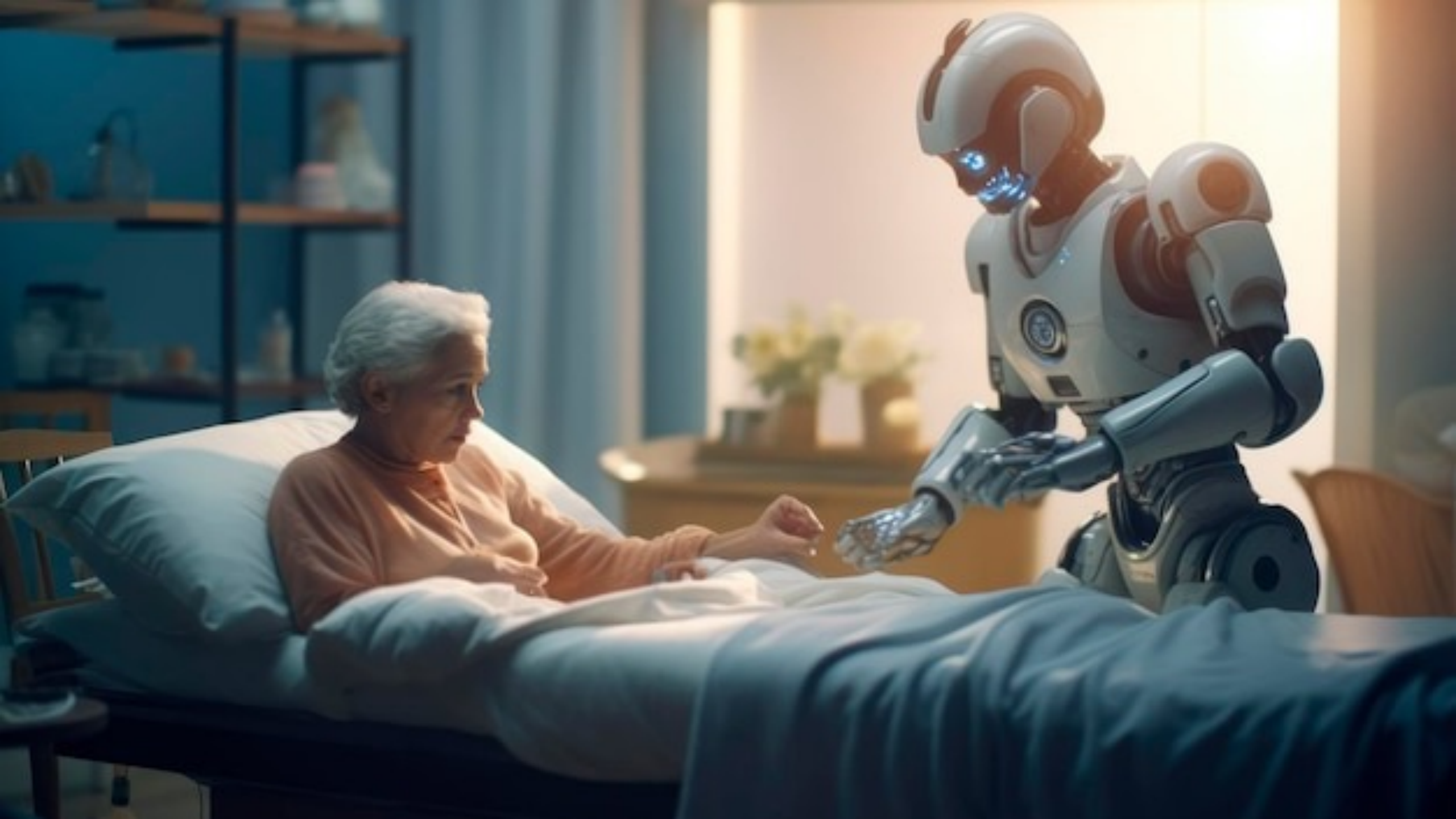
https://arxiv.org/pdf/2203.12602.pdf

Preliminary Results



Performance Metric	Average Value
Accuracy	74.76%
AUC	0.777
Sensitivity	88.33%
Specificity	60.0%
Positive Predictive Value	74.00%
F1-Score	78.61%

*** Using a cross-validation strategy, this involved training and testing five separate models on different 80%-20% splits of the data, results are the average of the five separate models.



תהנו מהמשך כנס המסתמים!

LEORPERL@GMAIL.COM

LEORPER@CLALIT.ORG.IL

054-9558228