Kleplijden en percutane klepinterventies

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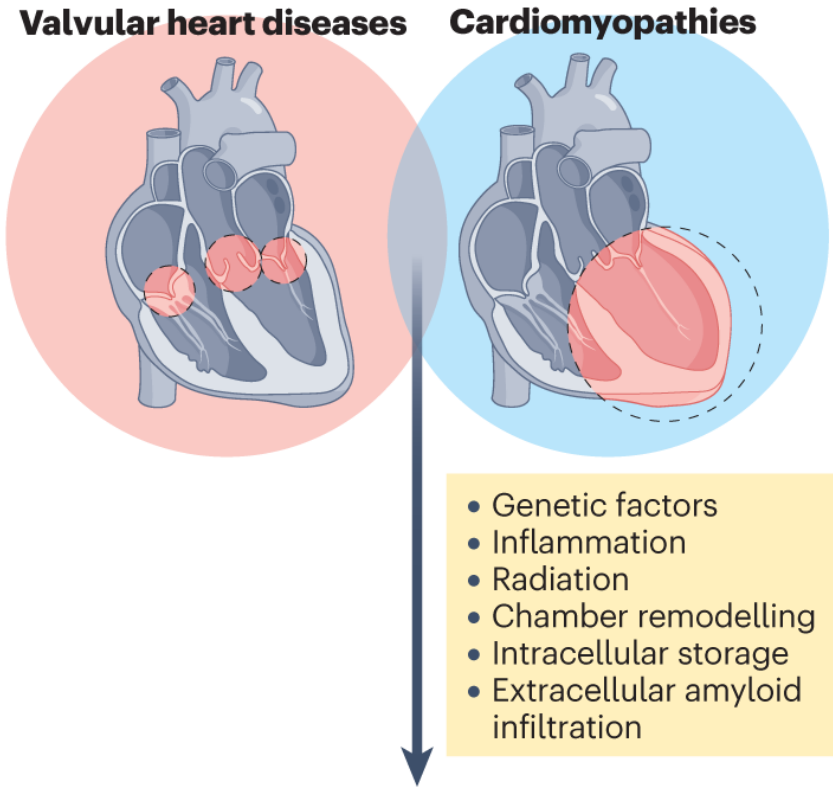
HARTFALEN ACADEMIE NEDERLAND

CVGK

Indeling

- ✓ **Samenhang cardiomyopathiën en hartklepproblemen**
- ✓ **TAVI historie, richtlijnen en casuïstiek**
- ✓ **Mitralisklep insufficiëntie richtlijnen en casuïstiek**
- ✓ **Casuïstiek buiten alle richtlijnen ;-)**
- ✓ **Discussie**

Samenhang tussen klep en cardiomyopathie



Valvular heart disease and cardiomyopathy coexistence
- Dilated cardiomyopathy
- Hypertrophic cardiomyopathy

Valvular heart disease with possible concomitant myocardial involvement
- Mitral valve prolapse
- Bicuspid aortic valve

Cardiomyopathy with possible concomitant valvular involvement
- Cardiac amyloidosis
- Mucopolysaccharidosis
- Fabry disease
- RASopathy

Acquired disease causing valvular heart disease and cardiomyopathy
- Autoimmune disorder
- Radiation-induced cardiac damage

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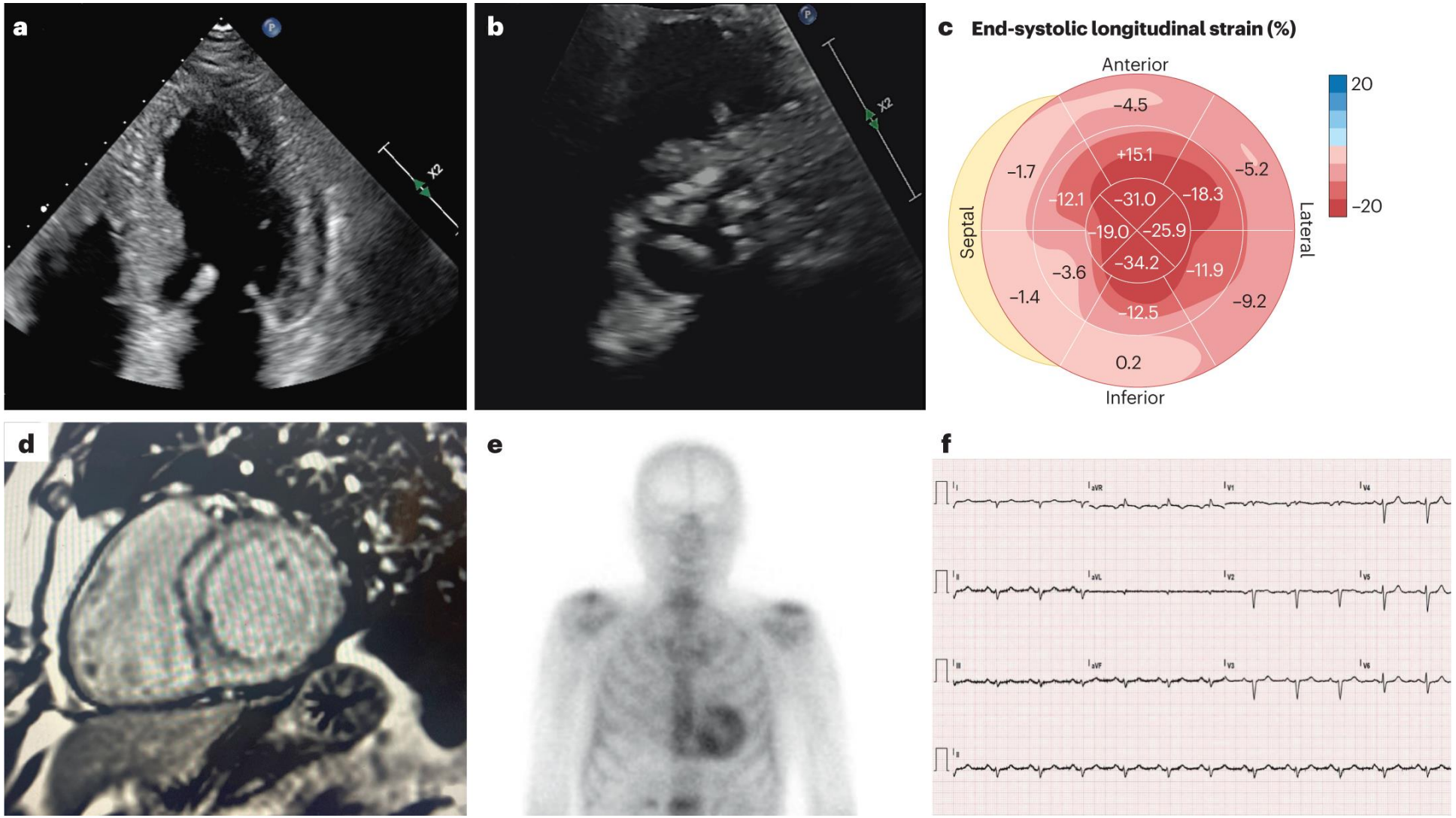
Ajmone Marsan, N., Graziani, F., Meucci, M.C. et al. Valvular heart disease and cardiomyopathy: reappraisal of their interplay. Nat Rev Cardiol (2023). https://doi.org/10.1038/s41569-023-00911-0

Amyloïdose – aortaklepstenose



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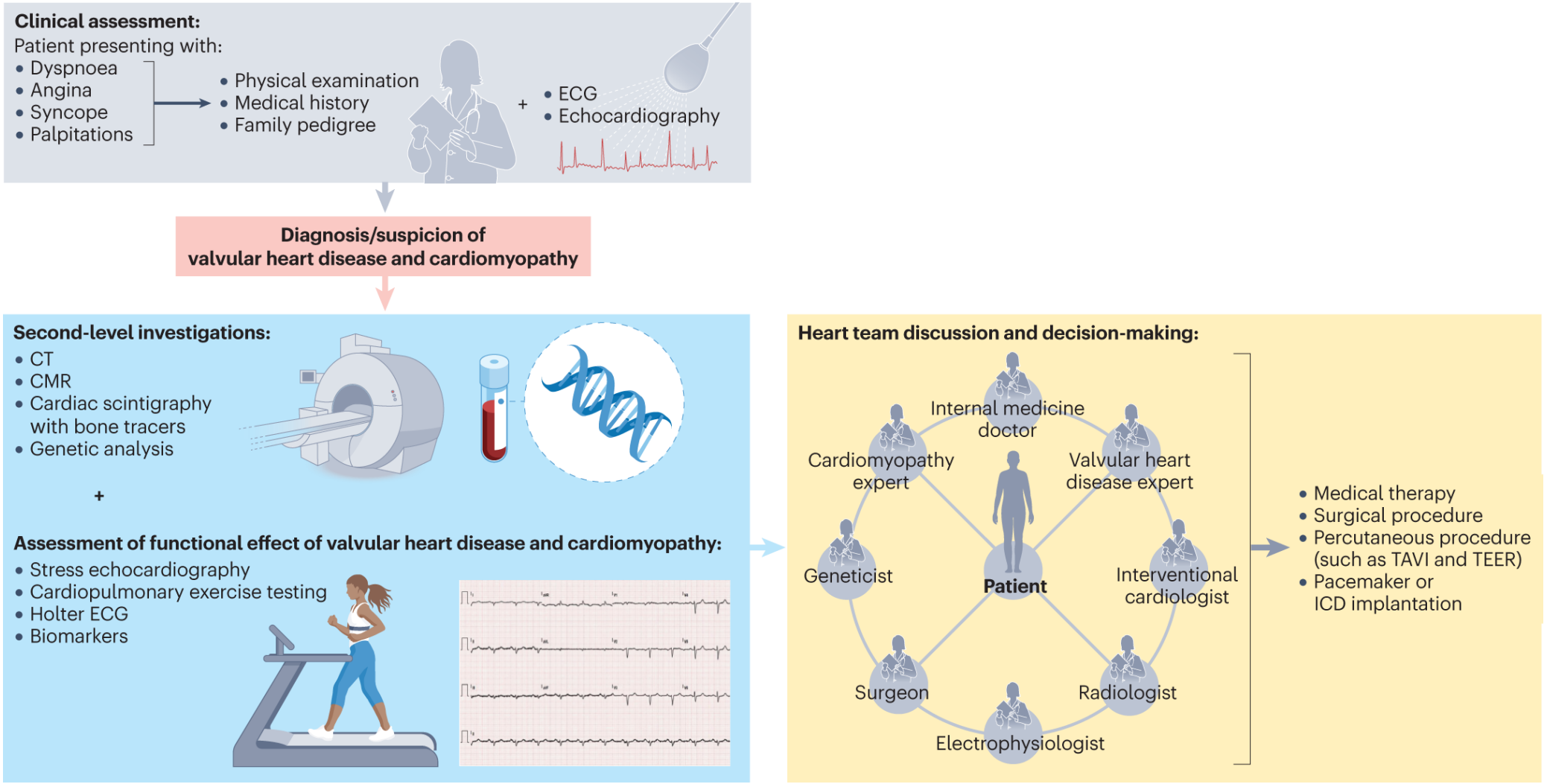
Ajmone Marsan, N., Graziani, F., Meucci, M.C. et al. Valvular heart disease and cardiomyopathy: reappraisal of their interplay. Nat Rev Cardiol (2023). https://doi.org/10.1038/s41569-023-00911-0

Analyse bij verdenking CMP icm kleplijden: teamwork!



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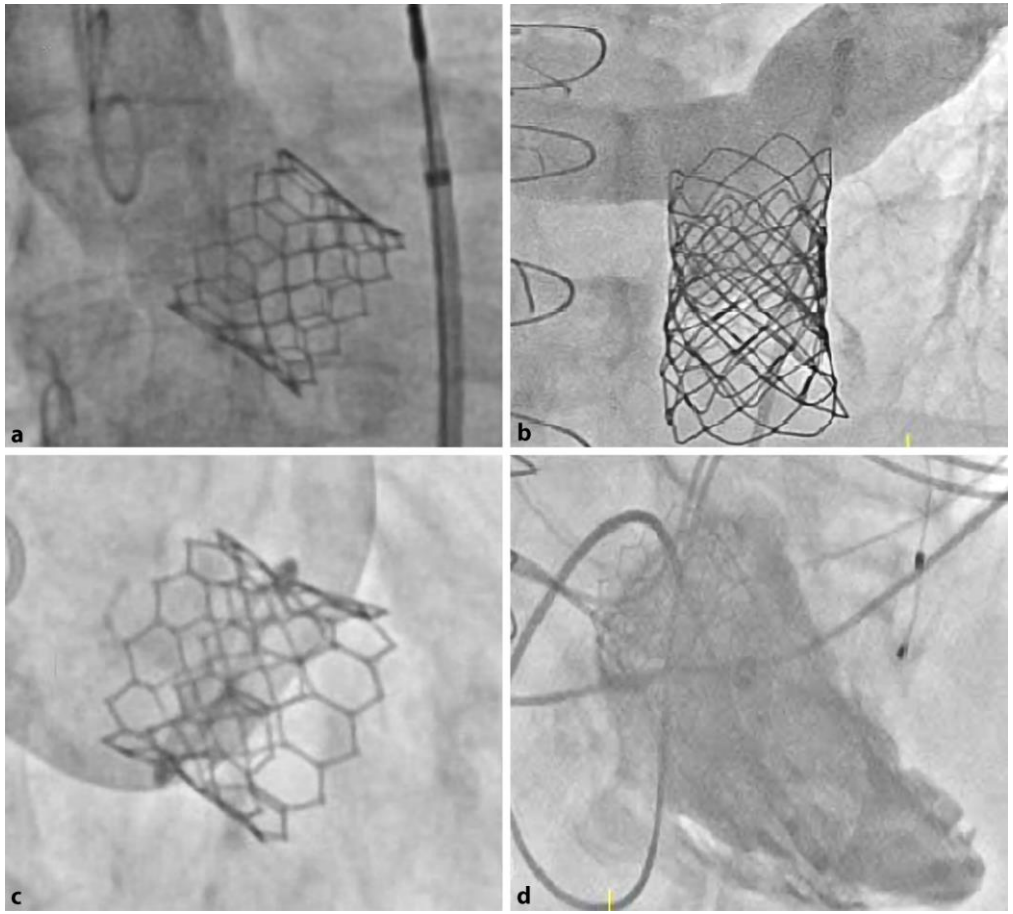
REFERENTIE NATURE!

Interventiecardiologie 2023: ‘Heel het hart’

Percutaneous valve in all four positions

H. M. Aarts · A. O. Kraaijeveld · P. R. Stella · M. Voskuil

Neth Heart J (2022) 30:443–444
https://doi.org/10.1007/s12471-022-01691-x



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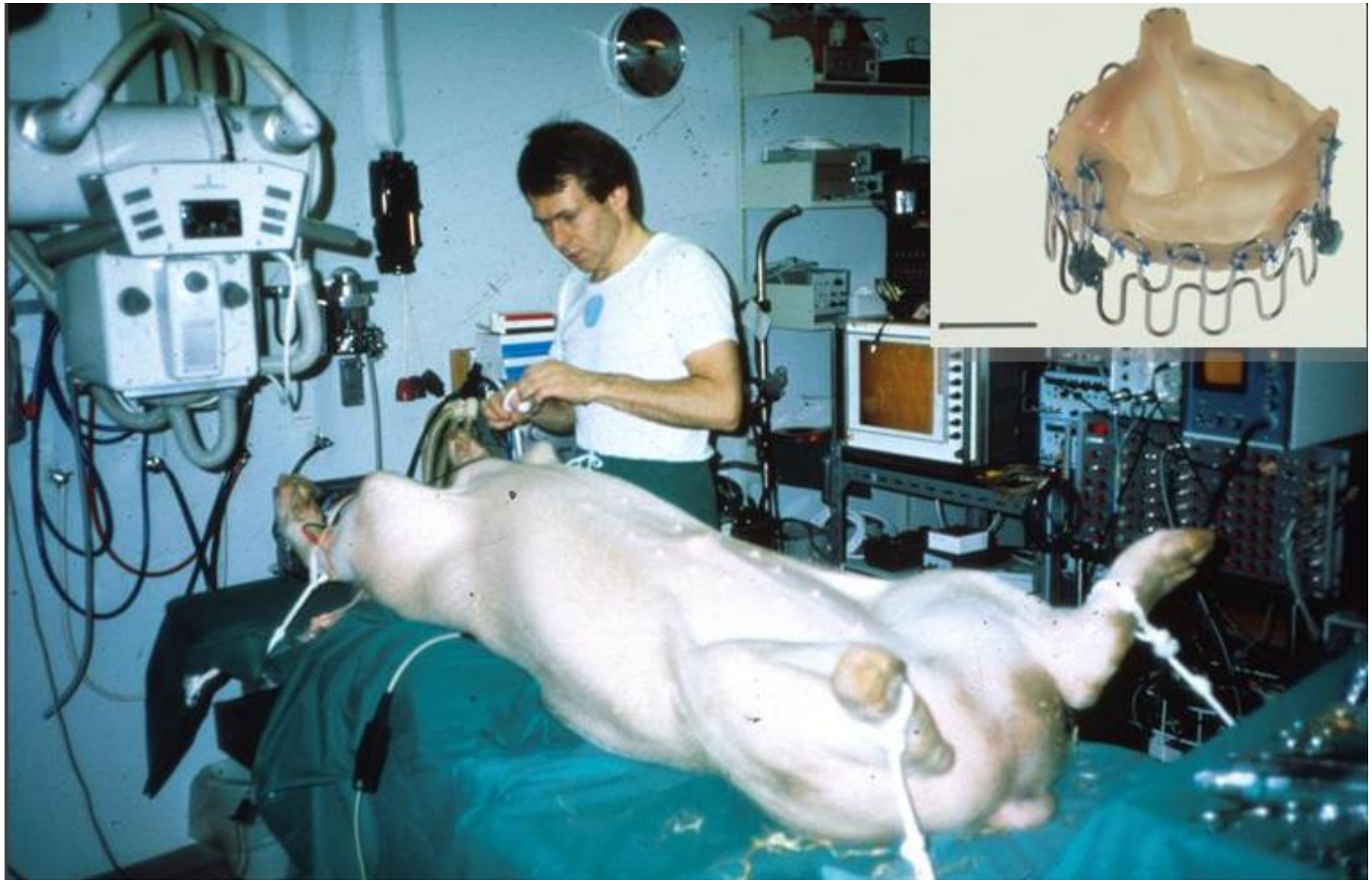
Henning-Rud Andersen 1988 ⇢ 2011



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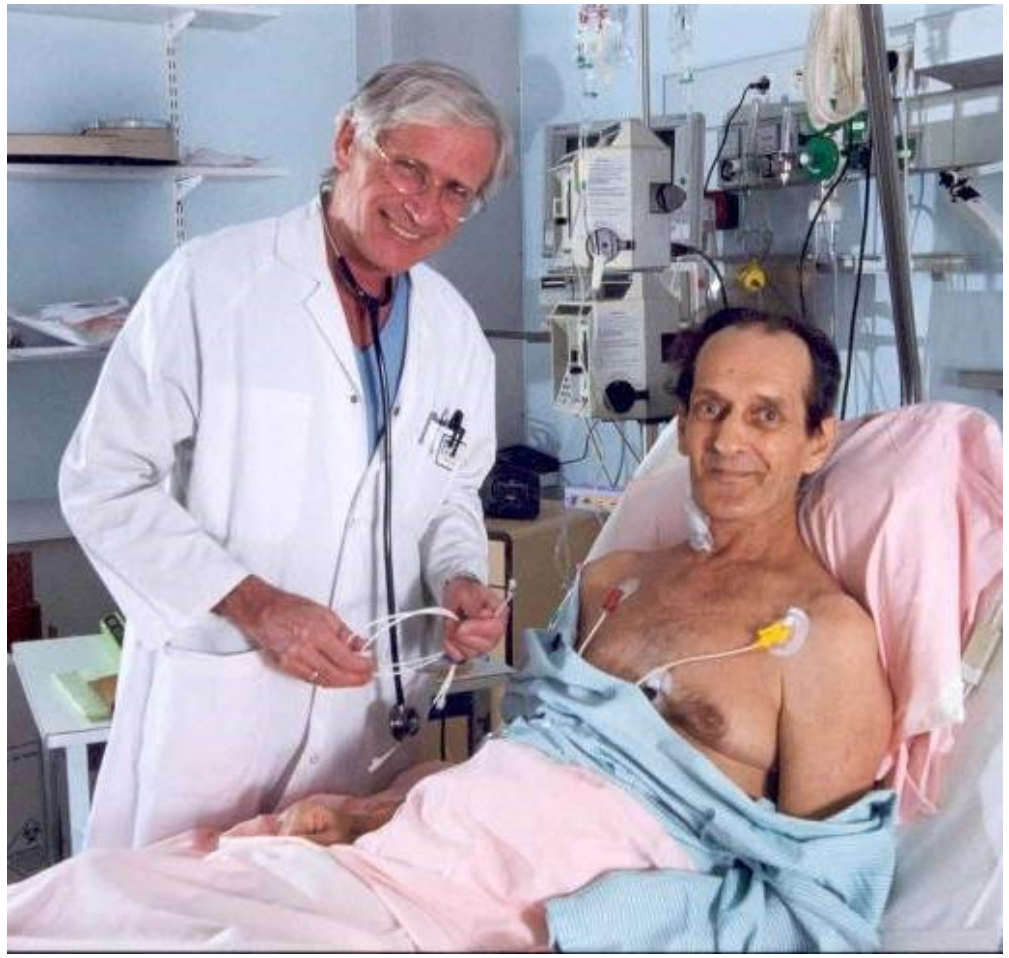
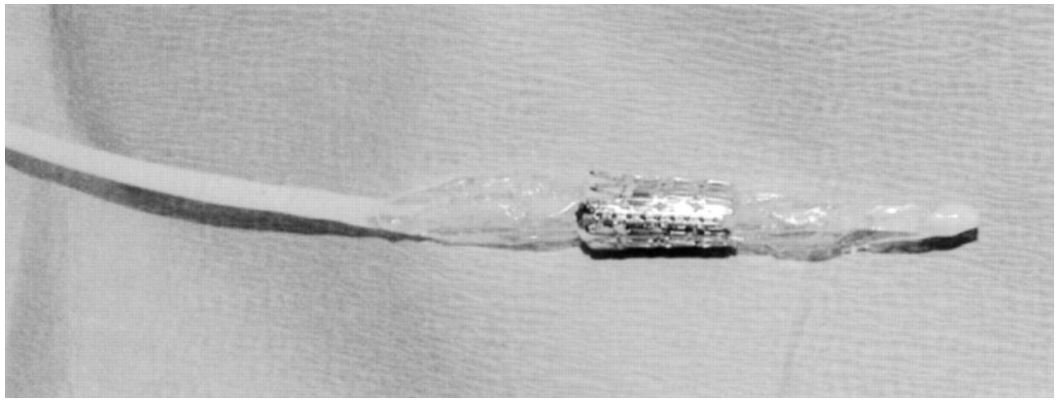
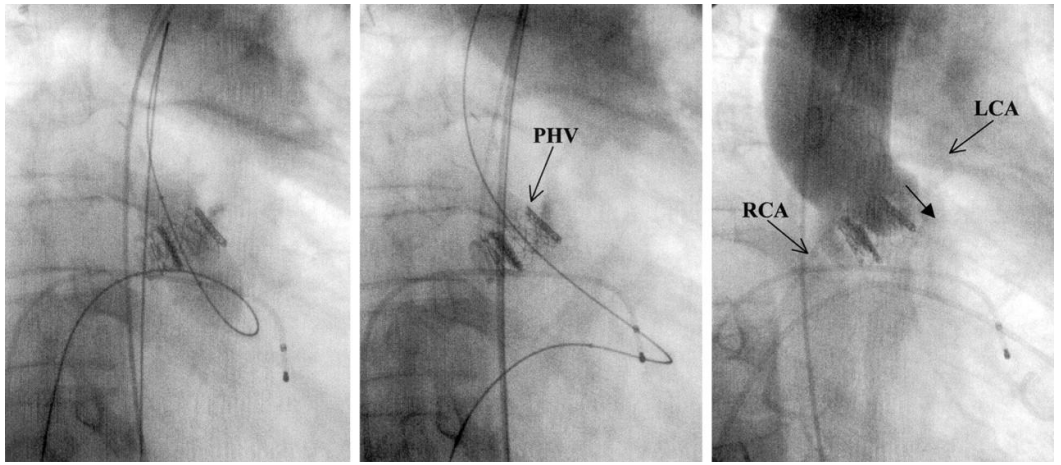
Henning-Rud Andersen 1988 ⇢ 2011

Alain Cribier – 2002 compassionate use in shock patiënt







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TAVI – Partner 3 trial op ACC 2019

"This is a historic moment,
and of all of us here should remember it as such"

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TAVI laag risico – meta-analyse

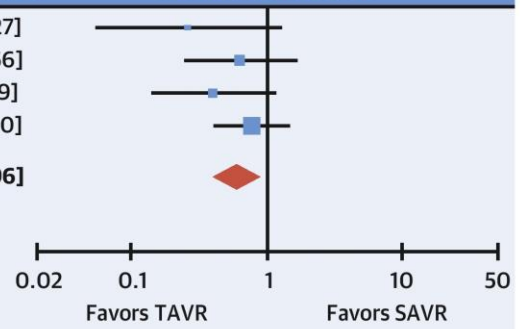
CENTRAL ILLUSTRATION: All-Cause and Cardiovascular Death at 1 Year After TAVR Versus SAVR in Low-Risk Patients

A

Study or Subgroup	TAVR Events	TAVR Total	SAVR Events	SAVR Total	Weight	Risk Ratio M-H, Random, 95% CI
SURTAVI (STS Below 3%)	2	131	7	123	8.4%	0.27 [0.06, 1.27]
NOTION	7	145	10	135	23.2%	0.65 [0.26, 1.66]
PARTNER 3	5	496	11	454	18.5%	0.42 [0.15, 1.19]
Evolut Low Risk	17	725	20	678	49.9%	0.79 [0.42, 1.50]
Total (95% CI)		**1,497**		**1,390**	**100.0%**	**0.61 [0.39, 0.96]**
Total events	31		48			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.28$, df = 3 (p = 0.52); $I^2 = 0\%$

Test for overall effect: Z = 2.12 (p = 0.03)

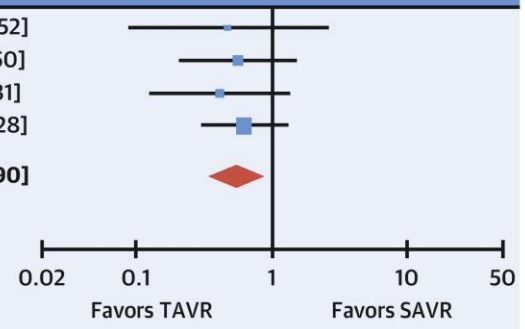


B

Study or Subgroup	TAVR Events	TAVR Total	SAVR Events	SAVR Total	Weight	Risk Ratio M-H, Random, 95% CI
SURTAVI (STS Below 3%)	2	131	4	123	8.8%	0.47 [0.09, 2.52]
NOTION	6	145	10	135	25.6%	0.56 [0.21, 1.50]
PARTNER 3	4	496	9	454	18.1%	0.41 [0.13, 1.31]
Evolut Low Risk	12	725	18	678	47.5%	0.62 [0.30, 1.28]
Total (95% CI)		**1,497**		**1,390**	**100.0%**	**0.55 [0.33, 0.90]**
Total events	24		41			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.41$, df = 3 (p = 0.94); $I^2 = 0\%$

Test for overall effect: Z = 2.37 (p = 0.02)



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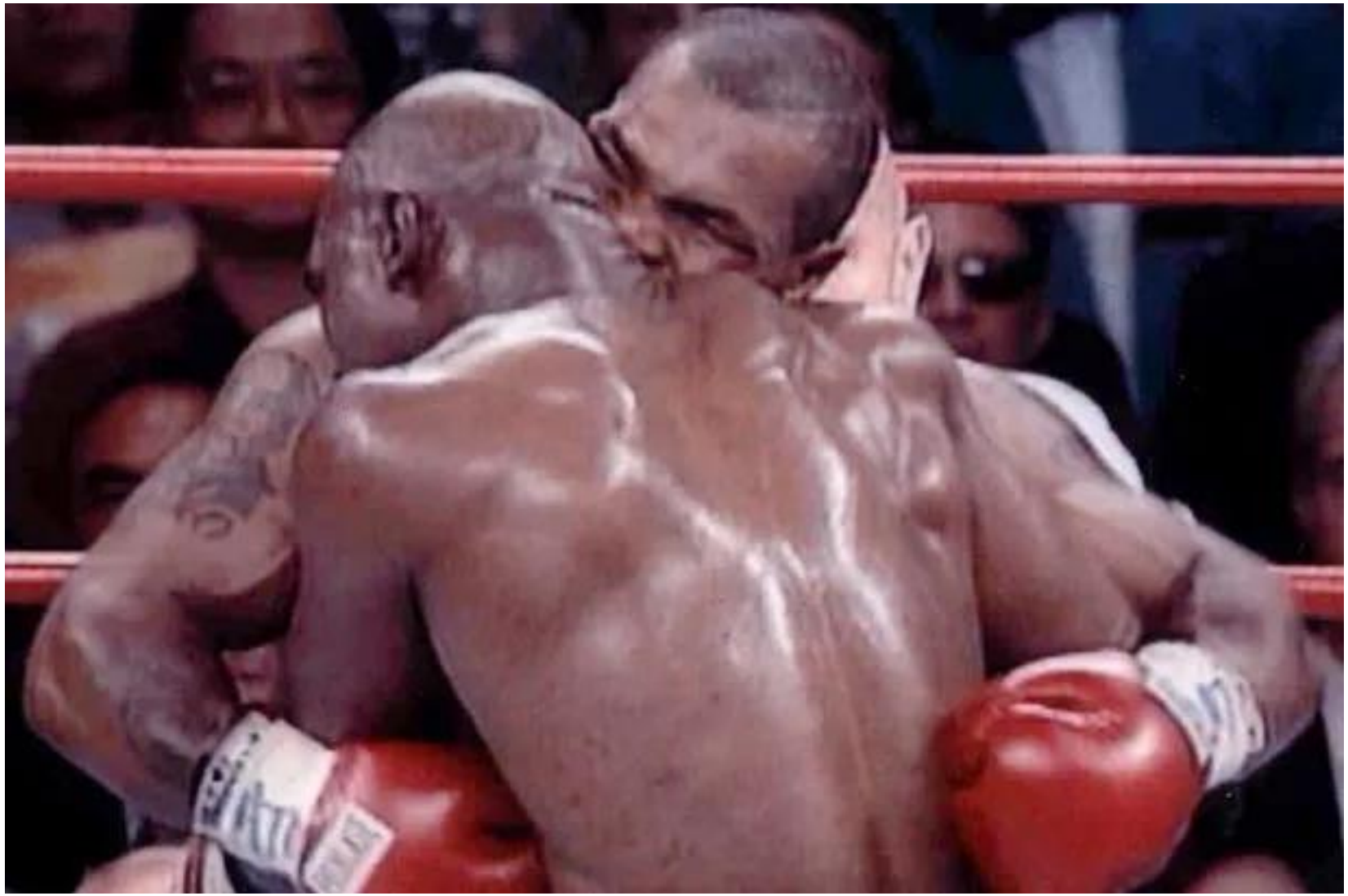
Kolte D, et al. J Am Coll Cardiol 2019;74:1532-40

Richtlijnen ←→ Klinische praktijk



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ESC guidelines 2021

	2017		2021	
Revised	The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality. In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	The choice between surgical and transcatheter intervention must be based upon careful evaluation of clinical, anatomical and procedural factors by the Heart Team, weighing the risks and benefits of each approach for an individual patient. The Heart Team recommendation should be discussed with the patient who can then make an informed treatment choice.	I
Revised	SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic EuroSCORE I <10%, and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).	I	SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/ EuroSCORE II <4%) or in patients who are operable and unsuitable for transfemoral TAVI.	I

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Vahanian A, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022;43:561-632.

ESC guidelines 2021

	2017		2021	
Revised	TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	I	TAVI is recommended in older patients (≥75 years), or in those who are high-risk (STS-PROM/ EuroSCORE II >8%) or unsuitable for surgery.	I
Revised	In patients who are at increased surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥10%, or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favoured in elderly patients suitable for transfemoral access.	I	SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical and procedural characteristics.	I

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Vahanian A, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022;43:561-632.

ACC/AHA guidelines 2020

Recommendations for Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR Is Appropriate

Referenced studies that support the recommendations are summarized in Online Data Supplement 11 to 13.

COR	LOE	Recommendations
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.[1–3]
1	A	2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.[1,4–8]
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.[1,4–10]

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Otto CM, et al. 2020 ACC/AHA guideline management of patients with valvular heart disease. Circulation 2021;143:e72-e227

Standpunt ZiN

Zorginstituut Nederland

> Retouradres Postbus 320, 1110 AH Diemen

Aan de minister voor Medische Zorg en Sport
Postbus 20350
2500 EJ DEN HAAG

2020038331

Datum 30 september 2020
Betreft Standpunt Transcatheter aortaklepimplantatie bij patiënten met symptomatische ernstige aortaklepstenose (update)

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Standpunt ZiN

Wij concluderen dat er een extra subgroep is aan te wijzen voor wie TAVI meerwaarde kan hebben, namelijk patiënten met een hoog operatierisico. Voor patiënten met een laag of gemiddeld operatierisico is TAVI nog niet voldoende bewezen effectief. Om gepast gebruik van TAVI in de praktijk te bevorderen is er door Nederlandse Vereniging voor Cardiologie en de Nederlandse Vereniging voor Thoraxchirurgie een indicatiedocument opgesteld, waarin beschreven staat welke patiënten onder de hoog risicogroep vallen en dus in aanmerking komen voor TAVI.

Belangrijkste onzekerheden TAVI:

1. **Pacemaker nog te veel voorkomende complicatie voor jonge pts**
2. **Duurzaamheid kleppen 5-10-15 jaar?**

Indicatierichtlijn TAVI NVVC/NVT

Hoog risico bij SAVR

• Leeftijd ≥80 jaar	Ja / Nee
• Eerdere OHO	Ja / Nee
• Frailty (bv Edmonton Frailty Score ≥matig kwetsbaar)	Ja / Nee
• Status na mantelveldbestraling	Ja / Nee
• Eerder CVA met restverschijnselen of TIA in de afgelopen 6 mnd.	Ja / Nee
• COPD (Gold ≥III)	Ja / Nee
• Nierfalen (GFR ≤30)	Ja / Nee
• LV Ejectiefractie ≤40%	Ja / Nee
• Chronisch gebruik van corticosteroiden/immunosuppressiva	Ja / Nee
• Verminderde mobiliteit	Ja / Nee
Indien alle vragen Nee	***SAVR***
Indien 1x JA: overweeg TAVI als alternatieve, gepaste behandeling	***TAVI of SAVR***
Indien >1x JA: voorkeur voor TAVI	***TAVI***

Bij uitkomst TAVI: is TAVI technisch mogelijk (toegang, natieve aortaklep en annulus)?

• Ja	***TAVI***
• Nee: conservatief (als SAVR wel mogelijk is evt. heroverwegen)	***conservatief of SAVR***

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TAVI of AVR?

- **U ziet op de polikliniek een 76-jarige patiënte met symptomatische ernstige aortaklepstenose (PG 70 mmHg, AVA 0,7 cm2, goede LVF)**
- **In de voorgeschiedenis van de patiënte: behandeld met methotrextaat ivm polyartritris, varices operatie**
- **Tevens sign coronairlijden (LAD en RCx)**
- **Wat zou u doen (richtlijnen!)?**

TAVI of AVR?

- **Loopt met rollator, woont zelfstandig met huishoudelijke hulp 1x/week. CT: aorta toegankelijk voor AVR, maar ook goed toegankelijk voor TF TAVI; twijfel over TAVI of AVR…**

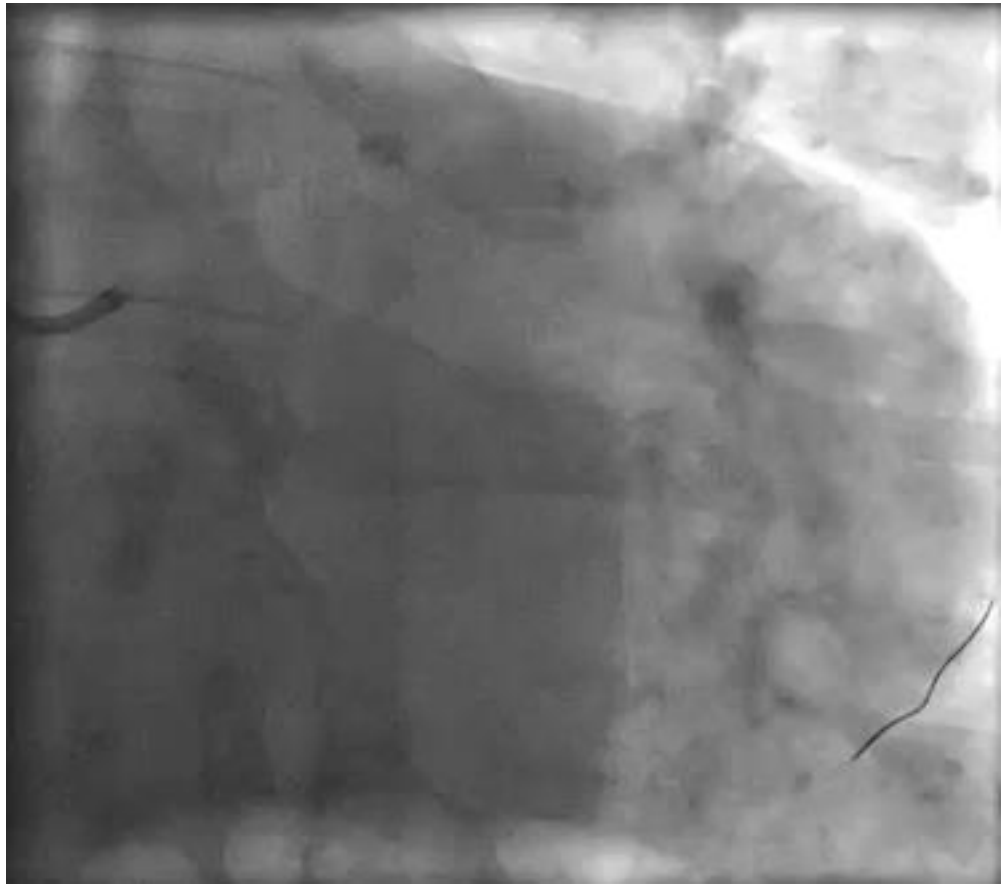
- **Herbesproken in MDO TAVI na advies geriater:**
  Matige kwetsbaarheid en matig mobiel (rollator afhankelijk)

- **Andere argumenten:**
  klein / geen sociaal netwerk
  ↓ kracht: ↑ kans pneumonie en verlengde revalidatie na OHO
  chronisch gebruik immuun suppressiva

- **Gezien op gezamenlijke poli CAR/CTC en erna in MDO TAVI**

CAG: PCI?

RCx



LAD/D

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Besluit TAVI team

- **TAVI**

- **Met of zonder PCI voor TAVI??**

Behandeling concomitant coronairlijden

PCI should be considered in patients with a primary indication to undergo TAVI and coronary artery diameter stenosis >70% in proximal segments.	IIa	C

➢ **Verschillende strategieën tussen Nederlandse TAVI-centra**

Gerandomiseerde onderzoeken:

- **PRO-TAVI trial NCT05078619 NL**
- **NOTION-3 trial NCT03058627 DEN**

Behandeling concomitant coronairlijden

Multicenter studie

466 patiënten
Randomiseren wel/geen PCI

Inmiddels > helft 466 geïncludeerd

ZonMw Doelmatigheid

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PROTAVI

ZonMw

Mitralis klep insufficiëntie

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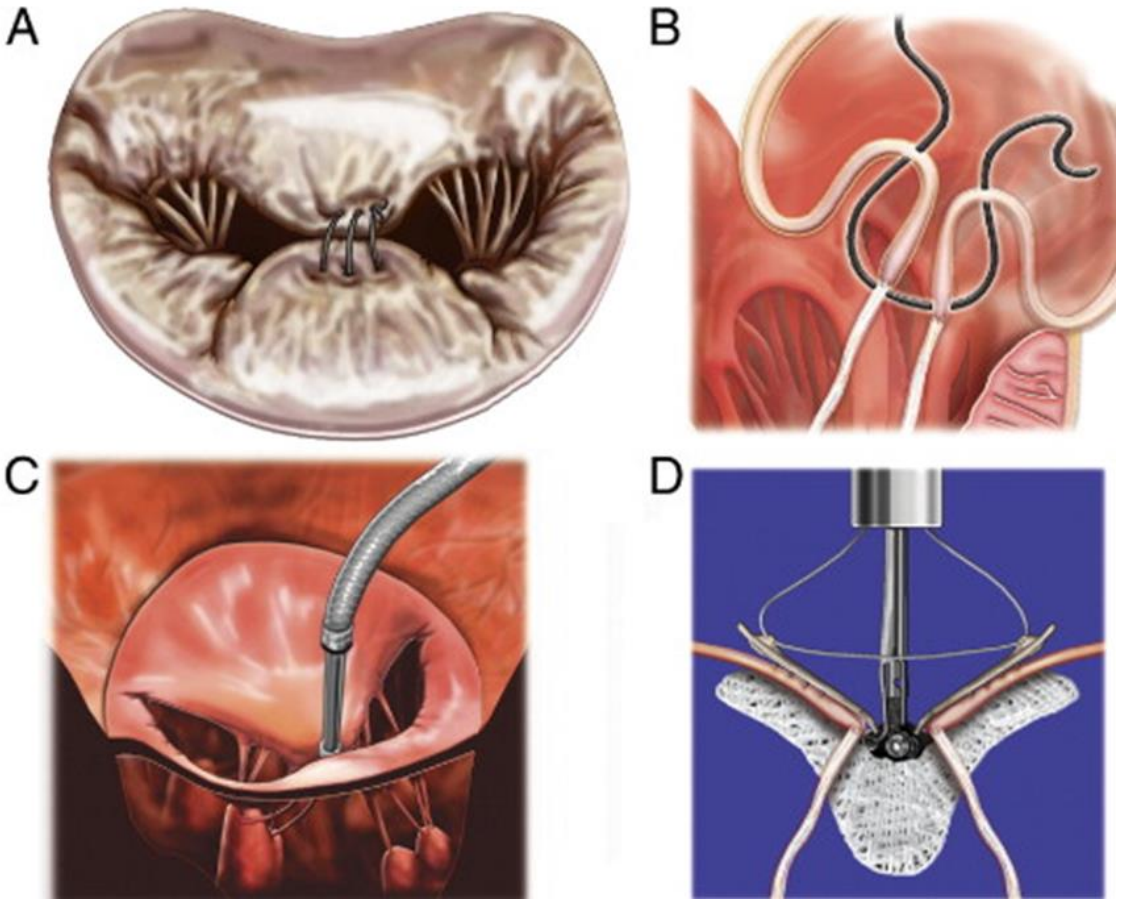
Transcatheter Edge-to-Edge Repair (TEER) – principe

Alfieri stitch



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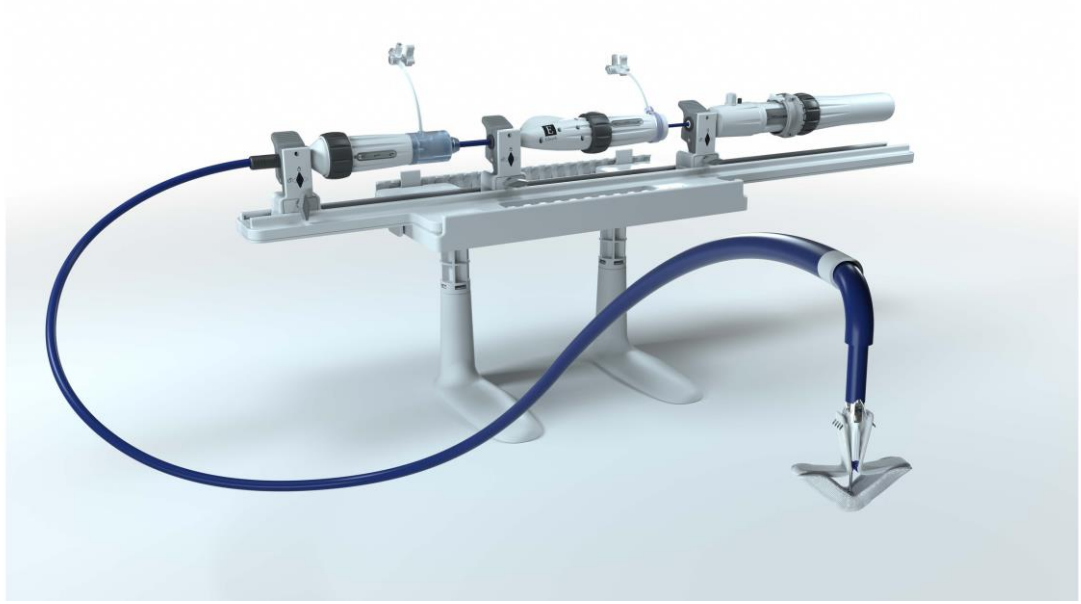
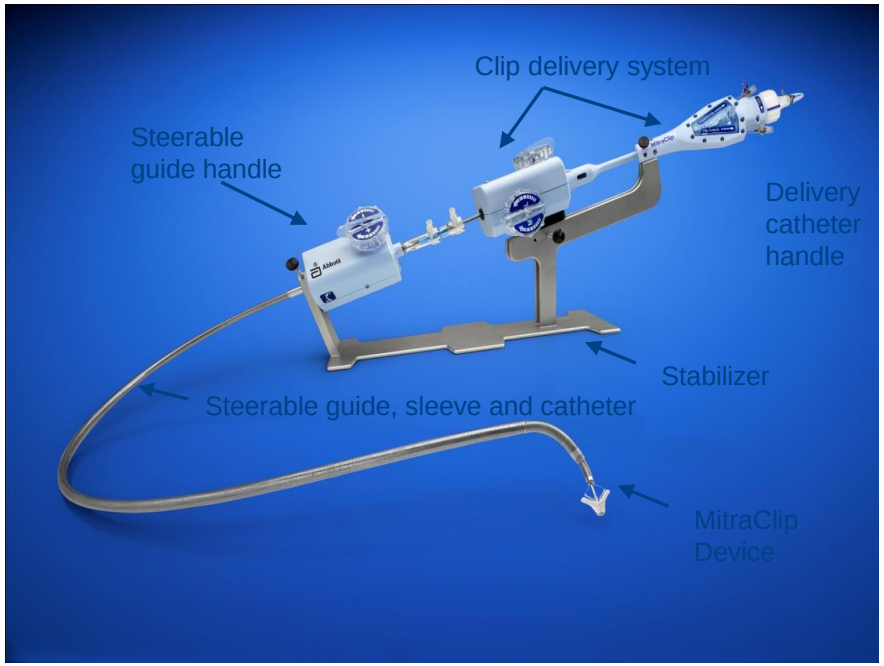
Mitraclip / Pascal – systeem





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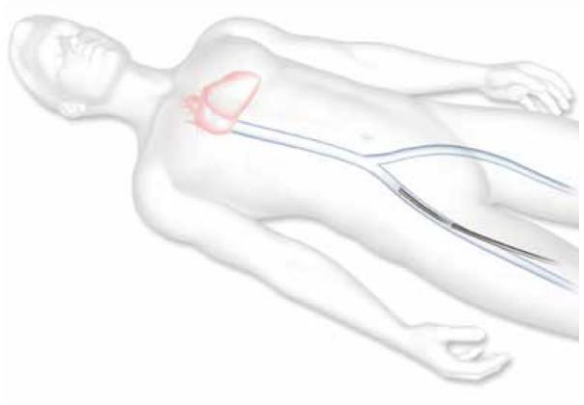
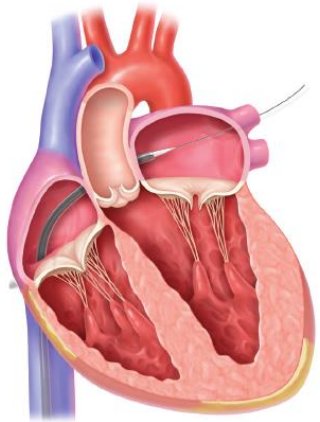
Mitraclip / Pascal – procedure

Patient and System Preparation



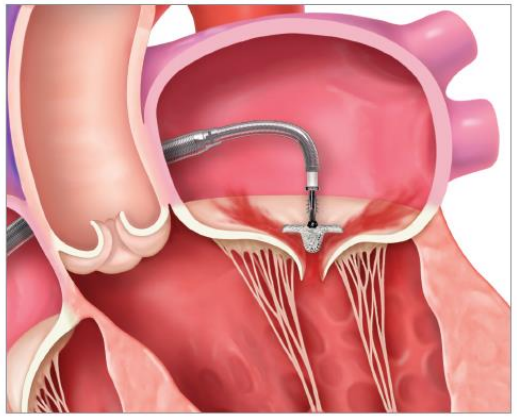
- The following considerations should be accounted for:
  - TEE probe will be in place for an extended period of time
  - Intubation under general anesthesia
  - 24 French sheath in femoral vein
  - Bladder/urinary catheter in place
  - Heparinization during procedure to ACT > 250
- System is prepared by removing all the air in the lumens of the Clip Delivery System and Steerable Guide Catheter
- System is functionally tested prior to use

Transseptal Crossing and Guide Insertion



A transseptal procedure is performed to gain access from the right atrium to the left atrium. The Steerable Guide Catheter (Guide) and Dilator are then carefully advanced into the left atrium over a wire. Once the Guide is in place and secured, the wire and Dilator are removed leaving the Guide in the left atrium.

Clip Delivery System Insertion and Steering in the Left Atrium



To introduce the Clip, the Clip Delivery System (CDS) is advanced through the Guide into the left atrium. A series of steering maneuvers and manipulations with the Guide and CDS are required to align the Clip perpendicular to the mitral valve plane, and the Clip Arms perpendicular to the line of coaptation. These maneuvers are done under echocardiographic and fluoroscopic guidance.

- Fully percutaneous procedure, right femoral vein is the entry port, then trans-septal puncture to reach the left atrium
- General anesthesia mainly for TEE guidance
- Usually 3 cardiologists (2 interventionalists en 1 imaging) en 1 anesthesiologist

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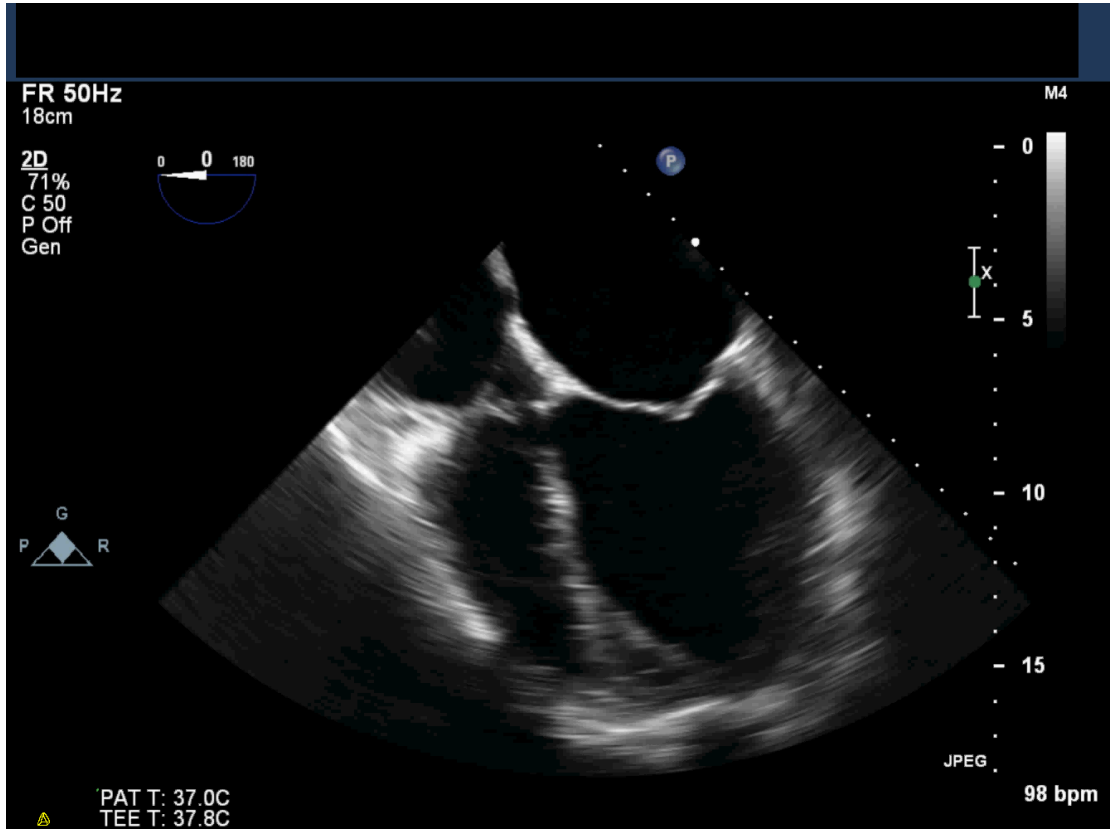
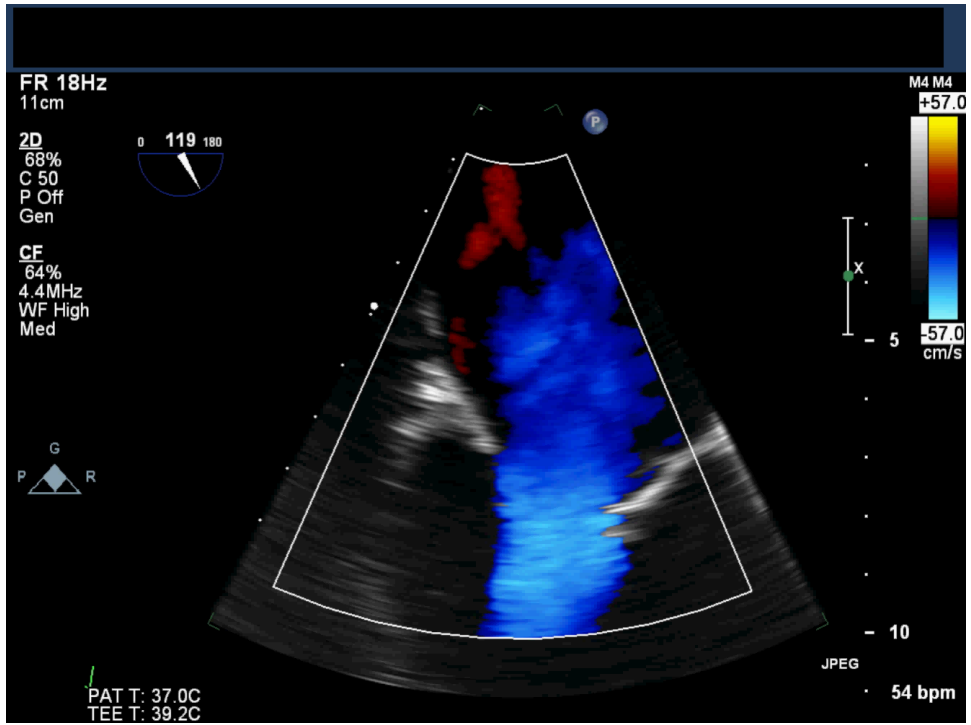
Mitraclip / Pascal – casus: vrouw 77j, DCMP, rolstoel





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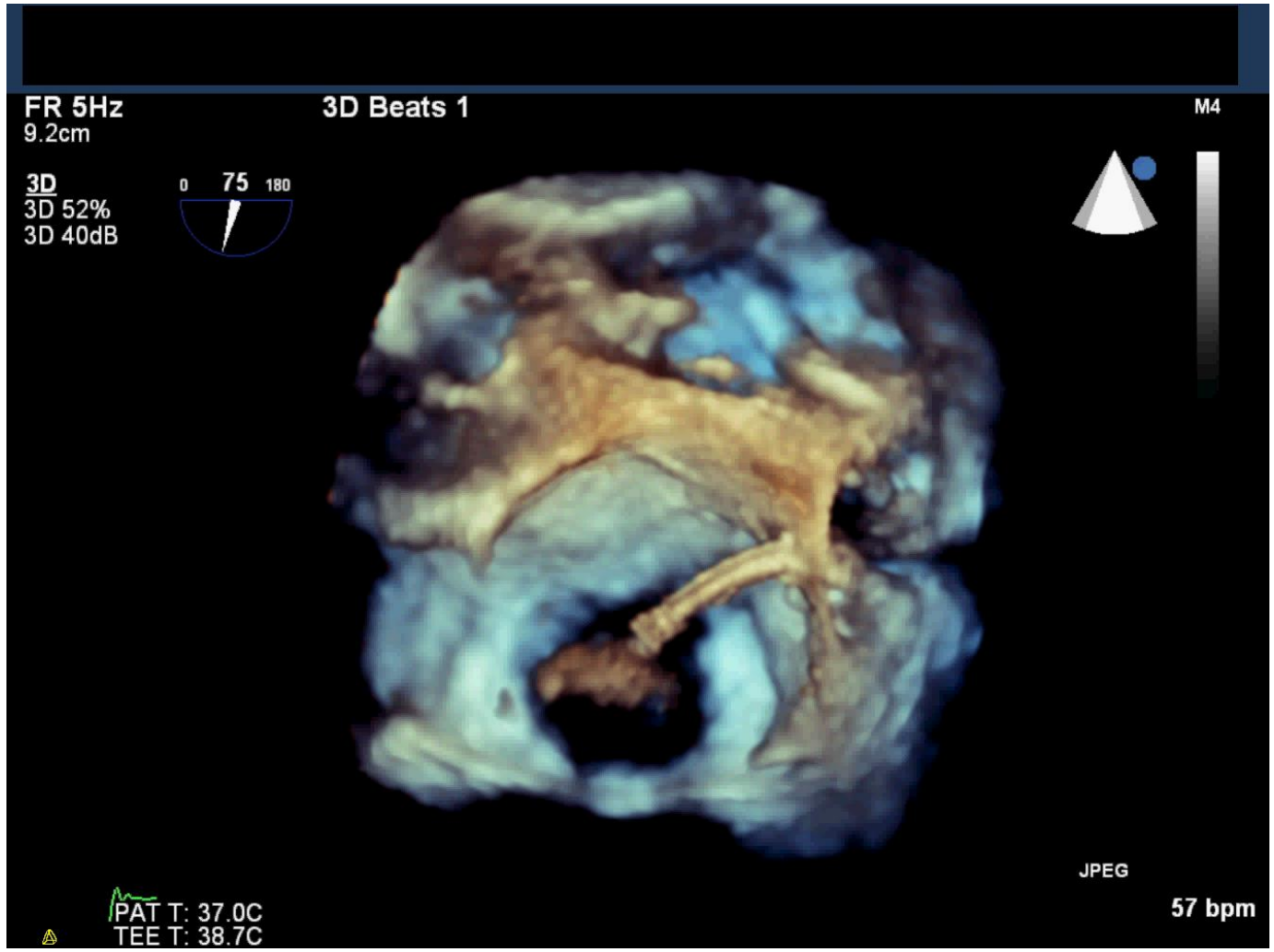
Casus – Echo in de lead!



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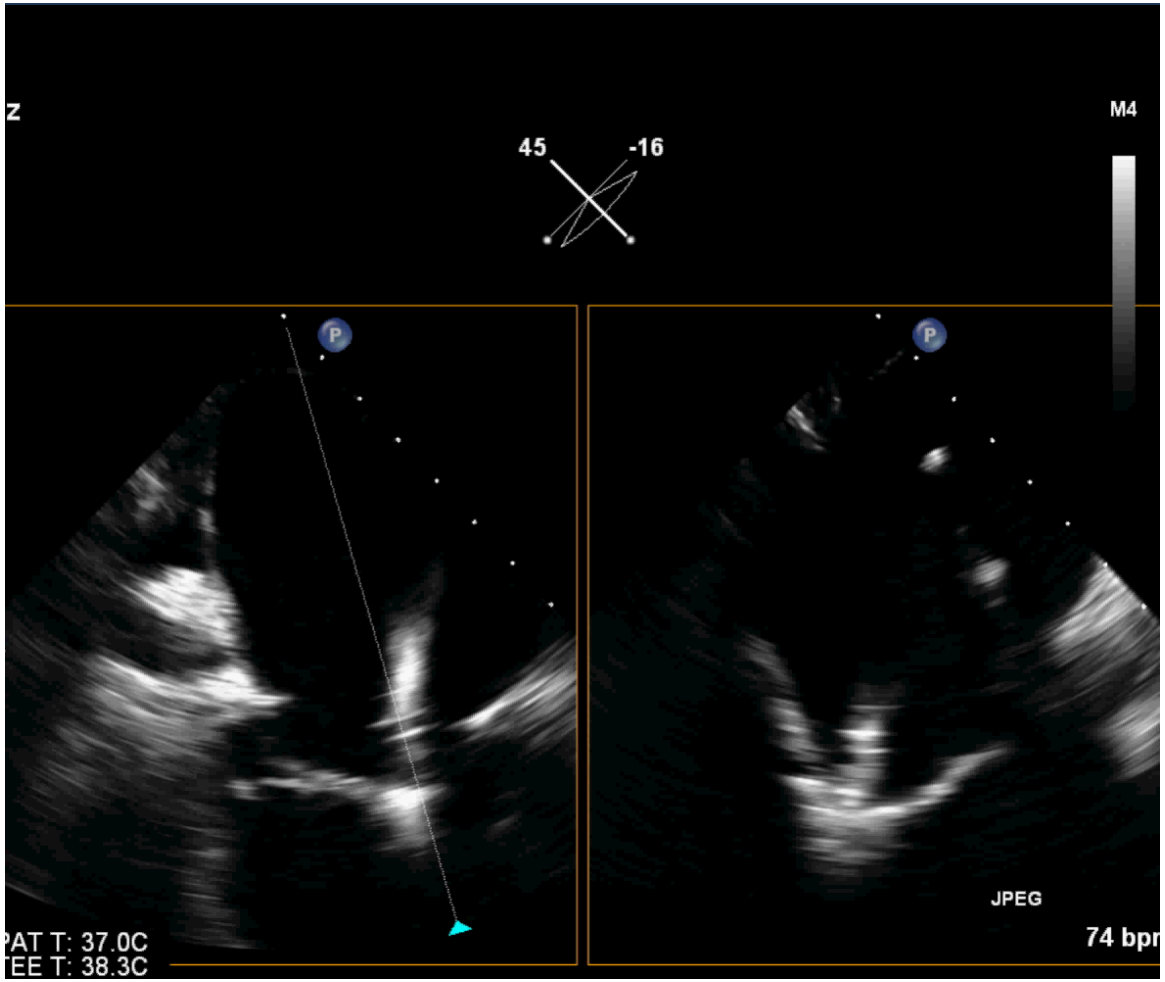
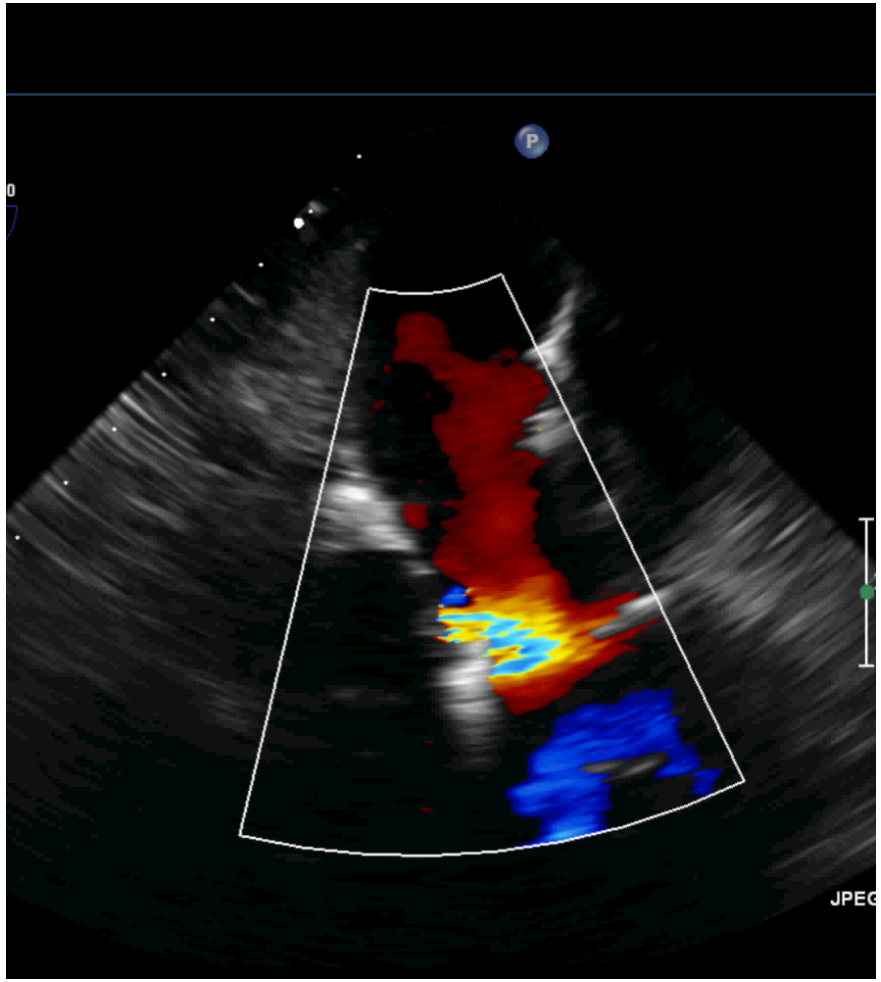
Casus – clip 1





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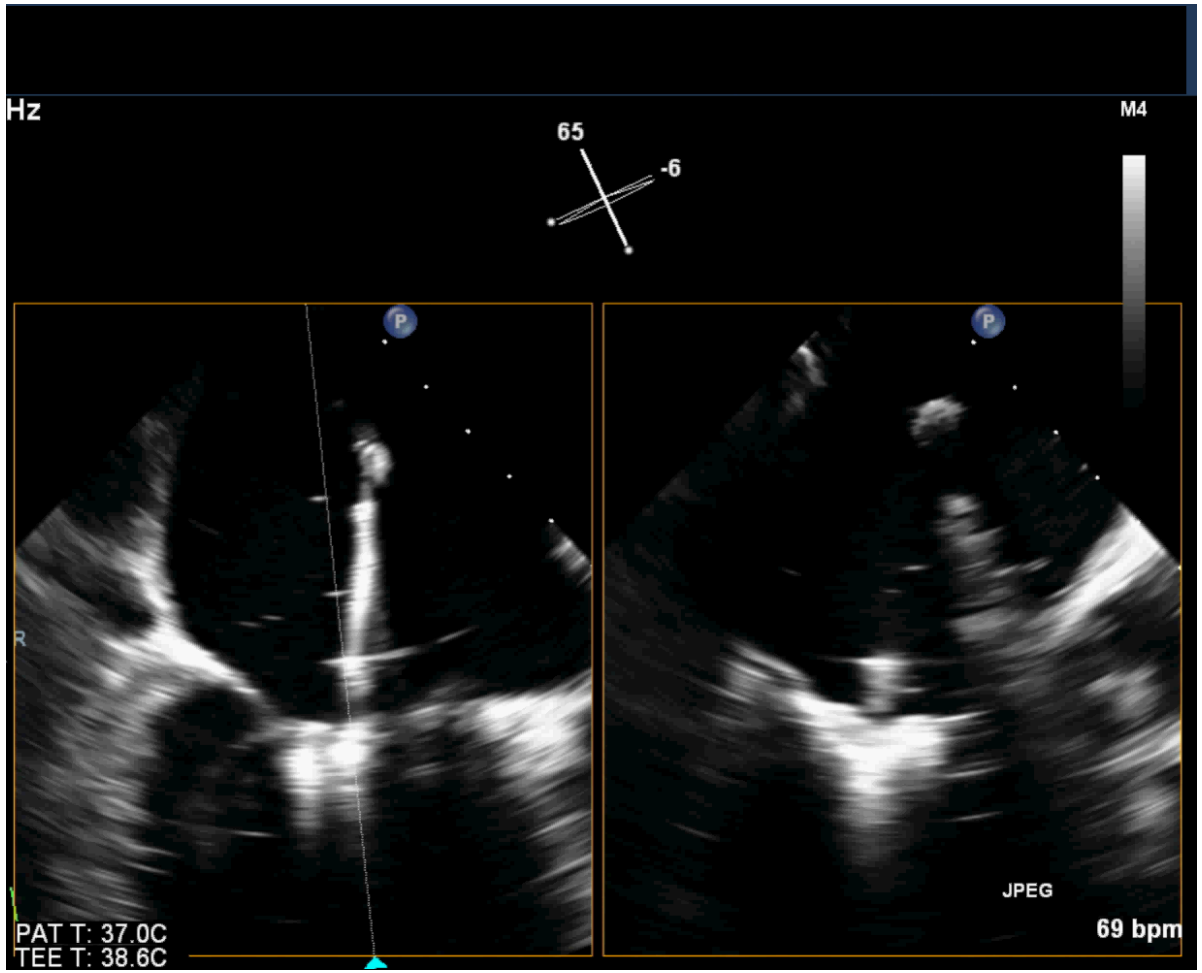
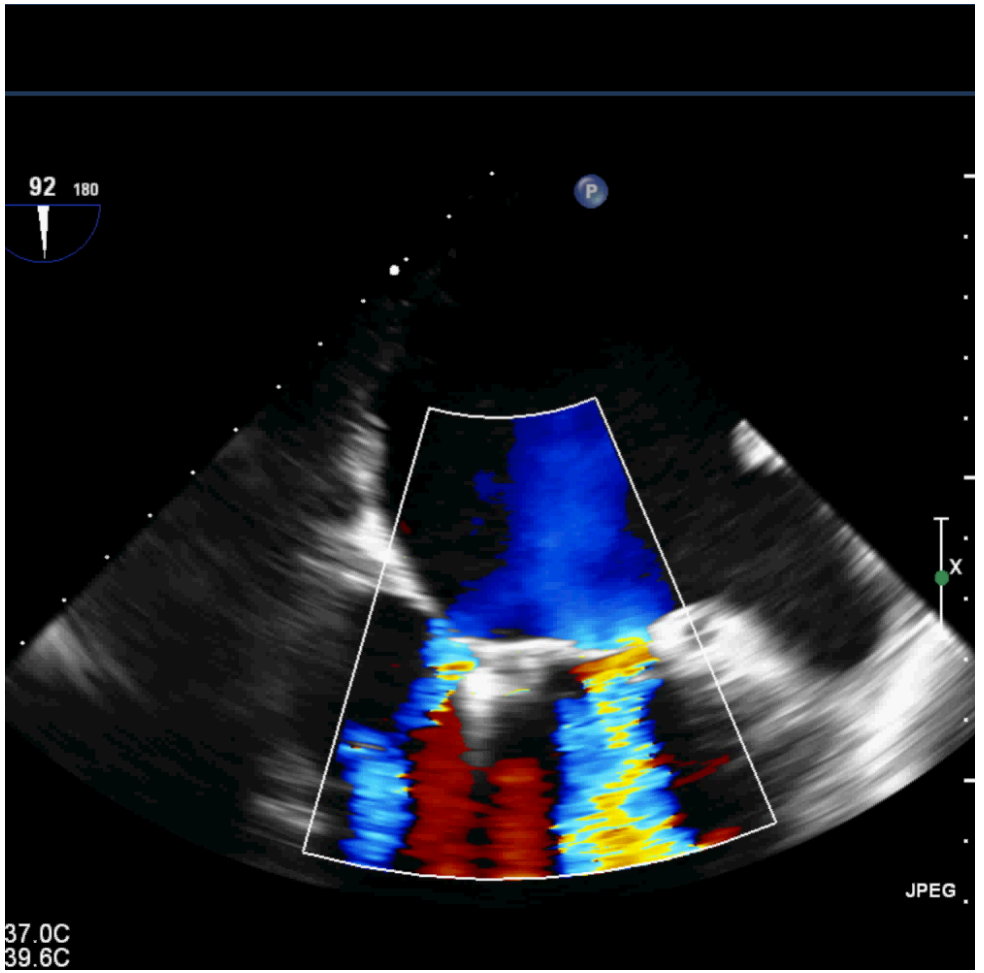
Casus – clip 2





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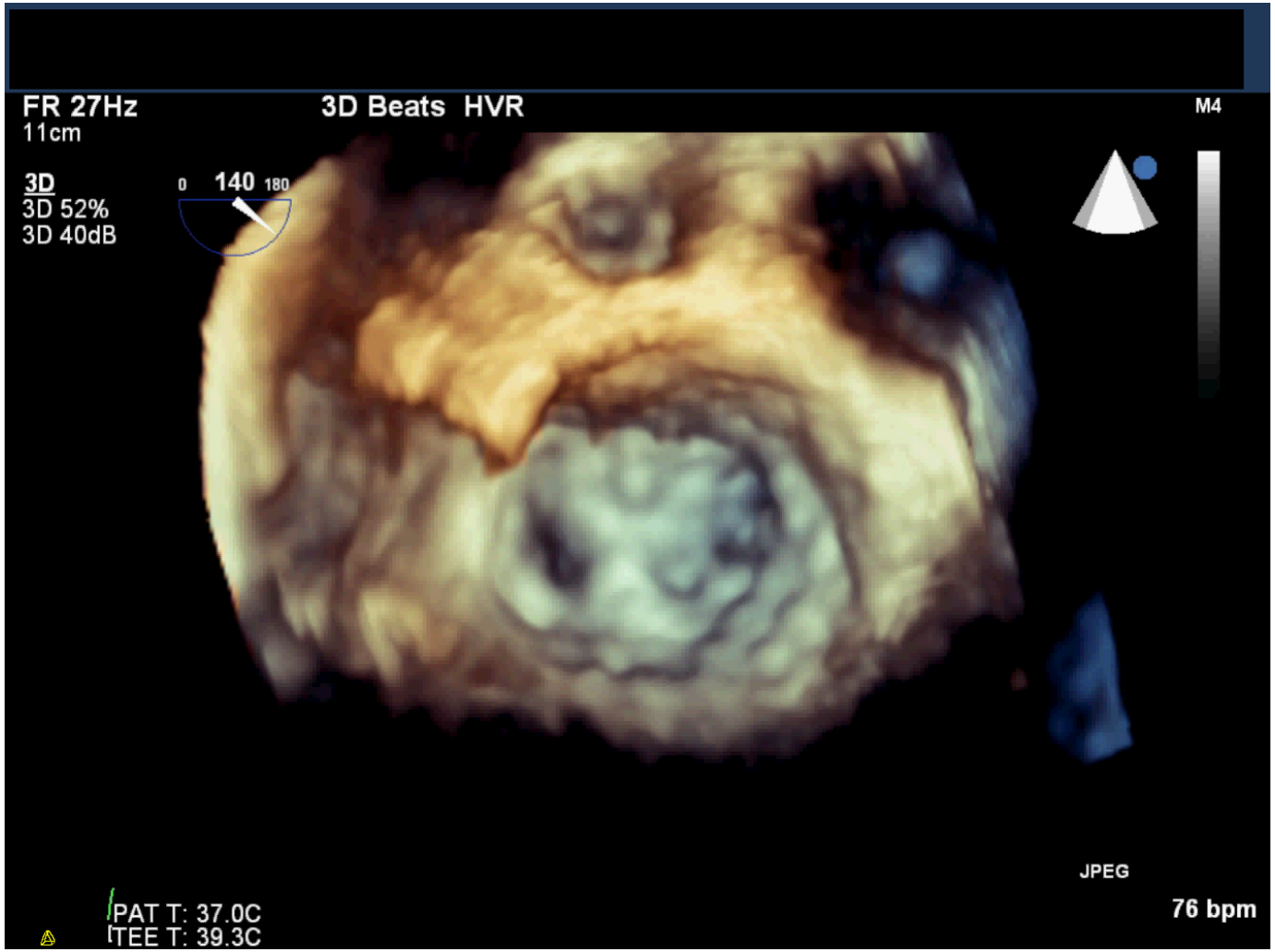
Casus – 3D echo eindresultaat



Mean gradient: 5 mmHg

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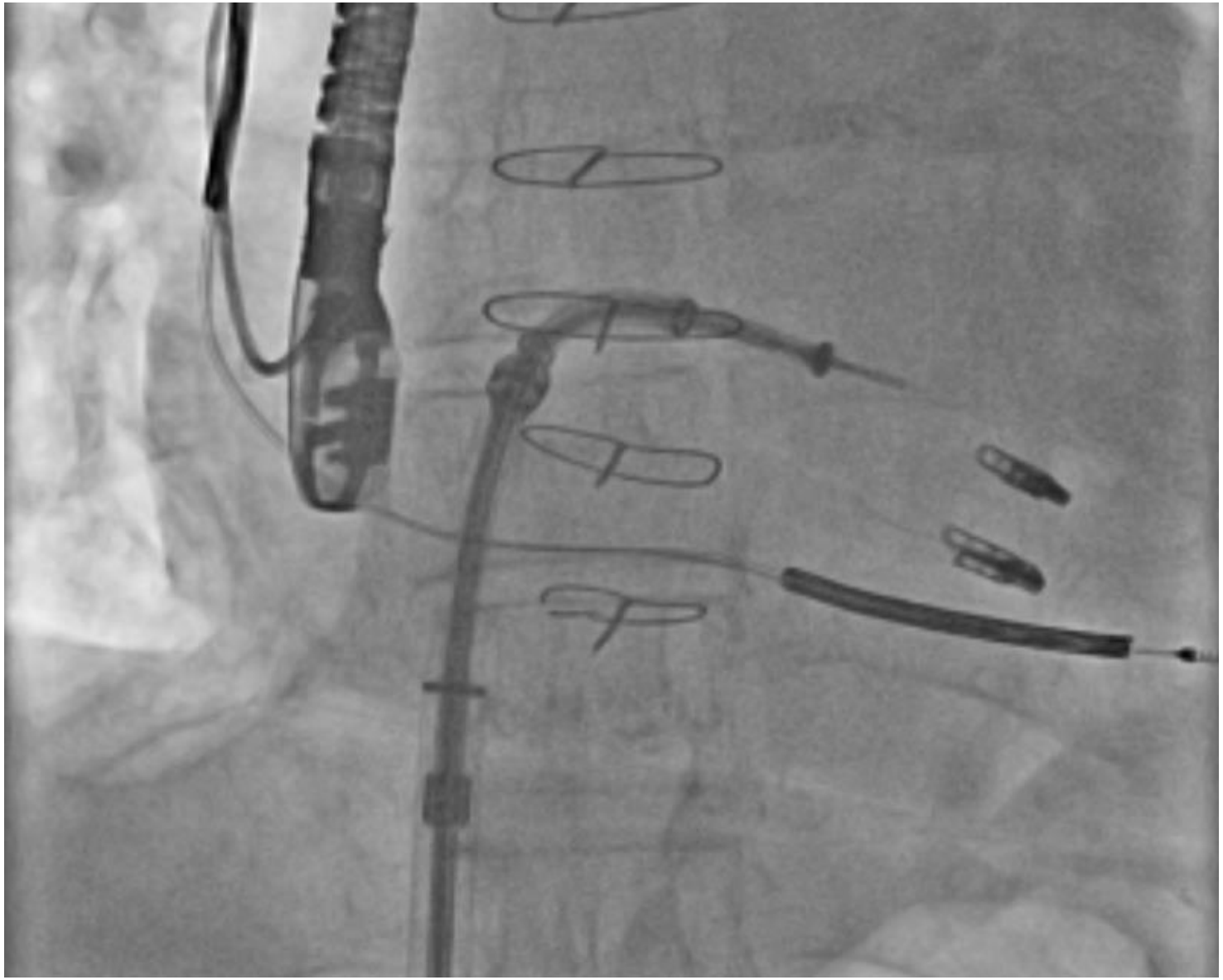
Casus – fluoroscopie eindresultaat



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ACC/AHA guidelines 2020 TEER

Recommendations for Intervention for Chronic Primary MR

Referenced studies that support the recommendations are summarized in Online Data Supplement 30.

COR	LOE	Recommendations
2a	B-NR	6. In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year.[17,18]

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021 Feb 2;143(5):e35-e71.

2021 ESC/EACTS Guidelines TEER

Surgical mitral valve repair should be considered in low-risk asymptomatic patients with LVEF >60%, LVESD <40 mm[d] and significant LA dilatation (volume index ≥60 mL/m^2 or diameter ≥55 mm) when performed in a Heart Valve Centre and a durable repair is likely.[285,288]	IIa	B
TEER may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are judged inoperable or at high surgical risk by the Heart Team and for whom the procedure is not considered futile.[299–302]	IIb	B

2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022 Feb 12;43(7):561-632.

Mitra-FR

Phase III MITRA.fr study: Percutaneous mitral valve repair improves mitral regurgitation but not outcome

ESC Congress News 2018 - Munich, Germany

28 Aug 2018

First data from the recently completed MITRA.fr trial
Francois Obadia (Hopital Louis Pradel, Lyon, France) i
high-level evidence relating to the safety and efficacy
secondary mitral regurgitation (SMR) and chronic hea

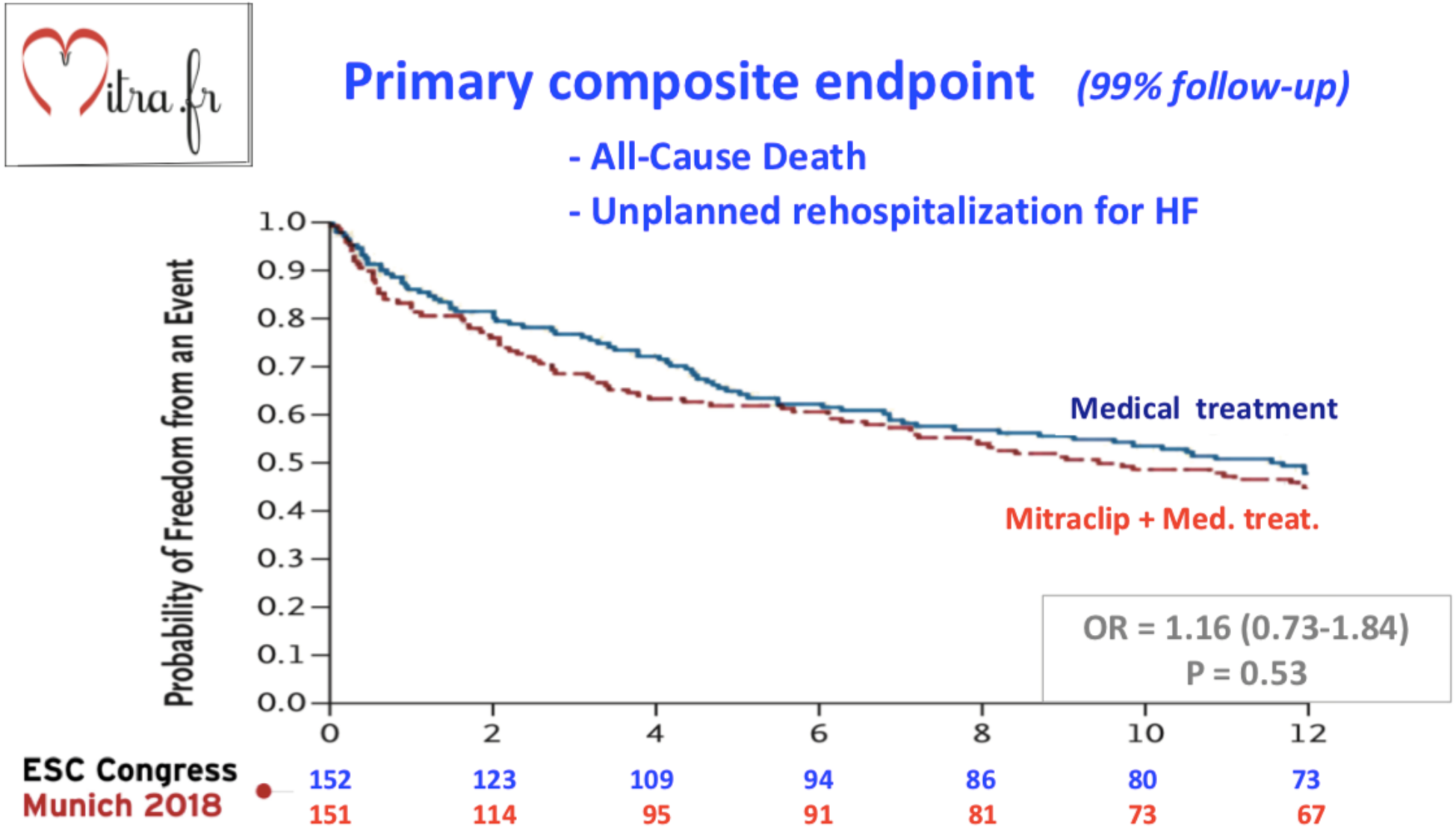
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

Mitra-FR – primaire uitkomst



ESC Congress
Munich 2018

UMC Utrecht

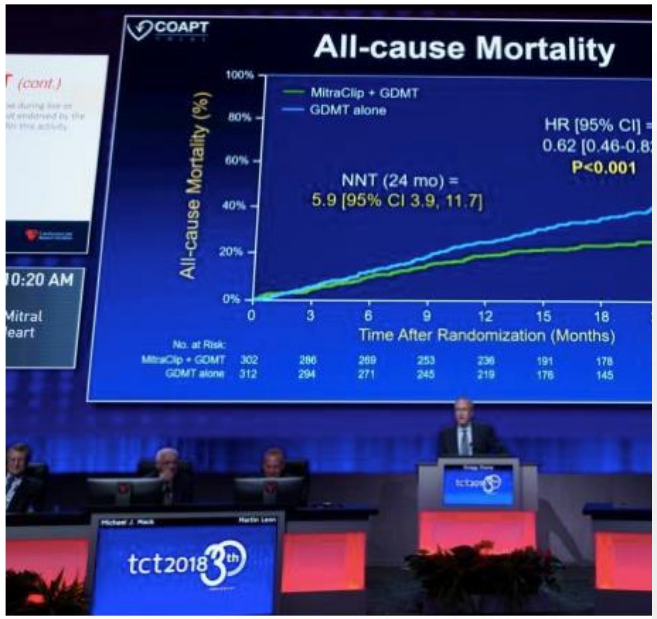
COAPT

NEWS | TCT 2018

COAPT: MitraClip Reduces Repeat Hospitalizations, Mortality in Functional MR Patients With Severe HF

Physicians responded with shock and excitement to findings, but struggled to reconcile the results with the MITRA-FR trial.

By Shelley Wood | September 23, 2018



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

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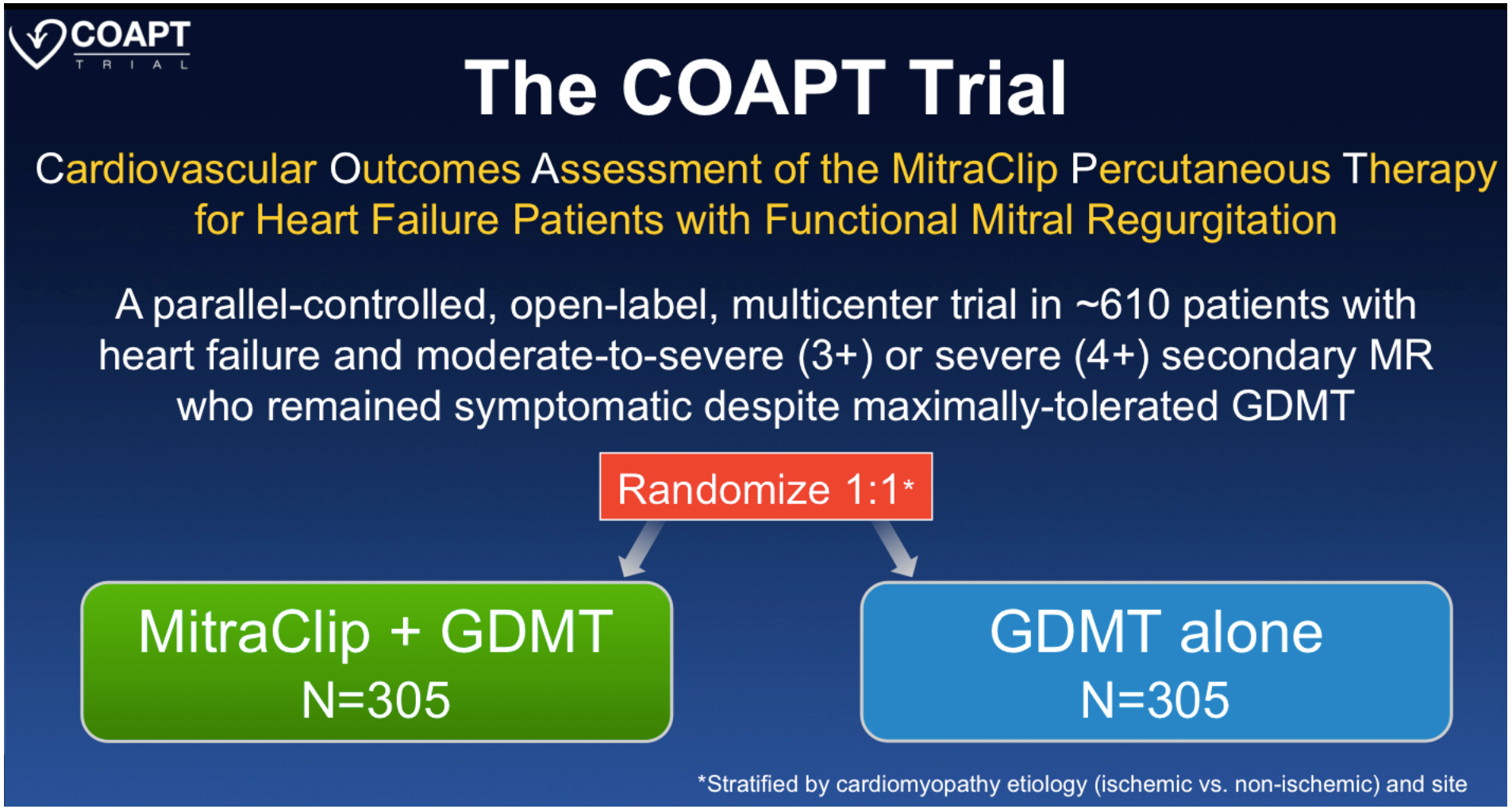
COAPT



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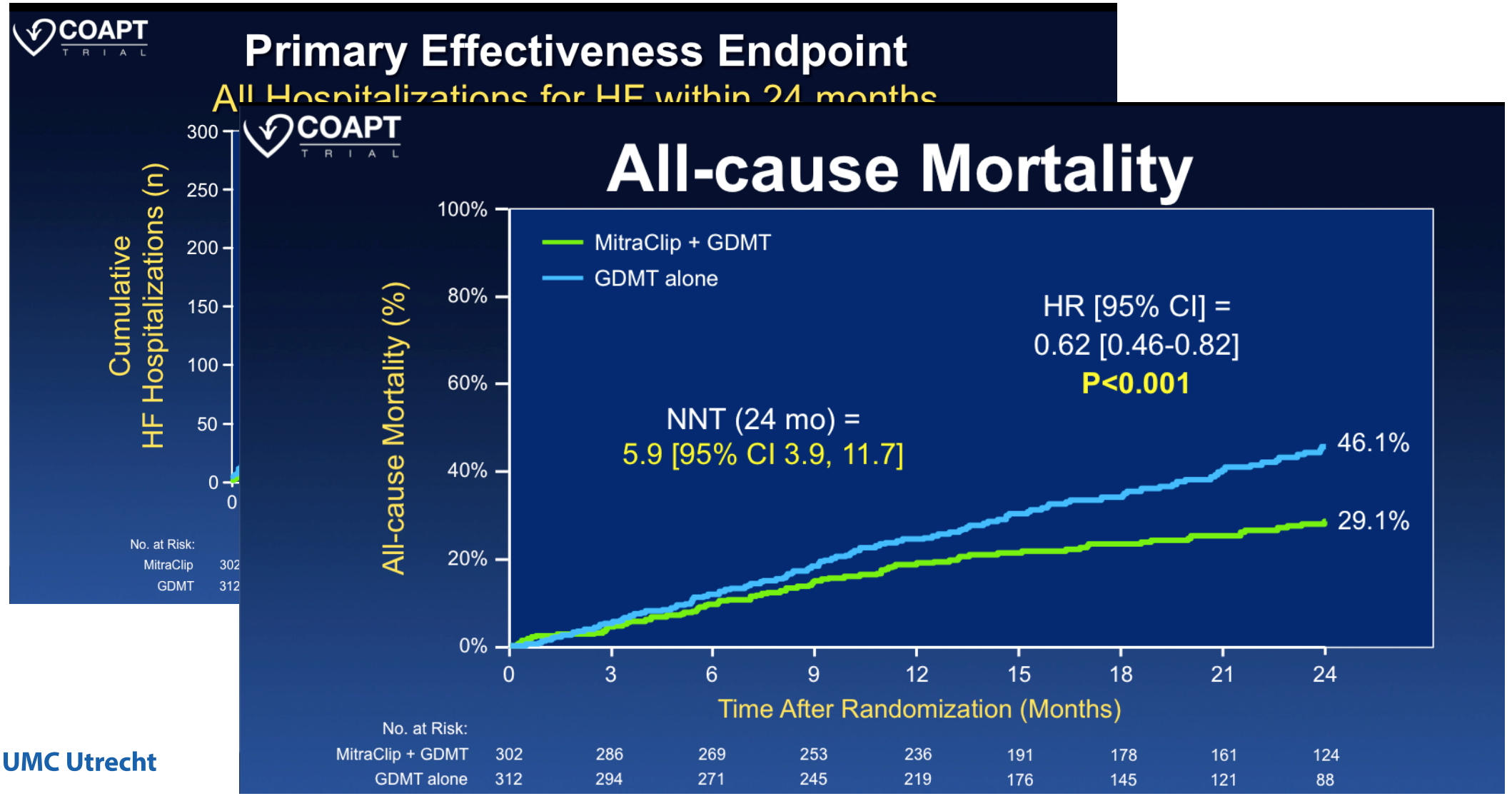
COAPT – uitkomsten



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MITRA-FR versus COAPT

proportionate versus disproportionate functional mitral regurgitation

	MITRA-FR (n=304)	COAPT (n=614)
Severe MR entry criteria	Severe FMR by EU guidelines: EROA >20 mm^2 or RV >30 mL/beat	Severe FMR by US guidelines: EROA >30 mm^2 or RV >45 mL/beat
EROA (mean ± SD)	31 ± 10 mm^2	41 ± 15 mm^2
LVEDV (mean ± SD)	135 ± 35 mL/m^2	101 ± 34 mL/m^2
GDMT at baseline and FU	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	CEC confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up
Acute results: No clip / ≥3+ MR	9% / 9%	5% / 5%
Procedural complications*	14.6%	8.5%
12-mo MitraClip ≥3+ MR	17%	5%

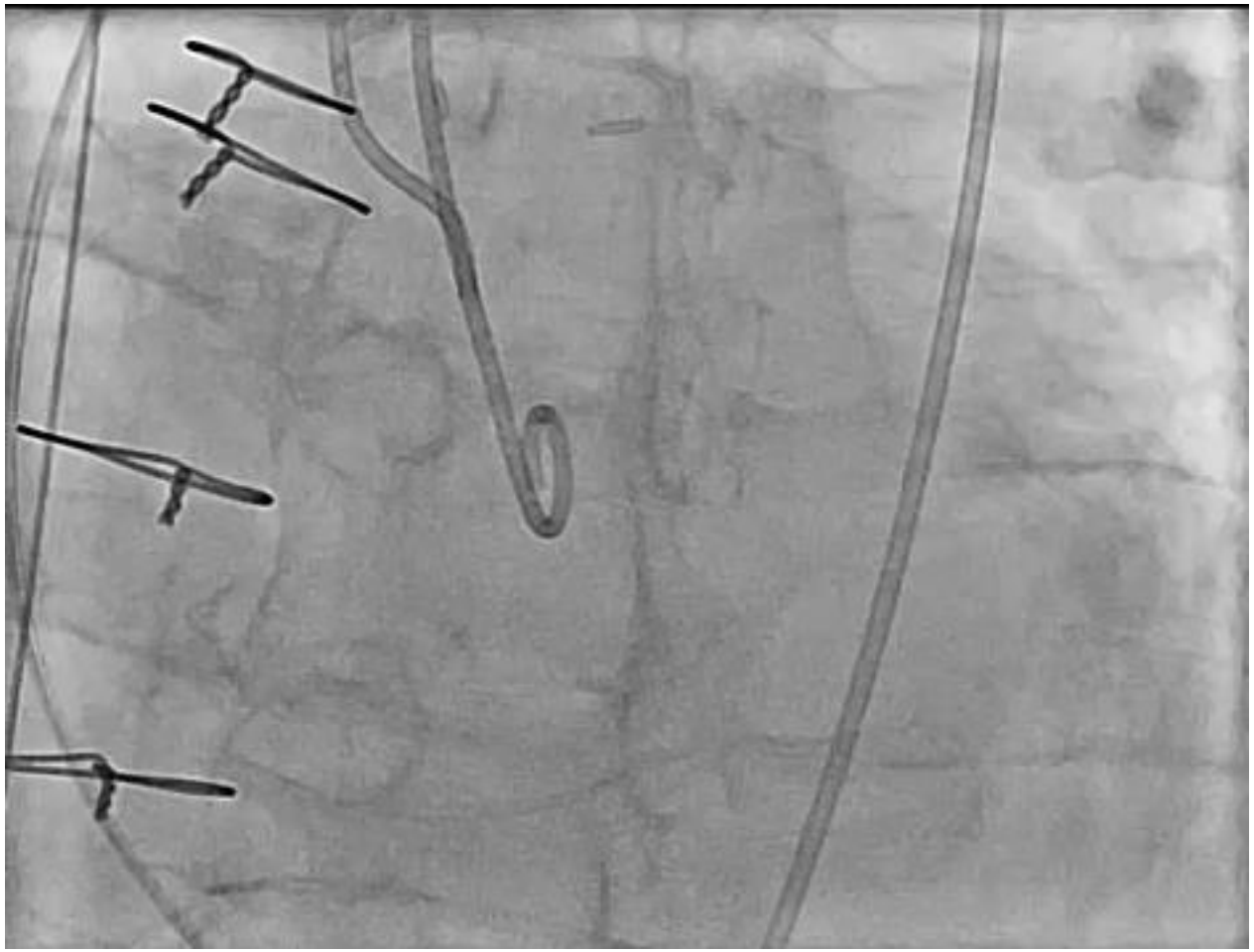
Conclusie TEER – patiënten selectie!

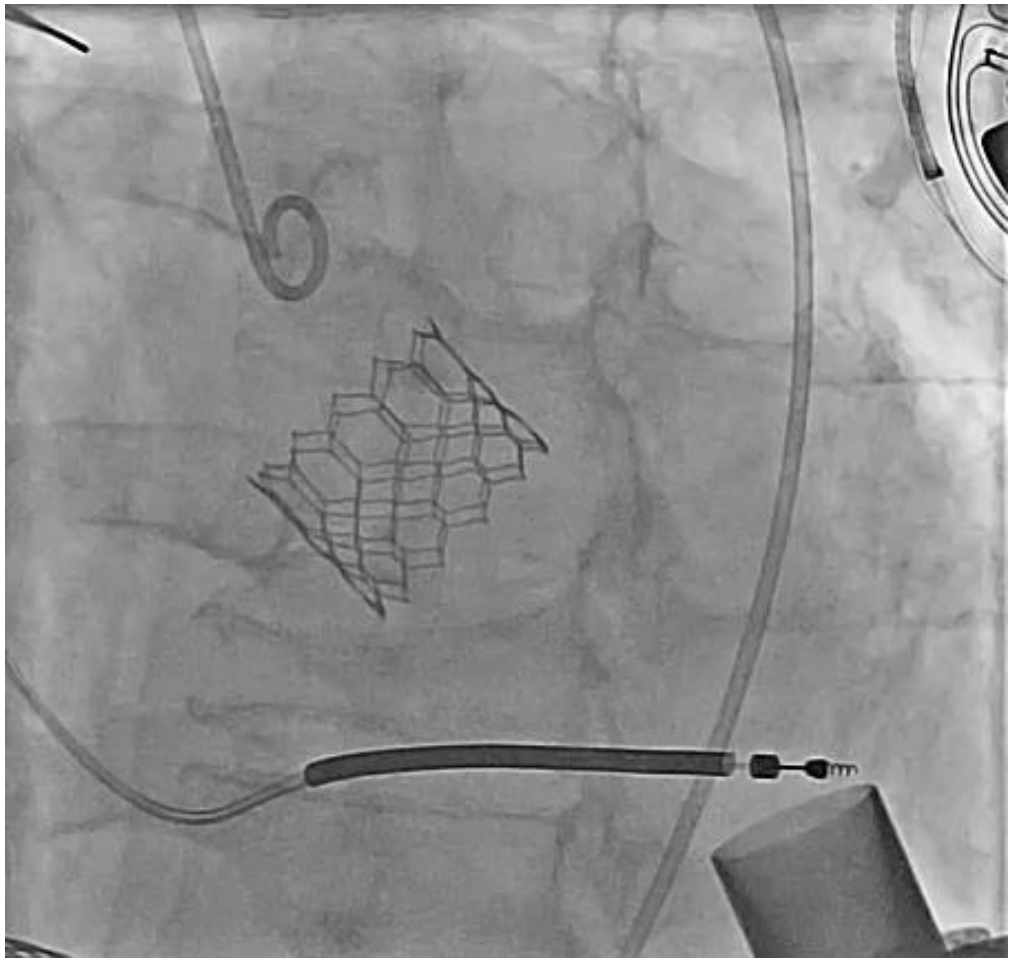
- **Ernstige MI**
- **Ideale patiënt: goede LVF, prolaps!**
- **LV niet *te* slecht: eind-systolisch < 70 mm en LV ejectie fractie > 20%**
- **RV niet te slecht**
- **Maximaal medicamenteus ingesteld**
- **Technisch optimaal resultaat nastreven**

Casus – 1 buiten alle richtlijnen

- **64-jarige man met DCM obv pathogene mutatie PLN-gen**
- **2021 LVAD implantatie**
- **Tweemaal IC opname ivm pneumonie**
- **Opname eind aug ivm ICD-shocks bij persisterend VF, uitgelokt door gedecompenseerd hartfalen bij toename van zijn aortaklep insufficiëntie**

Casus 1 – buiten alle richtlijnen - TAVI bij AoI / LVAD





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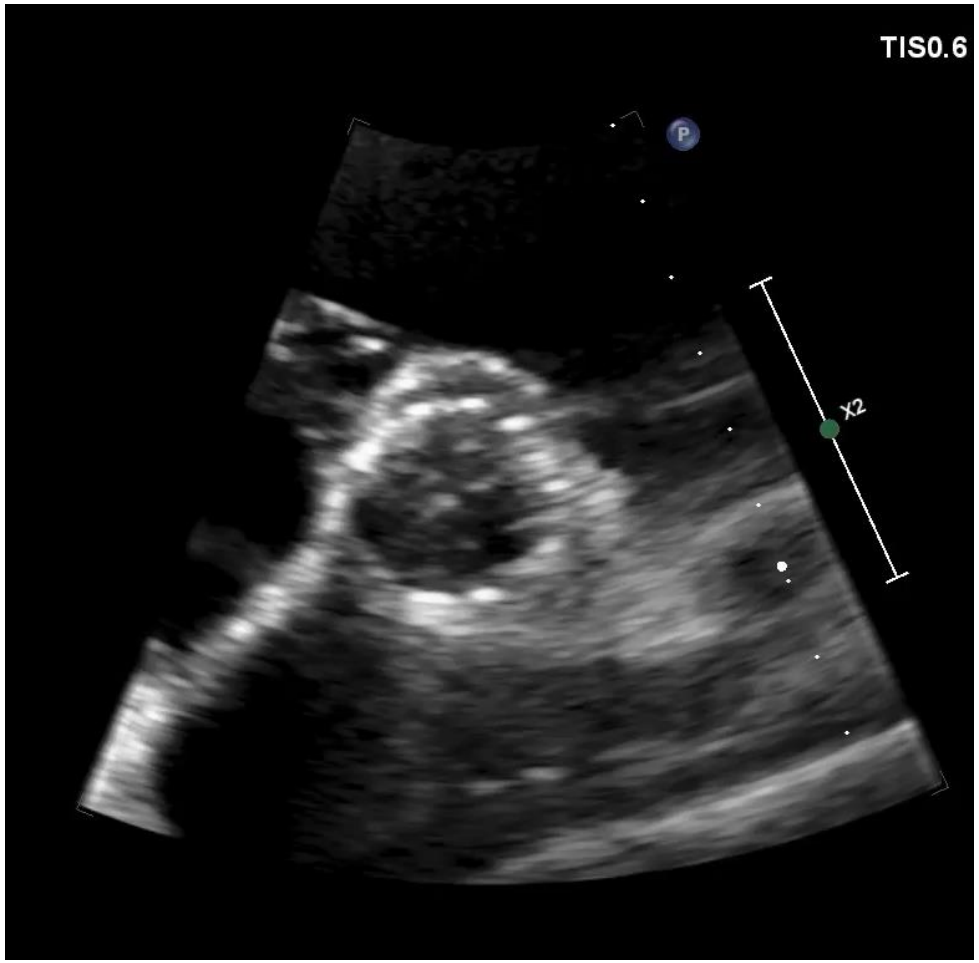
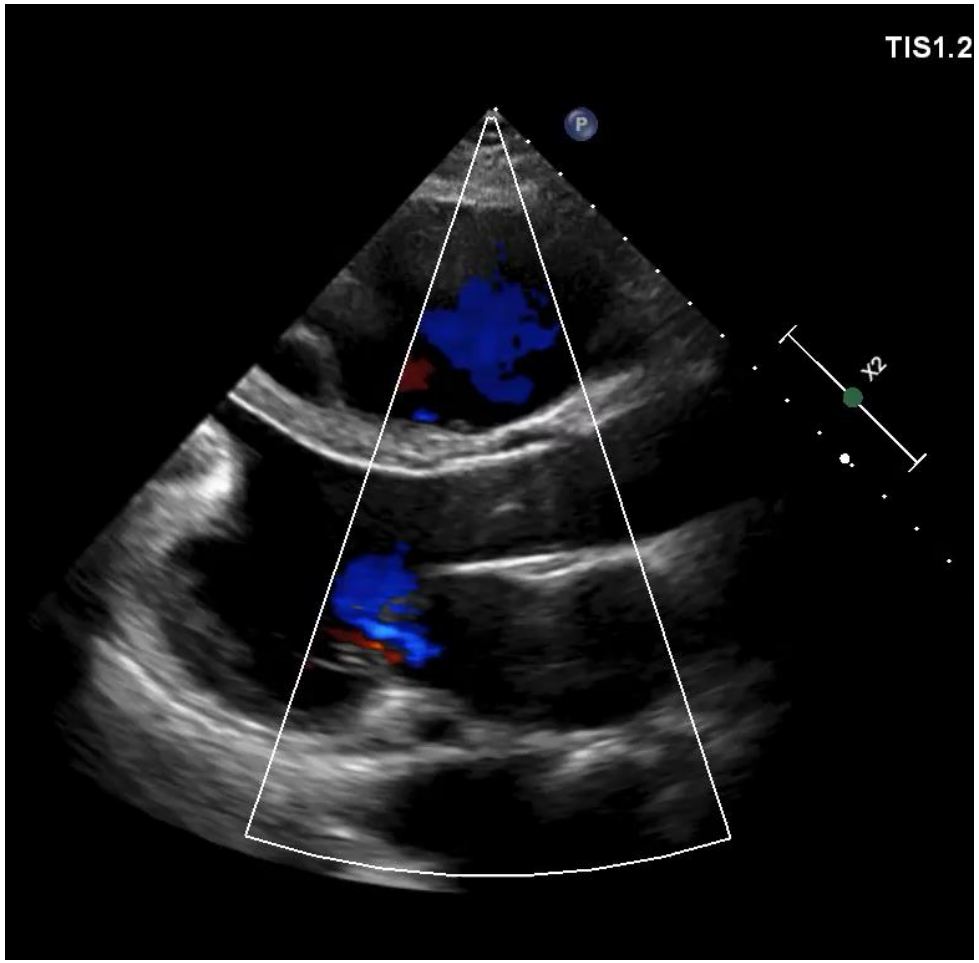
Casus 1 – buiten alle richtlijnen – echo na 4w





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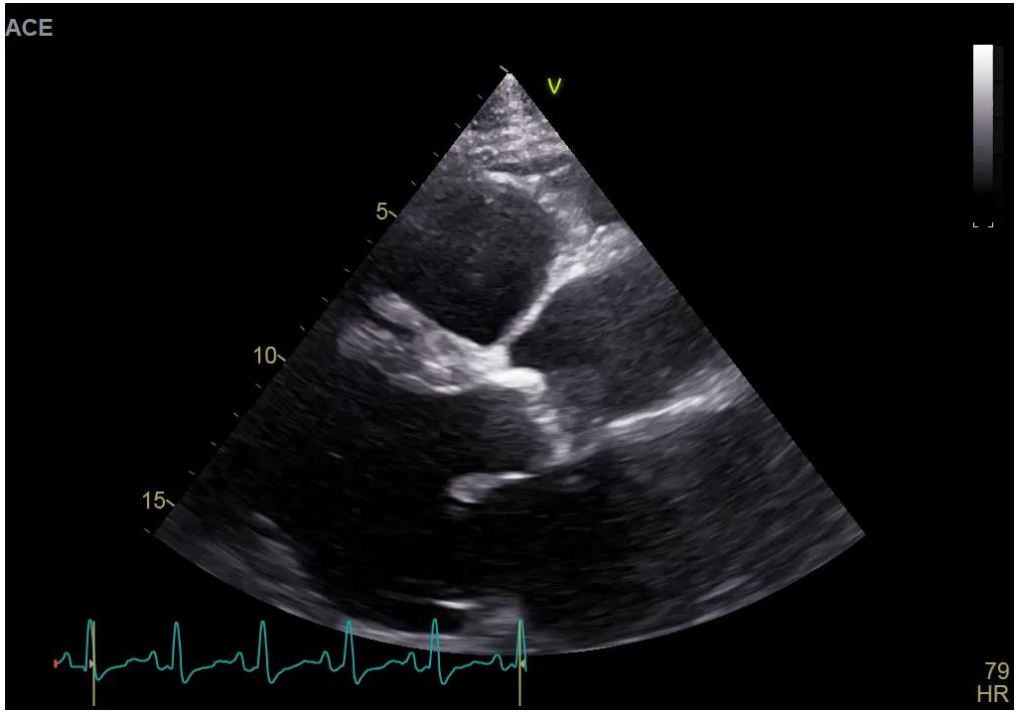
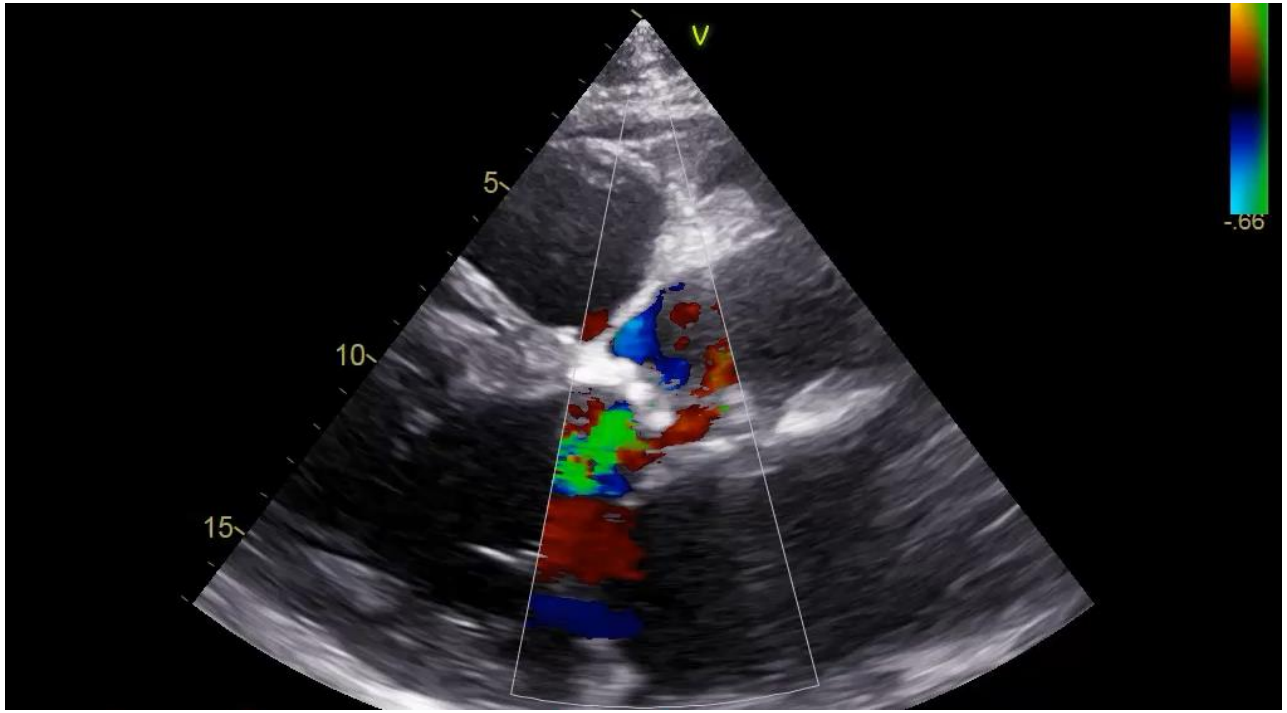
Casus 2 – buiten alle richtlijnen

- **57 jarige man, opname maart (2e keer) dit jaar met dec cordis elders icm longembolie wv NOAC**
- **Non ischemisch hartfalen, CAG in feb zonder coronairlijden**
- **Perfan en Furosemide**
- **Echter niet te ontwateren / persisterende cardiogene shock**

Casus 2 – buiten alle richtlijnen

Echo:
LVEF 15-20%, matige RVEF, bicuspide aortaklep, slechte opening (AVA 1,0 cm2, geïndexeerd 0,54 cm2/m2, PG 22 mmHg), matige AoI, matige MI/TI





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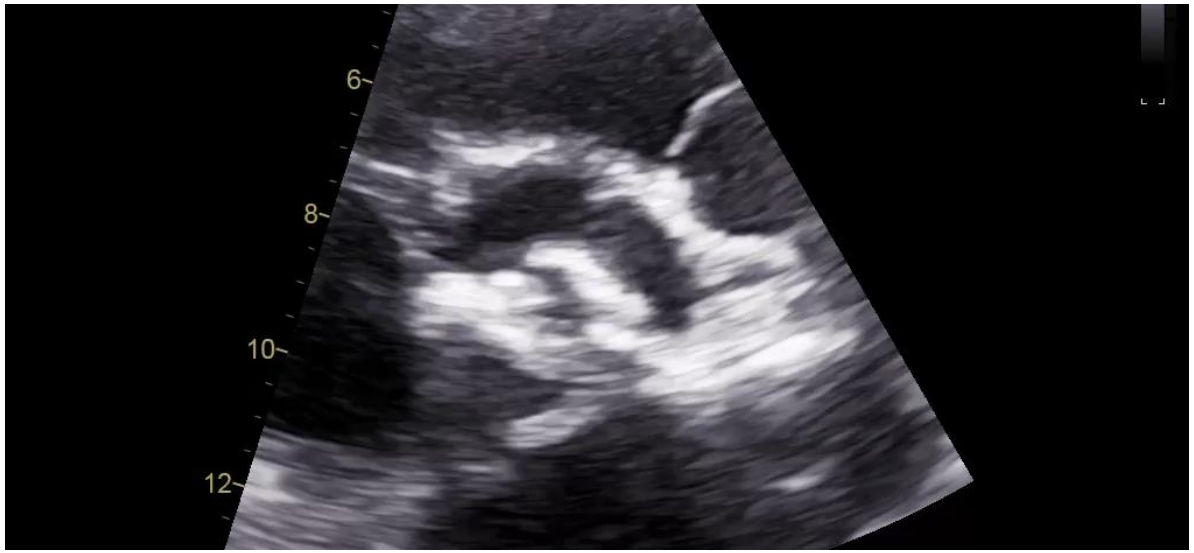
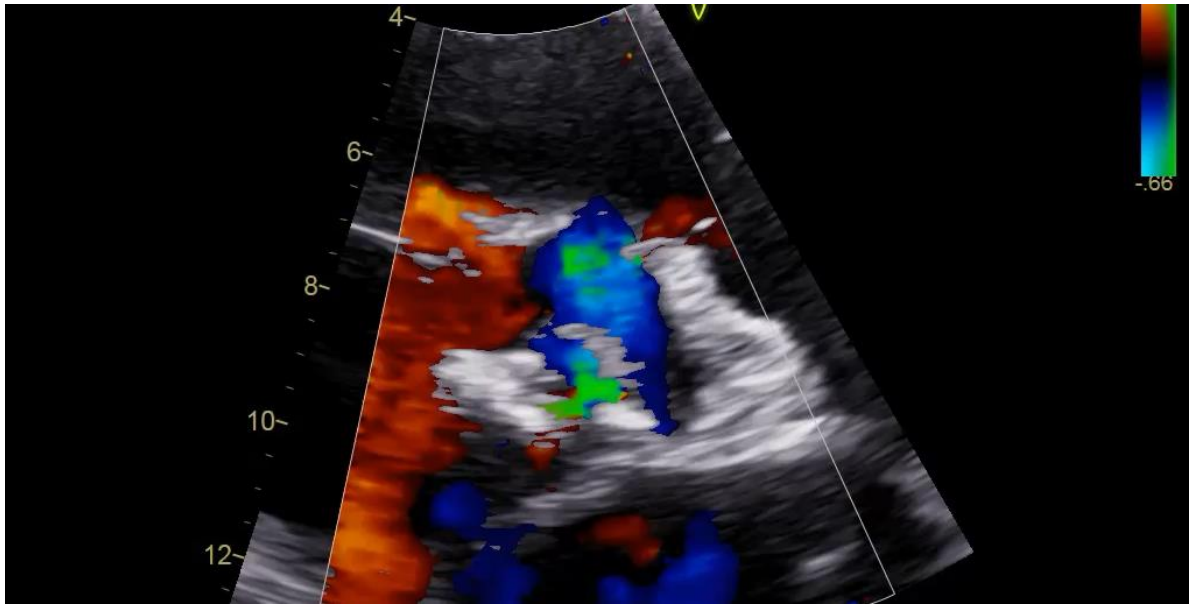
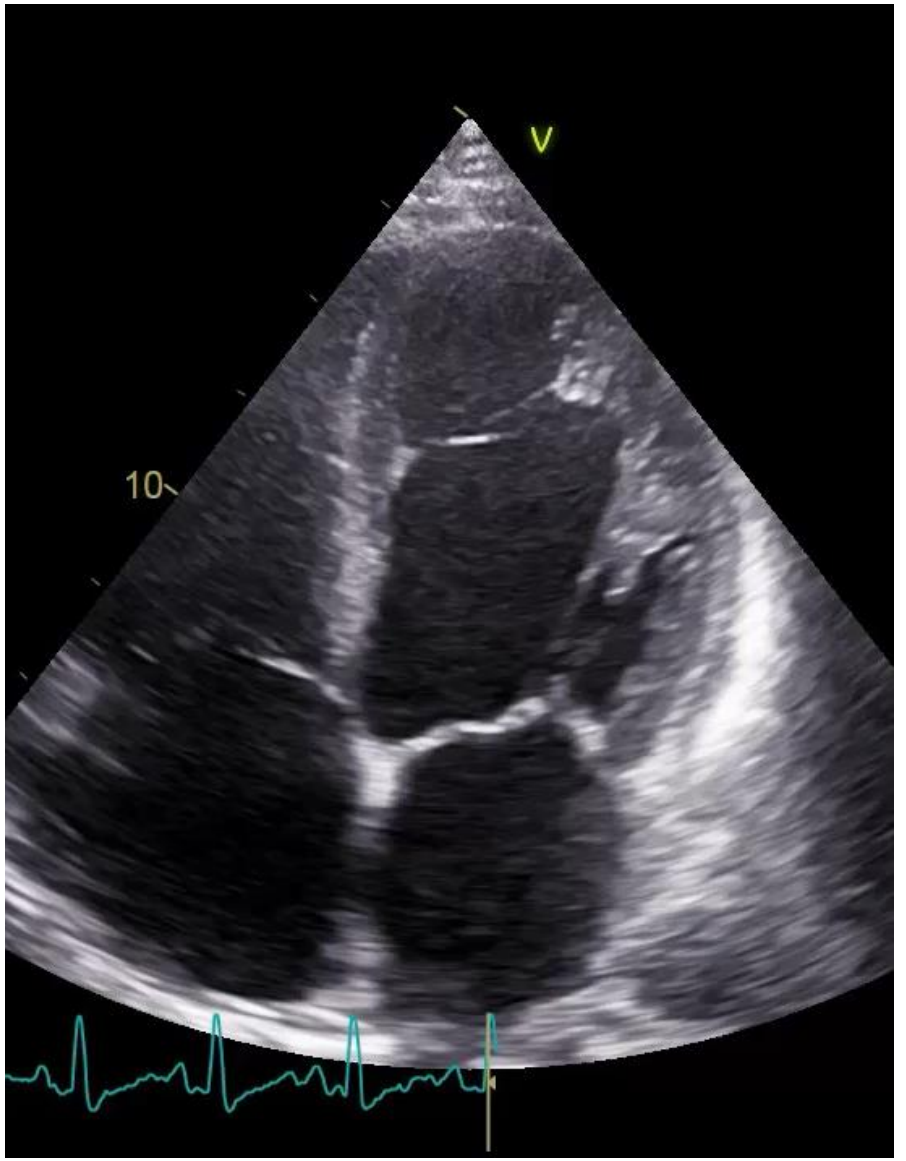
Casus 2 – buiten alle richtlijnen







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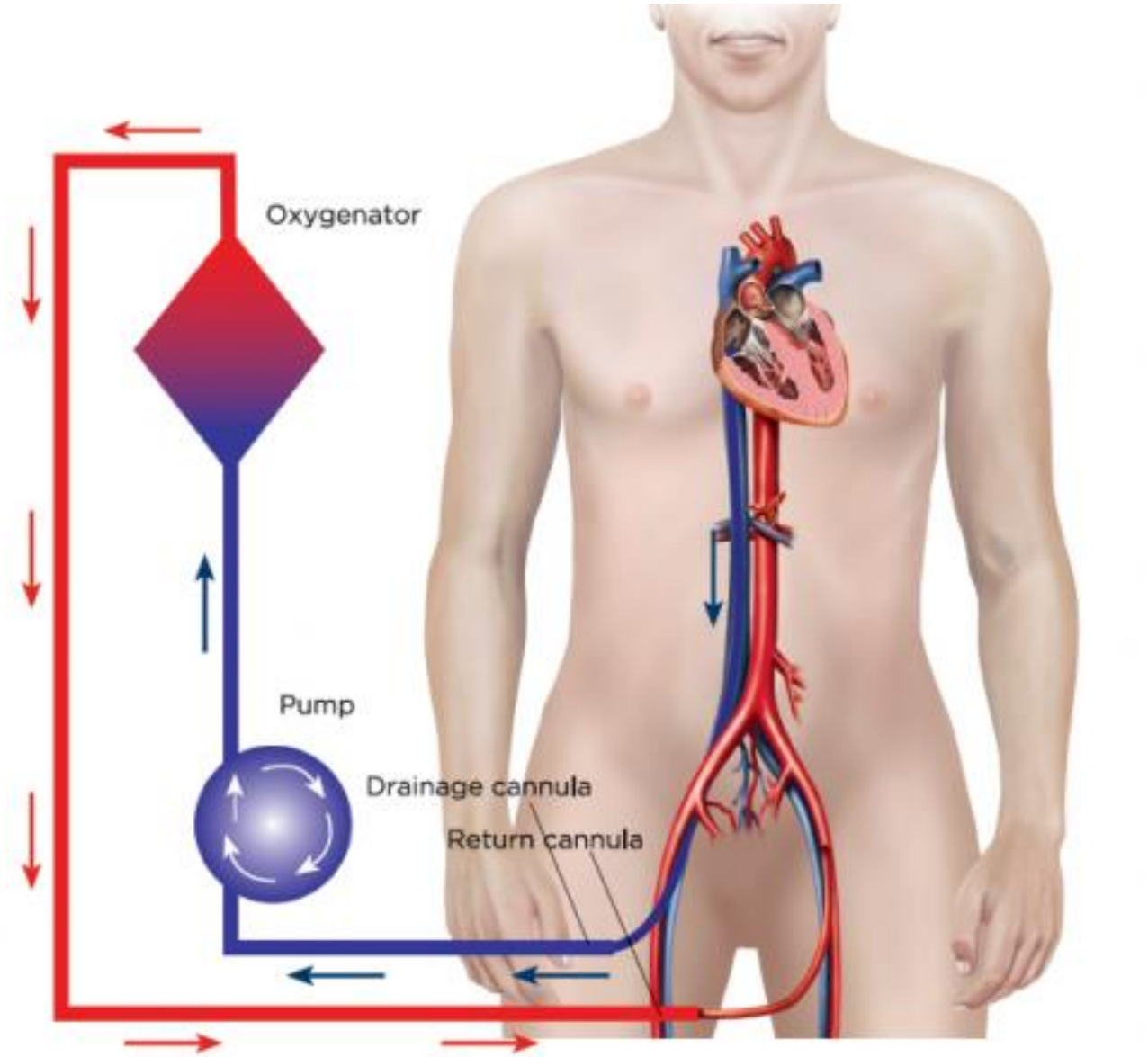
Veno-Arteriele ECMO (VA-ECMO)?



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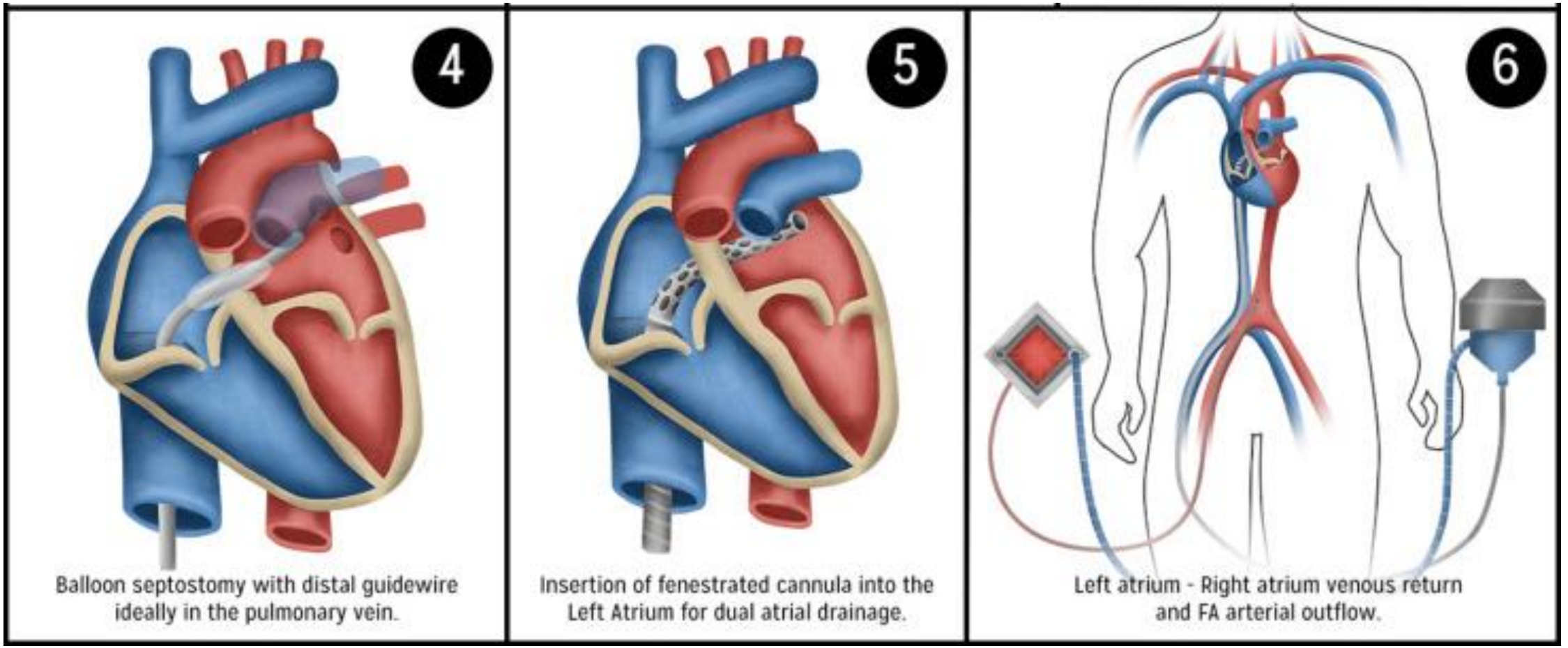
VA-ECMO geen optie: slechte LV en AoI: LAVA-ECMO



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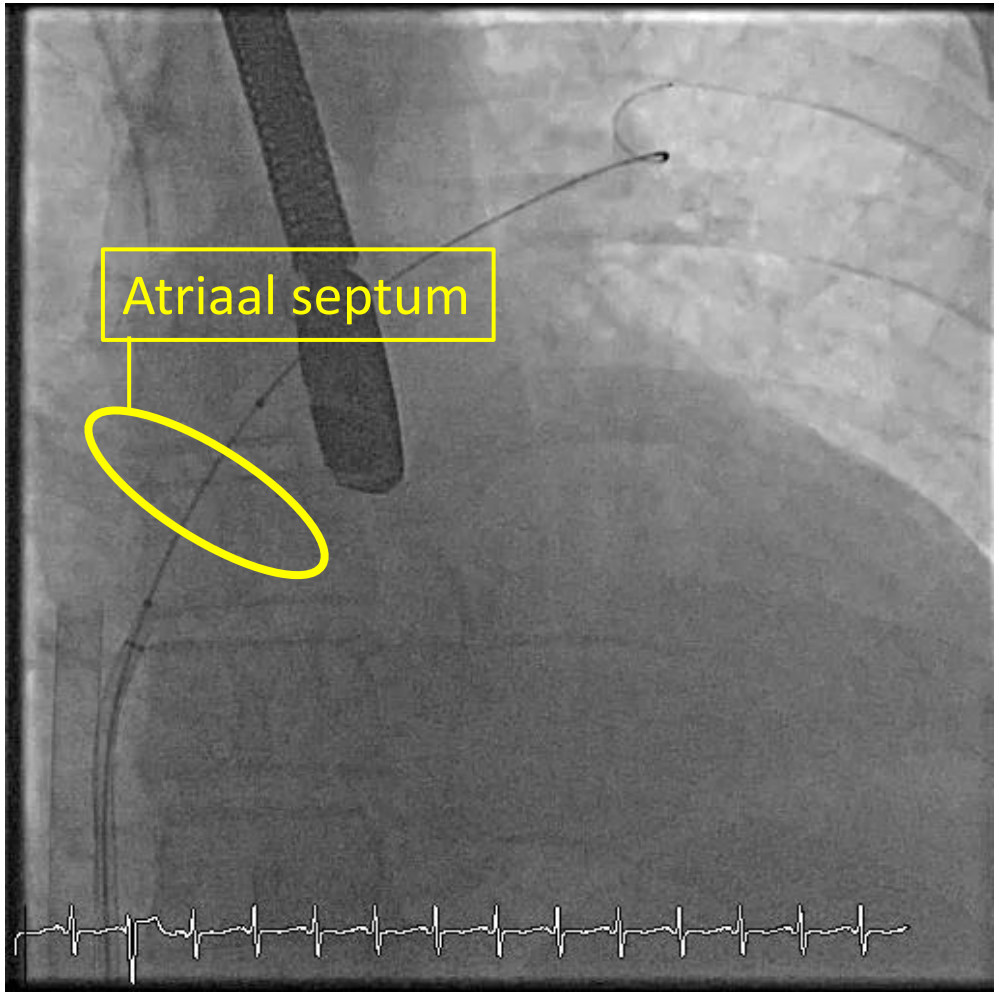
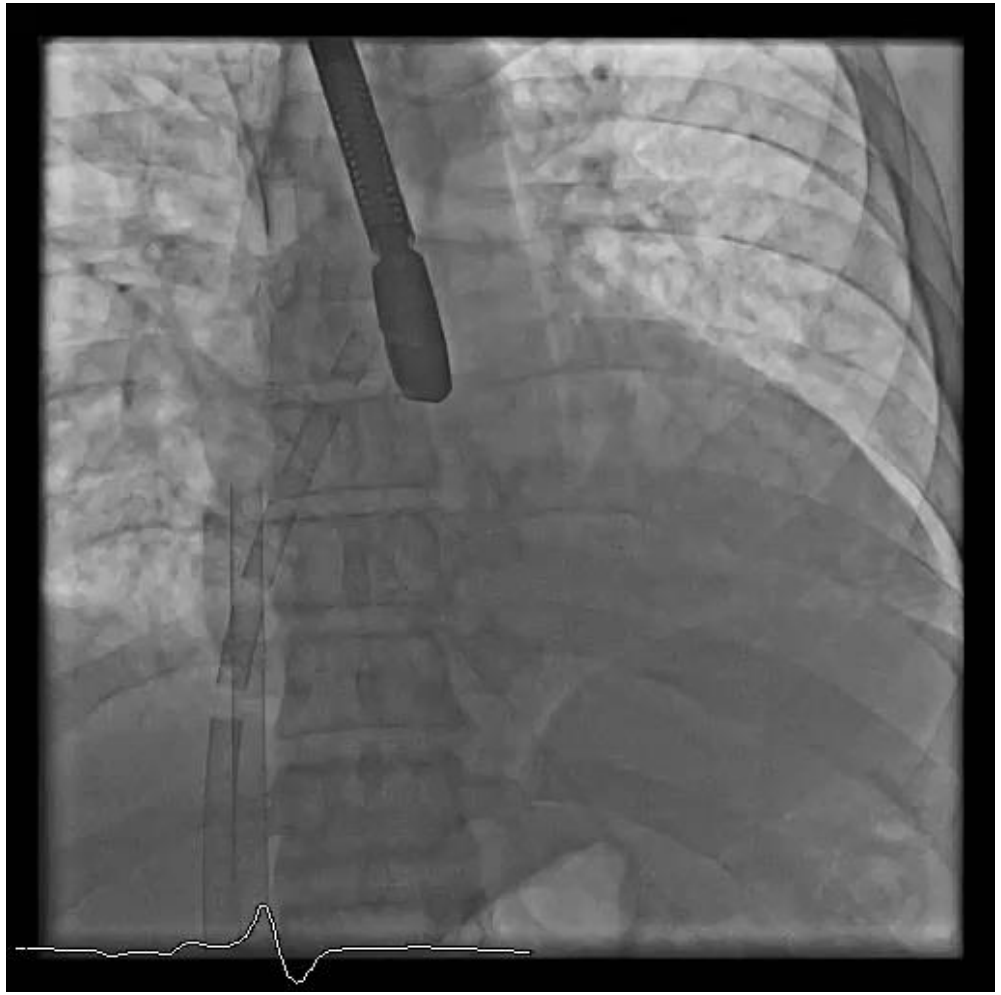
Left Atrial-Veno-Arterial Extracorporeal Membrane Oxygenation: Step-By-Step Procedure and Case Example. Struct Heart. 2022 Oct 31;6(6):100117.

LAVA-ECMO





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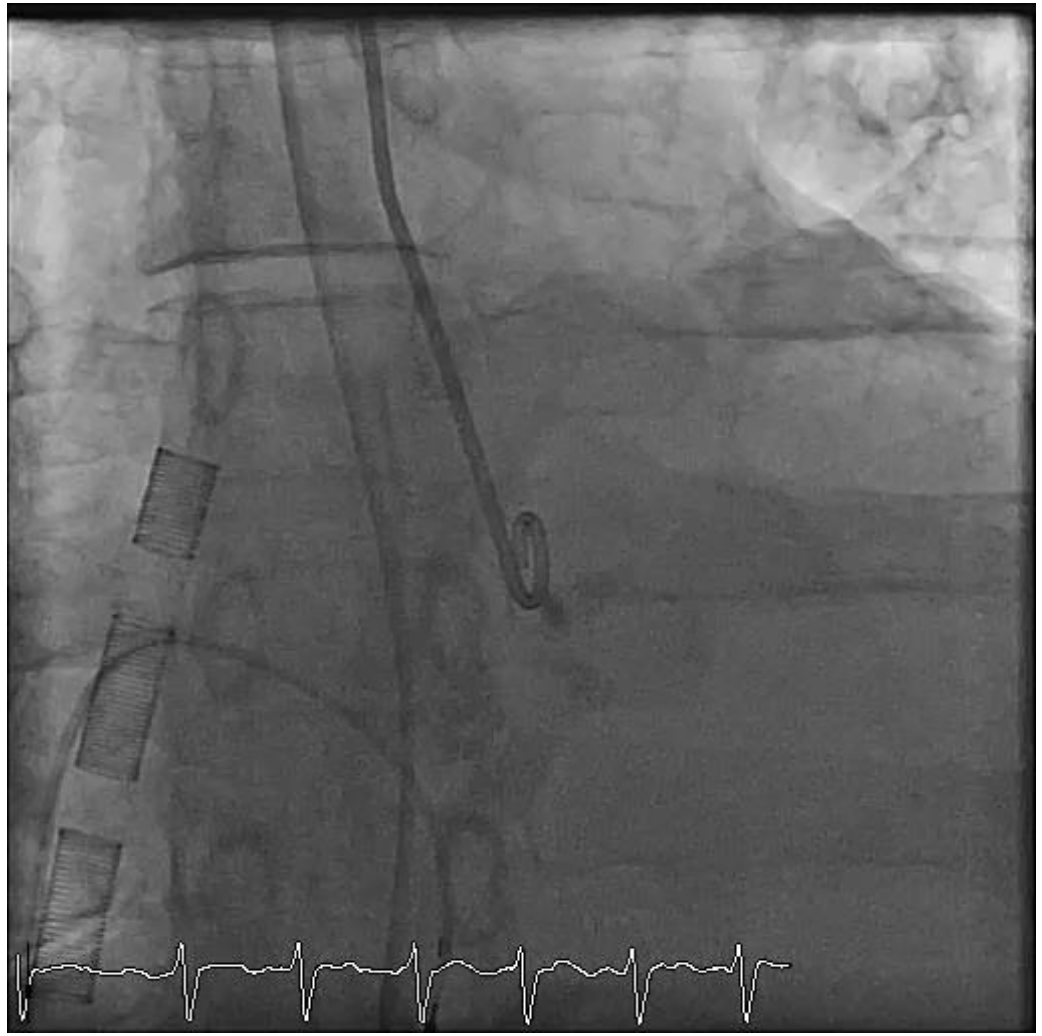
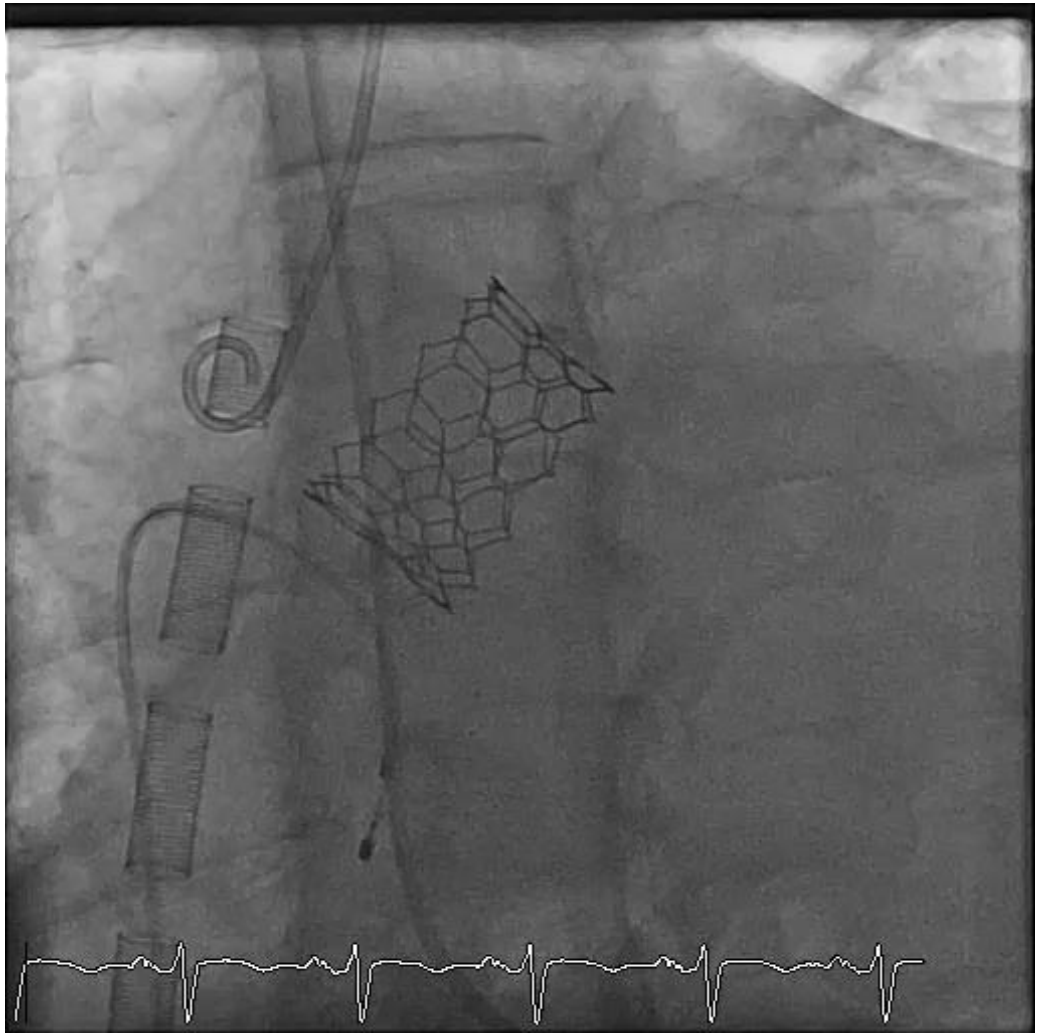
Casus 2 buiten richtlijnen – TAVI bij AoI onder LAVA-ECMO





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Casus 2 buiten alle richtlijnen – follow-up 5 mnd

- **Het gaat goed met Dhr. revalideert, maakt mooi vooruitgang**
- **ICU acquired weakness (oa slikstoornis) met zeer goed klinisch herstel**
- **Gesprekken met maatschappelijk helpen patiënt heel goed**

Conclusies

- **‘Structurele hart interventies’ steeds groter deel van werk in cathlab**
- **Technologische ontwikkeling gaat door (devices, imaging)**
- **Meer (percutane) mogelijkheden voor hartfalen patiënten:**
  - **Klepinterventies**
  - **Impella, ECLS**
  - **LVAD / Harttransplantatie**
- **Wachten op percutane Mitralisklep, tricus interventie**
- **Gelijk met groei (complexe) interventies:**
  - **-> Samenwerking met partners (imaging, CTC, 1e lijn) belangrijk!**

Percutane klepinterventies - discussie

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