TRANSCATHETER GEBONDEN AORTAKLEPVERVANGING (TAVI)

als optie voor patiënten met hartfalen

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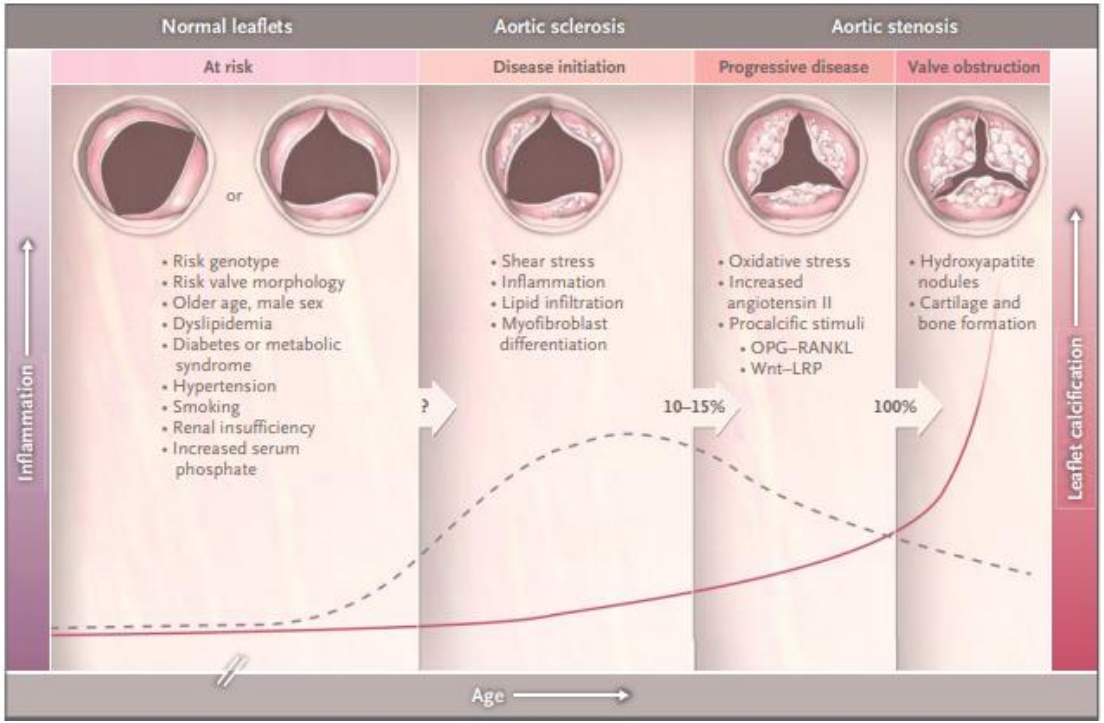
Continuing Nursing Education
22 januari 2019, 10:50-11:15

Erasmus MC
Universitair Medisch Centrum Rotterdam

Inhoud

- Degeneratieve aortaklepstenose
- TAVI bij symptomatische, ernstige aortaklepstenose
- TAVI bij patiënten met hartfalen en een matige aortaklepstenose
- Casus

Aortaklepstenose



N Engl J Med. 2014 21;371(8):744-56

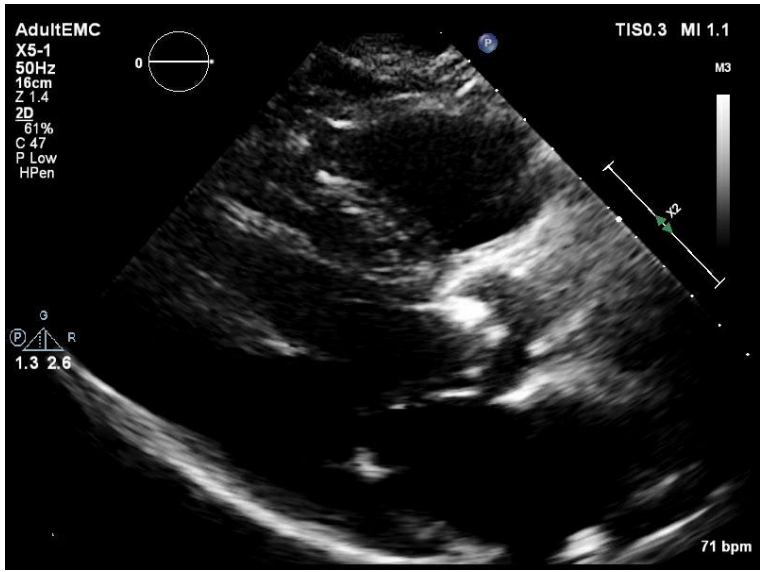
Aortaklepstenose

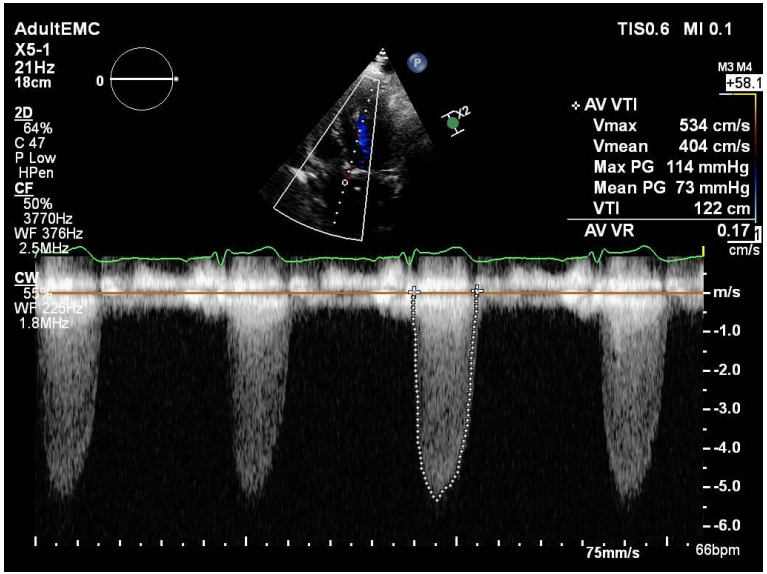
- Prevalentie 2.8% bij >75 jaar
  - ±10% bij 80-89 jaar

- Symptomen
  - Angina pectoris
  - Dyspneu
  - Syncopes
  - Decompensatio cordis

N Engl J Med. 2014 21;371(8):744-56

Ernstige aortaklepstenose





TTE: Zieke klep die slecht opent

Vmax >4m/s, PG>60mmHg, AVA<1cm²

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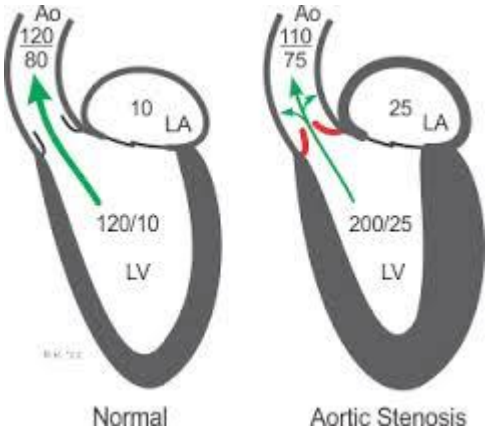
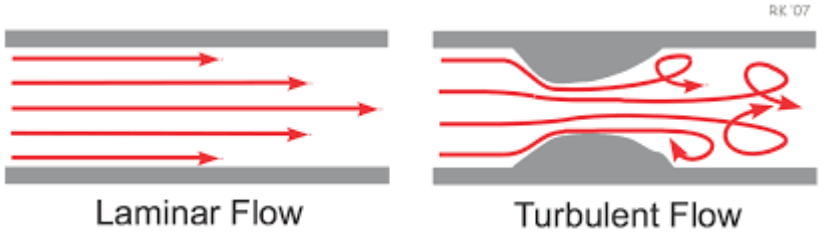
Gradiënt en snelheid over de klep



Drukverval

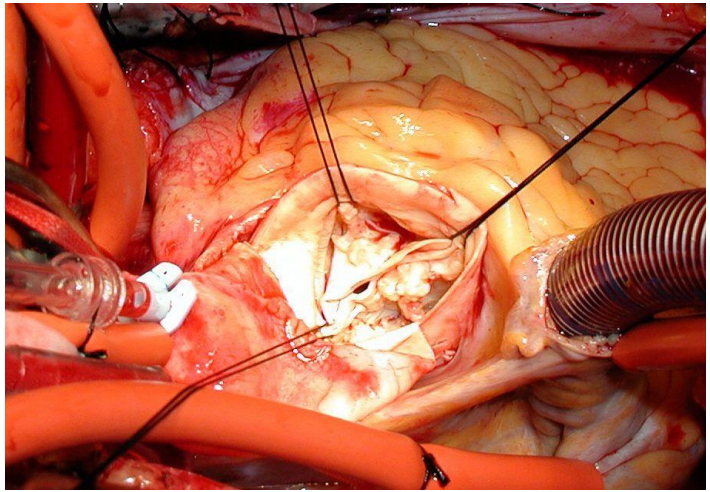


Verhoogde snelheid door vernauwing

Ernstige aortaklepstenose

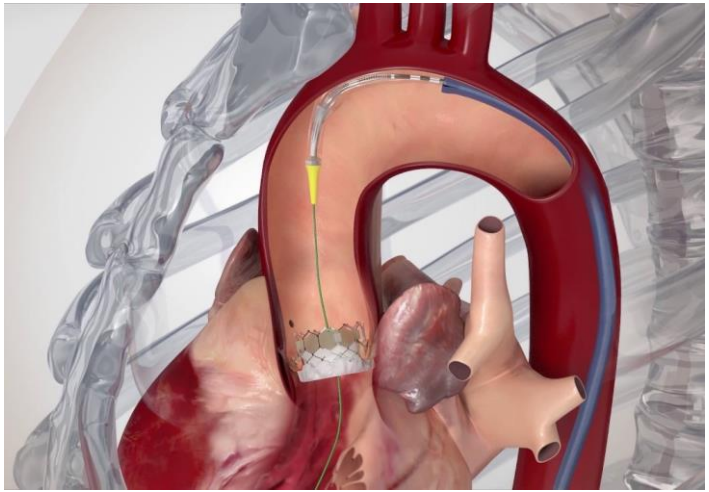
- Progressieve ziekte
- Als er symptomen ontstaan, sterft meer dan 50% van de patiënten binnen 2 jaar
- Tenzij..

Behandeling van aortaklepstenose



Chirurgische aortaklepvervanging (SAVR)

OF



Transcatheter aortaklep implantatie (TAVI)

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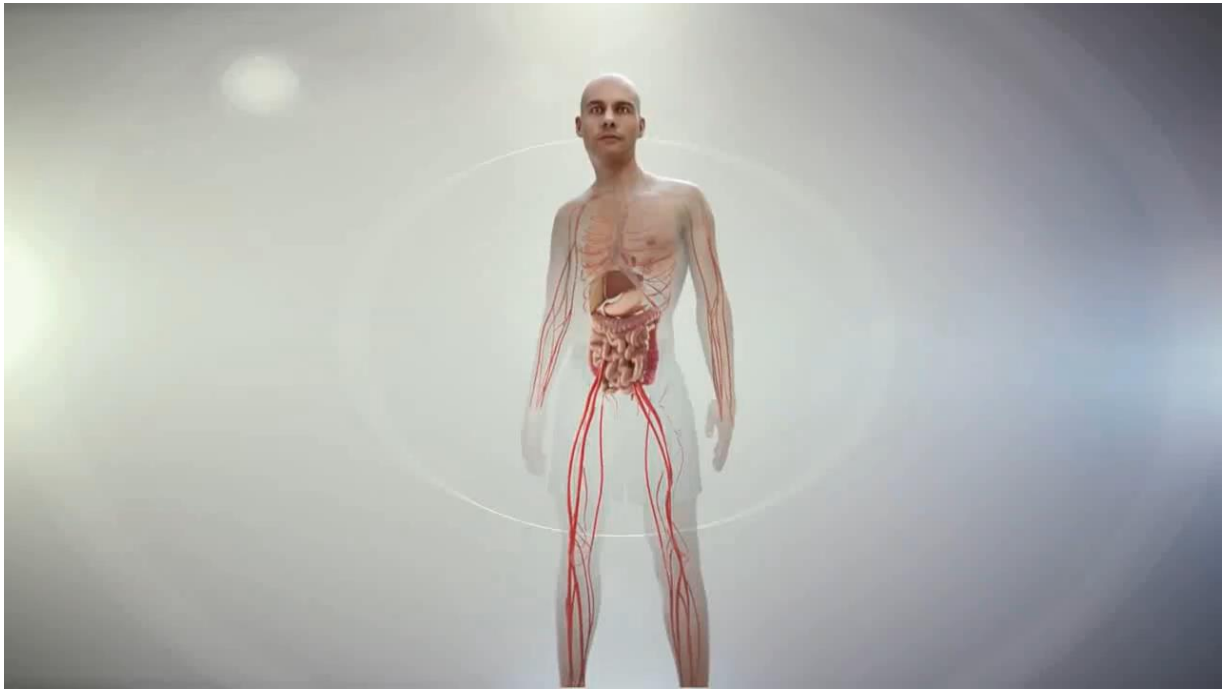
TAVI



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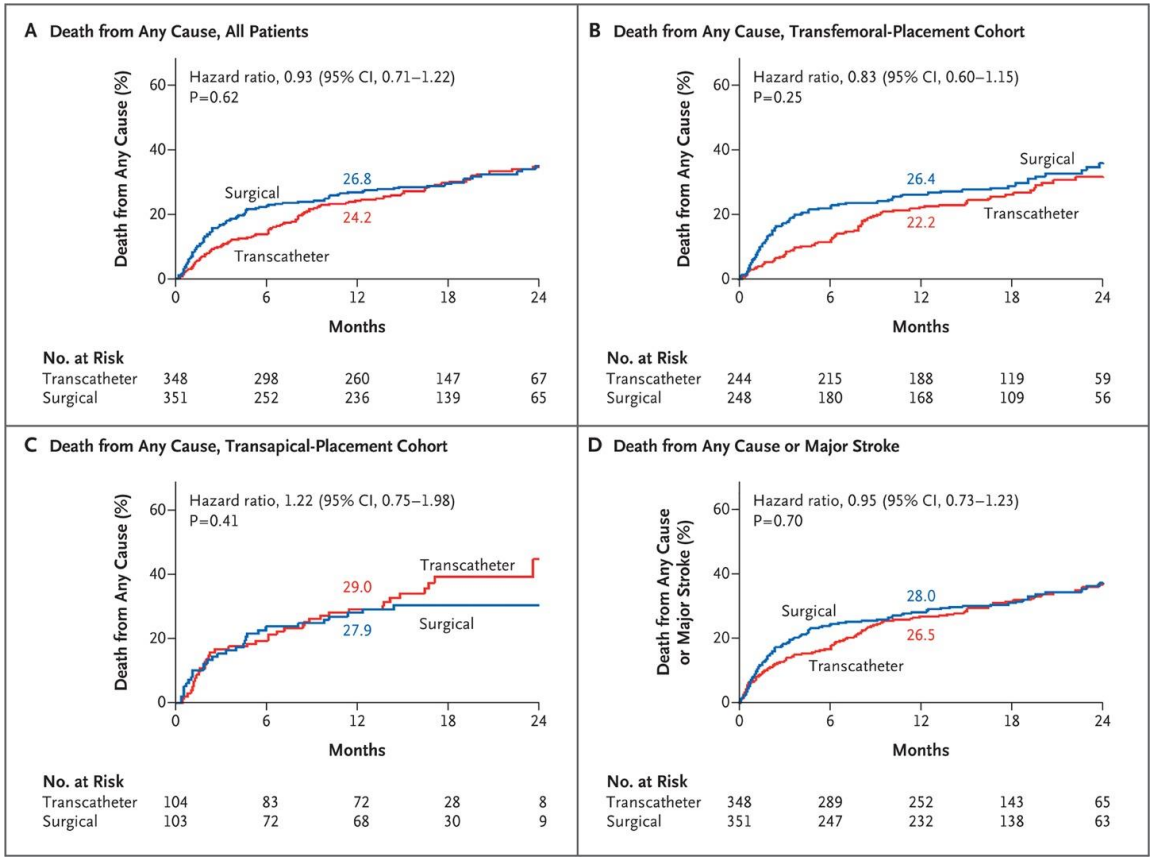
TAVI



TAVI vs. SAVR in hoog risico patiënten

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N Engl J Med 2011; 364:2187-2198

Huidige richtlijn (ESC 2017)

SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] 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 (see *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.	IIb	C
Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.	IIb	C
C) Asymptomatic patients with severe aortic stenosis (refers only to patients eligible for surgical valve replacement)		
SAVR is indicated in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (LVEF <50%) not due to another cause.	I	C
SAVR is indicated in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing symptoms on exercise clearly related to aortic stenosis.	I	C
SAVR should be considered in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing a decrease in blood pressure below baseline.	IIa	C
SAVR should be considered in asymptomatic patients with normal ejection fraction and none of the above-mentioned exercise test abnormalities if the surgical risk is low and one of the following findings is present: • Very severe aortic stenosis defined by a V_{max} >5.5 m/s • Severe valve calcification and a rate of V_{max} progression ≥0.3 m/s/year • Markedly elevated BNP levels (>threefold age- and sex-corrected normal range) confirmed by repeated measurements without other explanations • Severe pulmonary hypertension (systolic pulmonary artery pressure at rest >60 mmHg confirmed by invasive measurement) without other explanation.	IIa	C
D) Concomitant aortic valve surgery at the time of other cardiac/ascending aorta surgery		
SAVR is indicated in patients with severe aortic stenosis undergoing CABG or surgery of the ascending aorta or of another valve.	I	C

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

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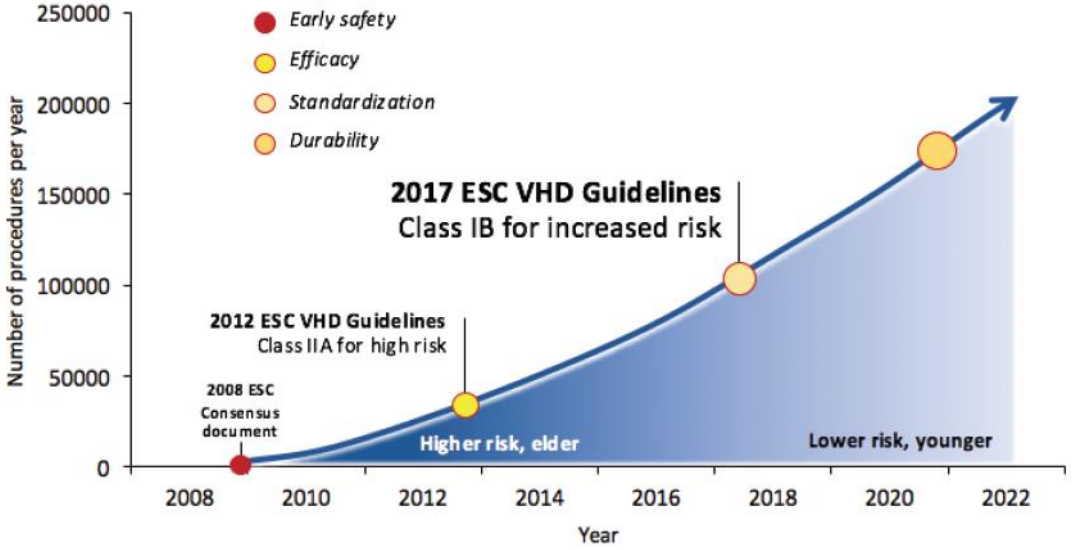
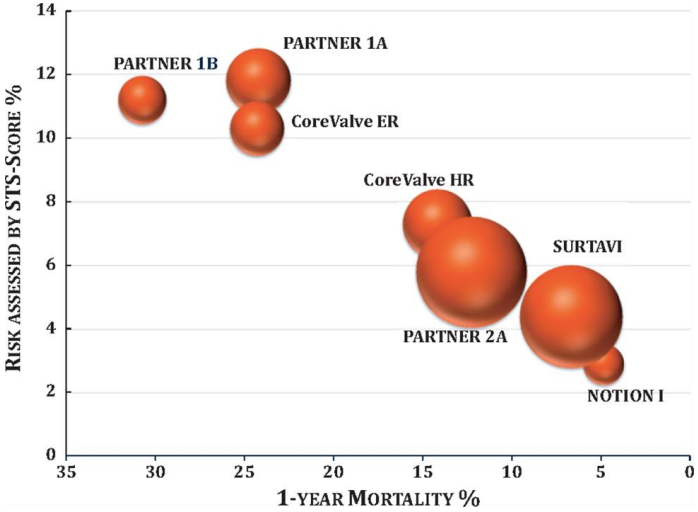
TAVI





Cardiac Interventions Today. 2018;12(2):51-3.

Eur Heart J. 2018;39(28):2643-2645. doi:10.1093/eurheartj/ehy228

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TAVI als optie
voor patiënten
met hartfalen

Hartfalen en AS in Nederland

- LV-dysfunctie in 25% van de ouderen
- Hartfalen treft 4% van de bevolking
  - Neemt toe met de leeftijd (15% in 70-80-jarigen)
  - Meer dan 30.000 ziekenhuisopnames per jaar
- 25% van 65-plussers ontwikkelt aortaklepsclerose
  - 16% progressie naar aortaklepstenose binnen 8 jaar
- Beide aandoeningen kunnen samen voorkomen

Nederlandse Hartstichting, 2018 URL: https://www.hartstichting.nl/hart-en-vaatziekten
Circulation 2012;126:501-6.

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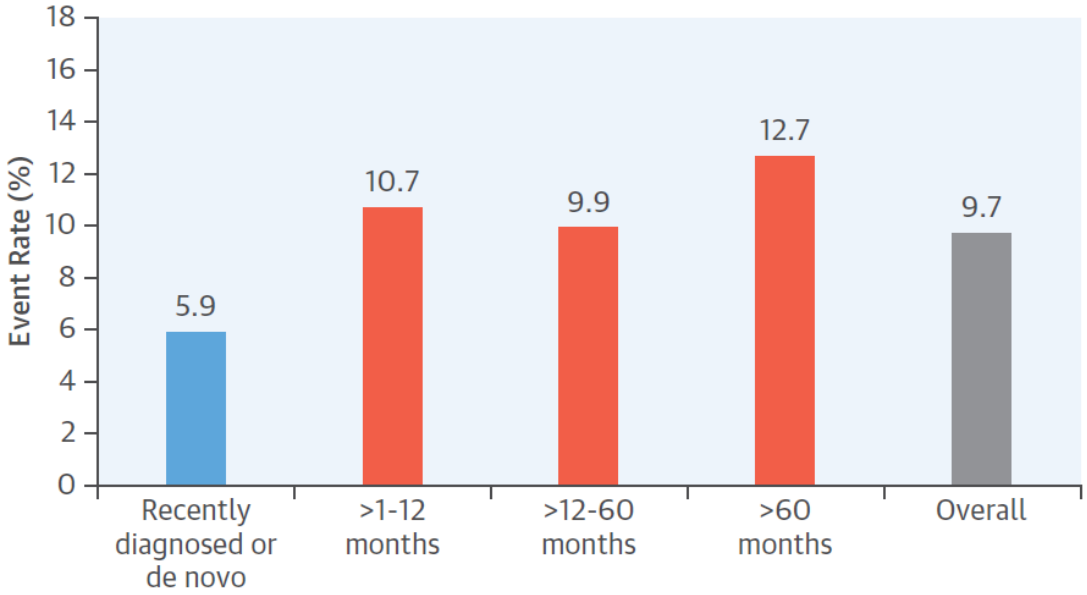
Impact van HF opname

30-Dagen Mortaliteit of heropname



Tijd van HF diagnose @ eerste opname

JACC 2017;69:3029-39

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LV dysfunctie en matige AS

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Prognostic Implications of Moderate Aortic Stenosis in Patients With Left Ventricular Systolic Dysfunction

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JACC 2017;69:2383-92

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LV dysfunctie en matige AS

	N=310
Age (mean ± SD)	72 ± 11
Male (n,%)	75%
Coronary artery disease (n,%)	72%
Prior myocardial infarction (n,%)	52%
Prior PCI (n,%)	35%
Prior CABG (n,%)	28%
COPD (n,%)	25%
eGFR in ml/min (mean ± SD)	61 ± 20
Peripheral arterial disease (n,%)	19%
Prior stroke (n,%)	43, 14%
NYHA-class (n,%) III IV	 29% 4%
Cardiac resynchronization therapy (n,%)	12%

Erasmus Medical Center Rotterdam

Leiden University Medical Center

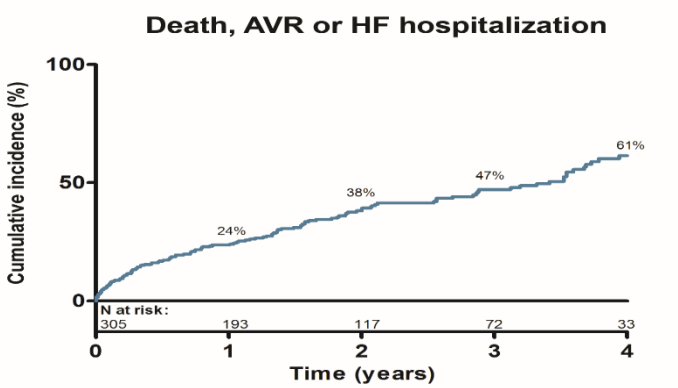
Quebec Heart and Lung institute

Columbia Medical University New York

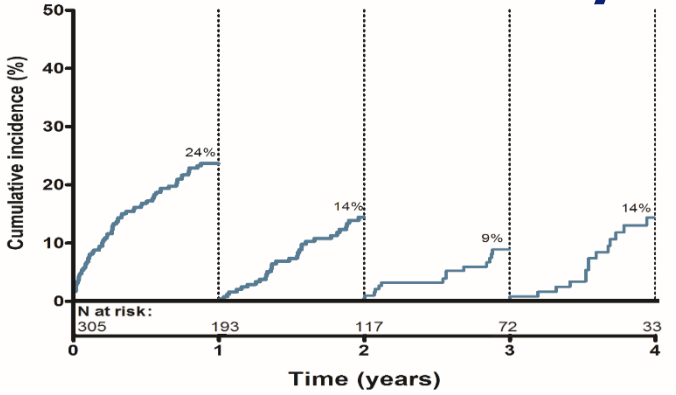
JACC 2017;69:2383-92

Gecombineerd Primair Eindpunt

Overall



Landmark Analyse



- **Events zijn frequent (61% @ 4 jaar FU)**
- **Meeste events gebeuren in het 1e jaar**
- **26% NYHA 1, 42% NYHA 2!**

JACC 2017;69:2383-92

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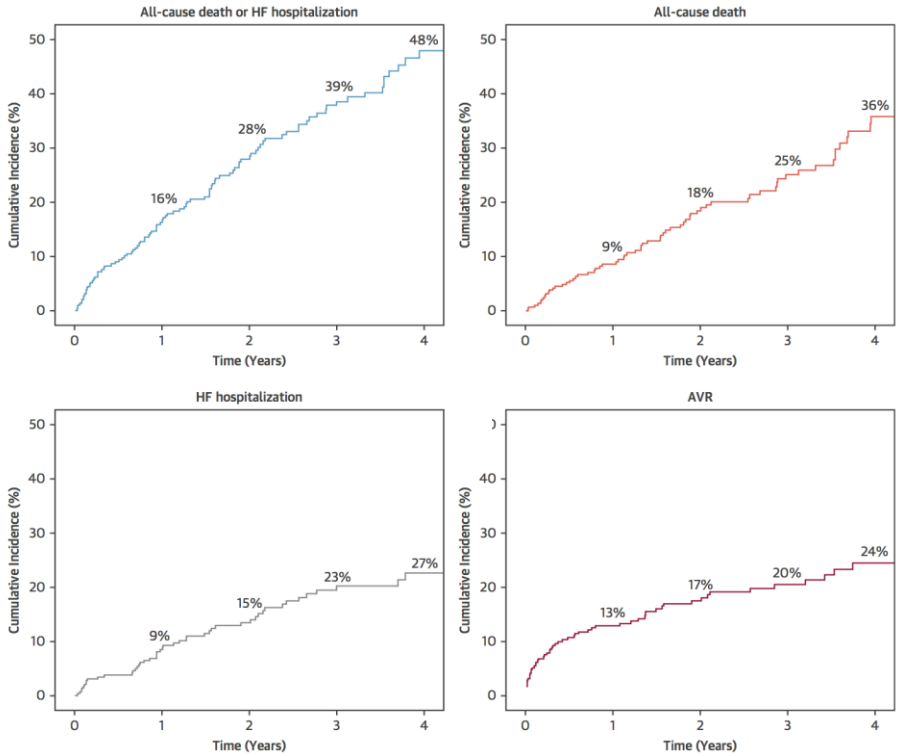
Individuele Eindpunten



JACC 2017;69:2383-92

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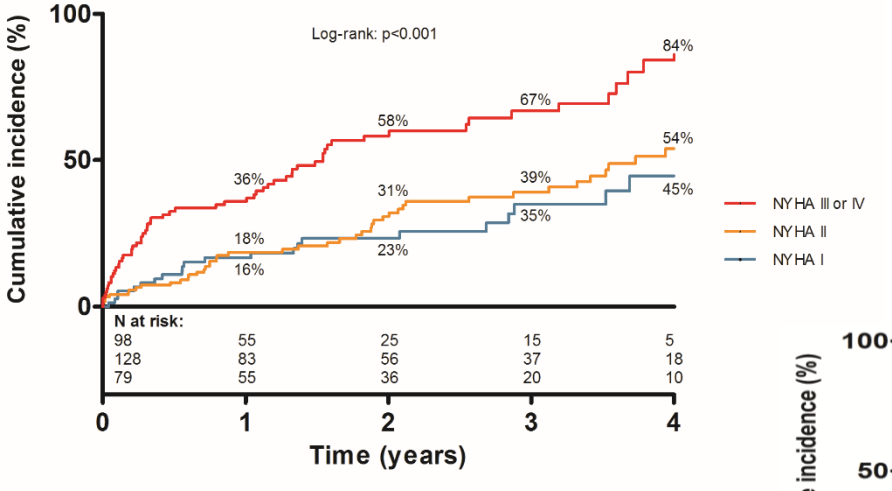
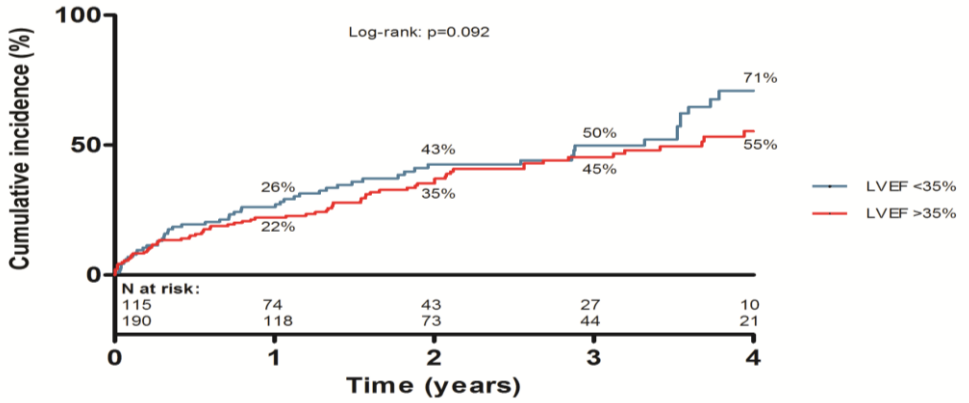
Impact van NYHA klasse & EF





JACC 2017;69:2383-92

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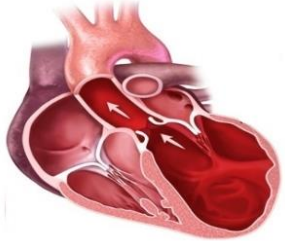
Heart Failure

Leading cause of hospitalizations



Increased AFTERLOAD

(sympathetic activity)

Impaired LV systolic function

Diastolic dysfunction

Beta-blockers
ACEi/ ARBs
MRAs
Diuretics

Coexistence of Heart Failure and Moderate Aortic Stenosis

High risk population

Early AVR may be beneficial

Aortic Stenosis

Most frequent valvulopathy

Increased AFTERLOAD

(trans-valvular gradient)

Impaired LV systolic function

Diastolic dysfunction

Moderate AS	**Severe AS**
Watchful Waiting	**Aortic Valve Replacement**

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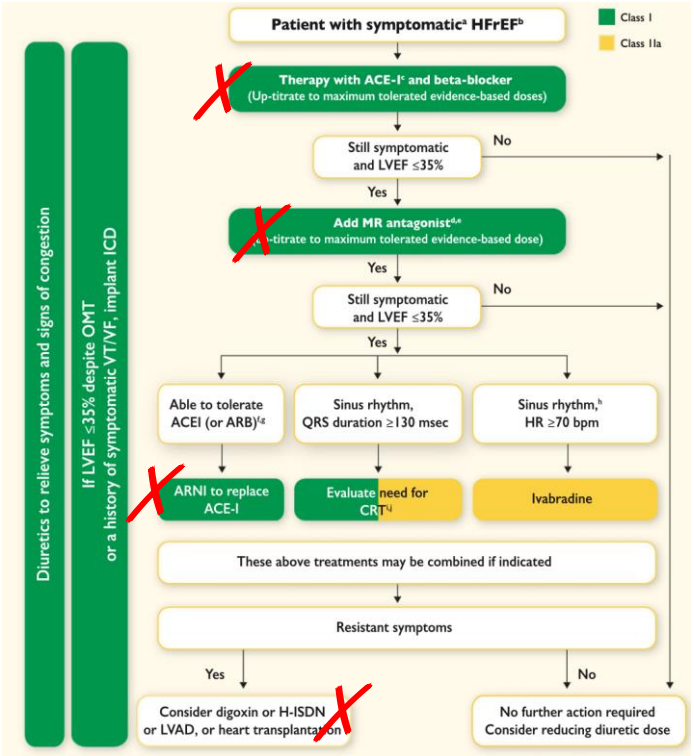
ESC Guidelines 2016



Afterload verlagers

EHJ 2016;37:2129-2200

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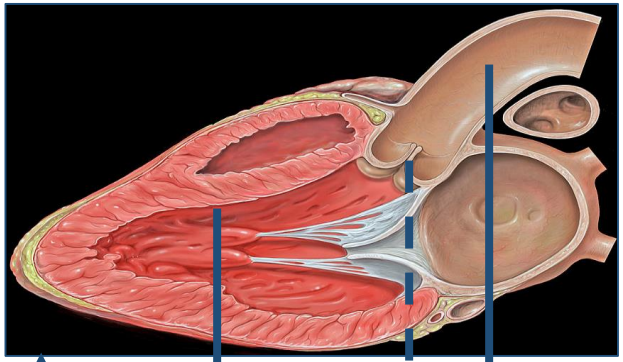
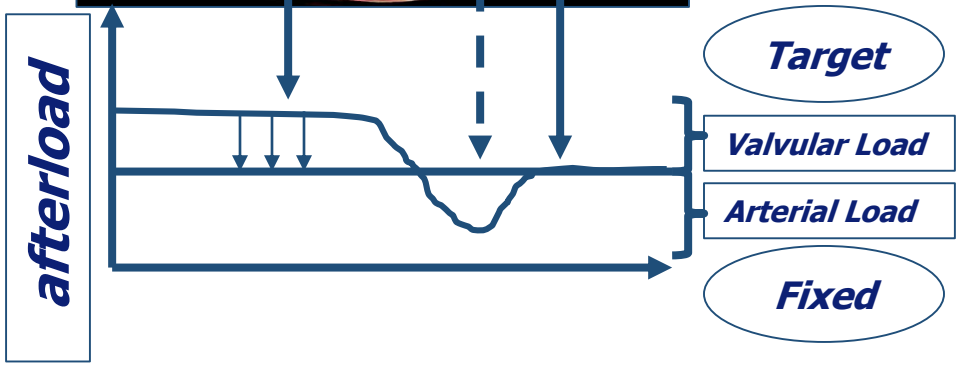
Hemodynamic Fundamentals





TAVI will reduce valvular load

Global Load ≅ Z_{VA} = Transaortic Mean ΔP + SBP / SVi

Elderly with decreased arterial compliance
- ✓ ***fixed BP***
- ✓ ***no response to vasodilators***
- ✓ ***no medical options to reduce arterial load***

JACC 2012;60:169-80.

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AVR bij matige AS

Duke Echocardiographic Database

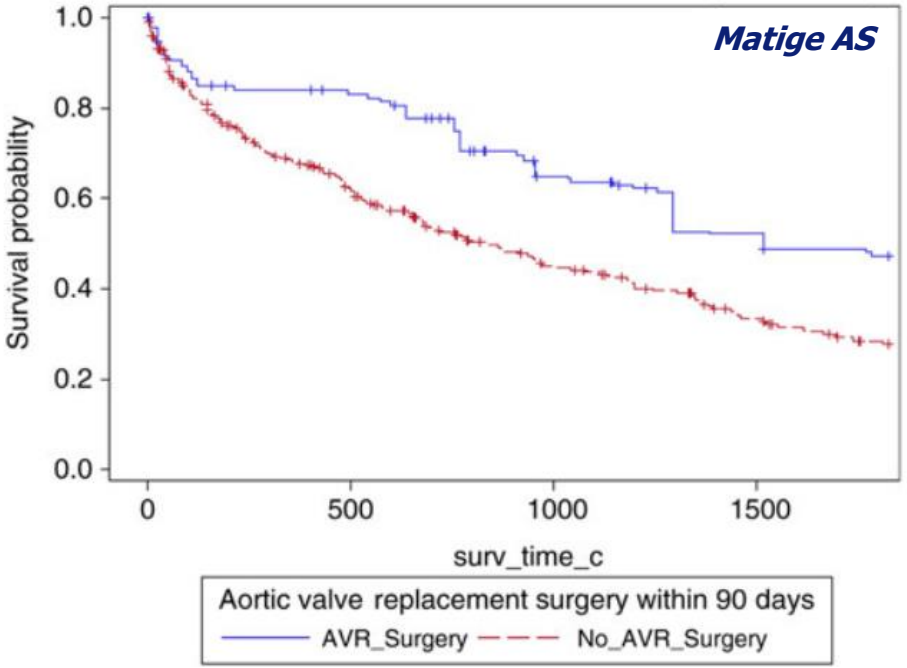
N = 132.804

AS indien MG > 25 mmHg of v_{max} 3 m/s

N = 1634 patiënten met AS en LV syst dysfunctie

N = 1090 met matige AS, 26% SAVR

N = 544 met ernstige AS, 48% SAVR



European Heart Journal 2016;37:2276-86.

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Matige Prosthesis-Patient Mismatch

Laval Hospital

N = 2576 patiënten na SAVR

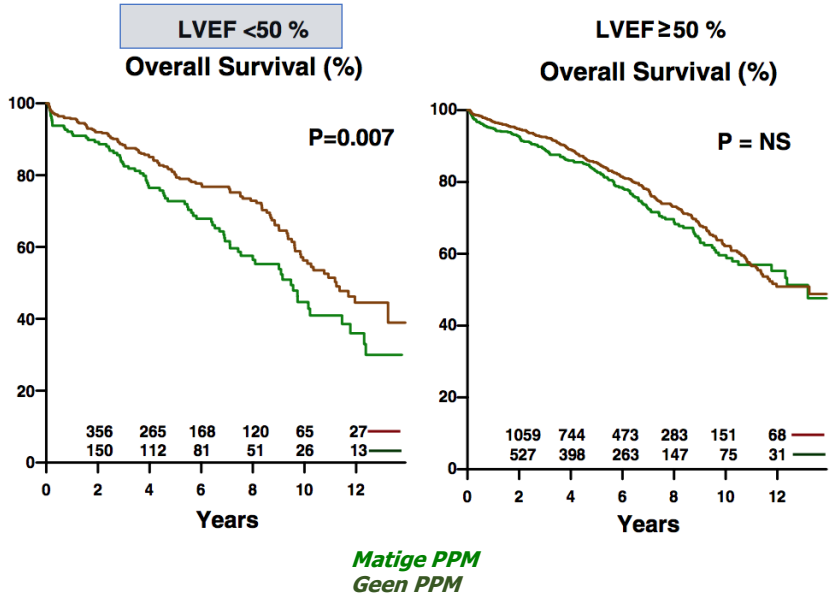
N = 1739 insignificante Patient-Prosthesis mismatch

N = 797 met matige Patient-Prosthesis mismatch

0.65 < AVA_i ≤ 0.85 cm^2/m^2

N = 40 met ernstige Patient-Prosthesis mismatch

Matige PPM verhoogt mortaliteit als EF < 50%



JACC 2009;53:39-47.

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TAVR UNLOAD Concept

TAVR UNLOAD Trial

International Multicenter Randomized

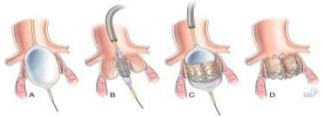
LV-EF< 50% & Moderate AS

R

- **TAVR + OHFT**
- **OHFT alone**

Follow-up: 1, 6 months 1 & 2 years

Clinical endpoints Symptoms Echo QoL



TAVR Unload

AHJ 2016;182:80-88.

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Geographies

International, multi-center, randomized trial

N = 600 Patients

30 sites ***5 sites*** ***3 sites***

Belangrijkste Inclusie Criteria

- NYHA klasse ≥ 2
- NT-proBNP > 1500 pg/mL (= 177.4 pmol/L) of HF opname in afgelopen jaar
- Behandeld met hartfalen therapie volgens richtlijn
  - Indien indicatie, eerst CRT
  - HF medicatie hoeft niet per se op hoogst haalbare dosis
  - Bevestigd door HF cardioloog op individuele basis
- LVEF < 50% , maar > 20%
- Anatomie geschikt voor implantatie TF SAPIEN 3 THV

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Belangrijkste Inclusie Criteria (2)

Matige AS =

✧*Aortic valve area (AVA) > 1.0 cm^2 and ≤1.5 cm^2 op echo in rust*

OF

✧*AVA ≤ 1 cm^2 met low flow in rust maar > 1.0 cm^2 met lage dosis DSE*

OF

✧*AVA ≤ 1 cm^2 en indexed AVA > 0.6 cm^2/m^2 @ echo in rust of DSE*

✓ *NB: Onafhankelijk Echo Corelab bepaalt geschiktheid patient*

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Belangrijkste Exclusie criteria

- LVEF < 20% of continue behoefte voor iv inotropica
- Opname wegens acuut gedecompenseerde HF binnen 2 weken voor randomisatie
- CRT implantatie binnen 3 maanden
- PCI of CABG binnen 3 maanden
- Indicatie tot revascularisatie aldus heart team
- Ernstige AI
- Congenitale uni- of bicuspide aortaklep

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Belangrijkste Exclusie criteria (2)

- Tevens niet-aortaklep gerelateerde ziekte met indicatie tot chirurgische vervanging
- AVR in het verleden (mechanisch of bioprothese)
- Ernstige MI wegens degeneratieve mitralisklep ziekte
- Ernstige NFS: GFR < 30 mL/min of dialyse behoeftig
- Te weinig kalk in aortaklep voor succesvolle TAVI middels Edwards SAPIEN3
- Levensverwachting < 2 jaar wegens kanker of niet-cardiale ziekte

Primaire eindpunt @ 1 jaar

- Primaire eindpunt beoordeeld op 1 jaar follow-up in alle 600 patienten. Minimale follow-up is 2 jaar.
  - Mortaliteit
  - Disabling stroke
  - Opname voor hartfalen, aortaklep gerelateerde ziekte of non-disabling stroke
  - Wijziging in Kansas City Cardiomyopathy Questionnaire (kwaliteit van leven)

TAVR UNLOAD - Team

Hartfalen Specialist

Heart Team

Verwijzend Cardioloog

TAVR UNLOAD

Thorax-Chirurg

Beeldvorming Specialist

Interventie Cardioloog

TAVR Unload

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Inclusie van patiënten

- Wereldwijd in totaal 70 patiënten geïncludeerd

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  - *Nu 16 patiënten gescreend*
    - 5 TAVI
    - 4 OHFT
    - 6 screeningsfailure
    - 1 patiënt nog in screening

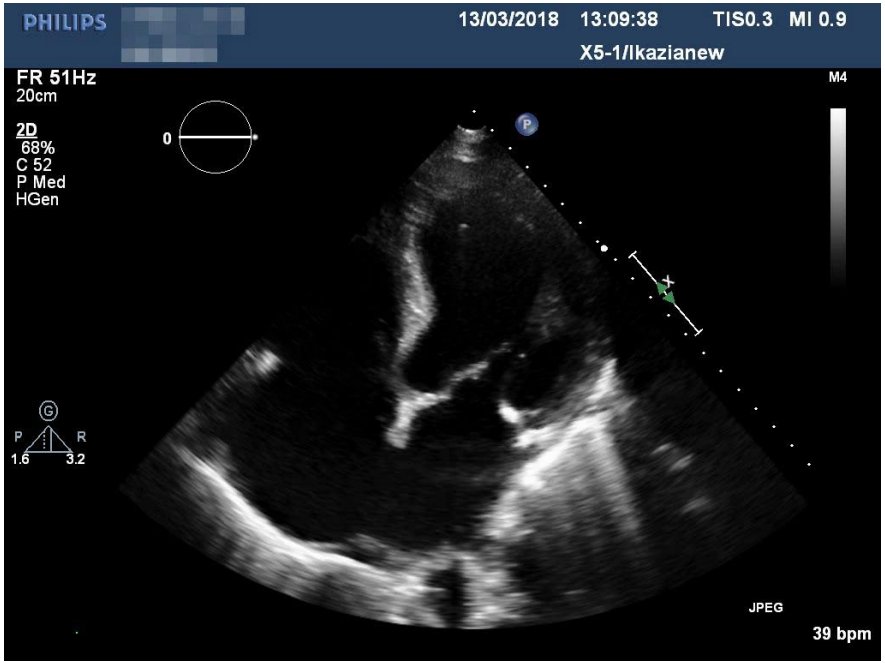
Casus

Dhr. De V., 78 jaar

Voorgeschiedenis
PCI RCA/LCX ‘99, PCI LAD ’18, AF, DM type 2, iCMP

Anamnese
Recent opname. Afgenomen eetlust. NYHA II.

LO
L 178cm, G 67kg, RR 130/60 mmHg
Systolische souffle graad II/VI



Slechte LV functie (EF 25%)

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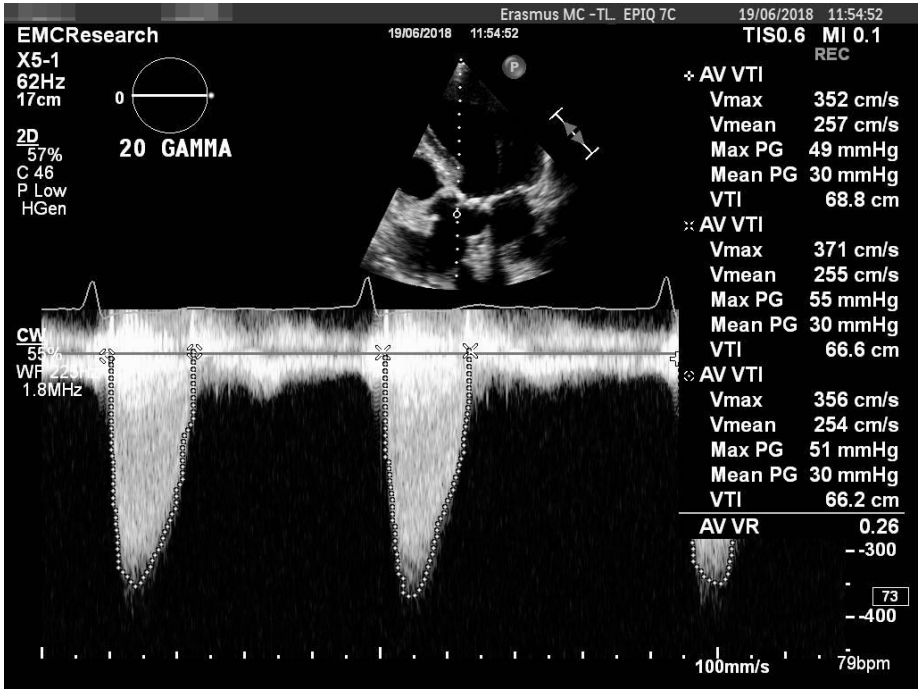
Echocardiografie



Slechte LV functie (EF 25%)
Matige aortaklepstenose
AVA 1.1cm^2 bij DSE

Geschikt voor TAVR UNLOAD

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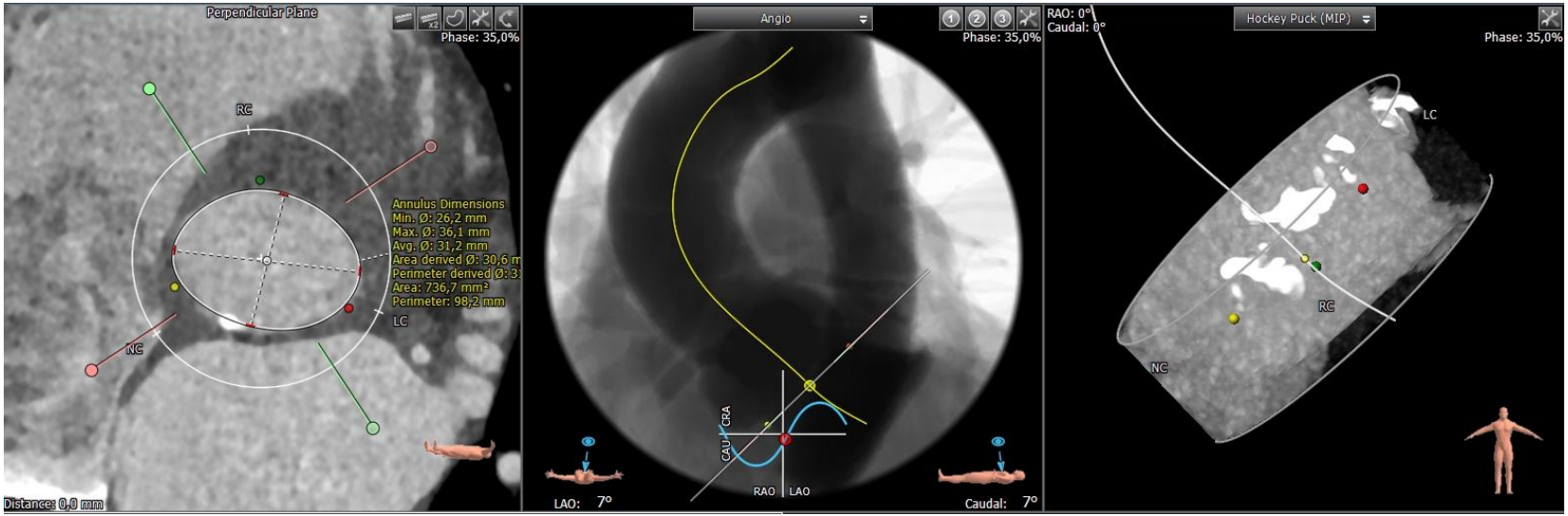
Voorbereiding (CT)



Annulus area 737mm2 - Diameter 30,6mm

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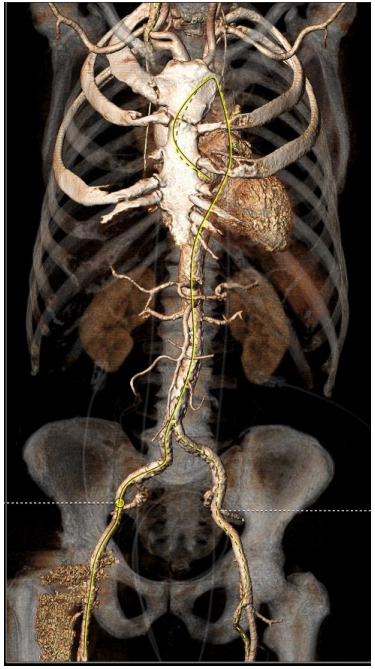
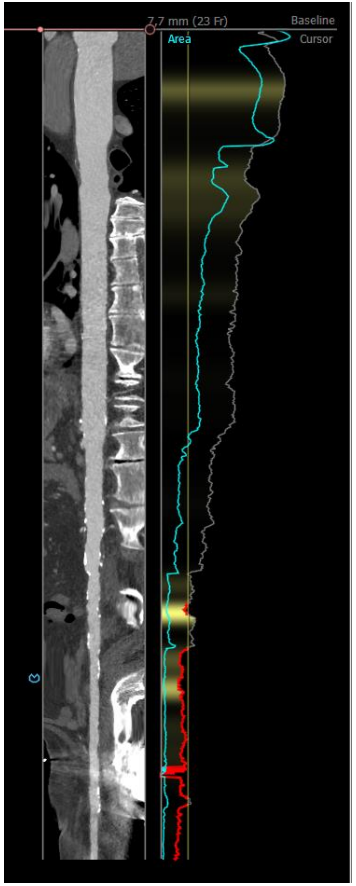
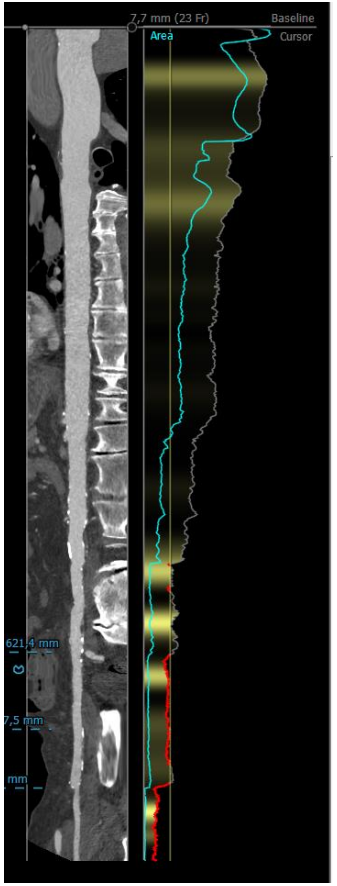
Femorale vaten



Rechts 7.4 mm *Links 7.8 mm*



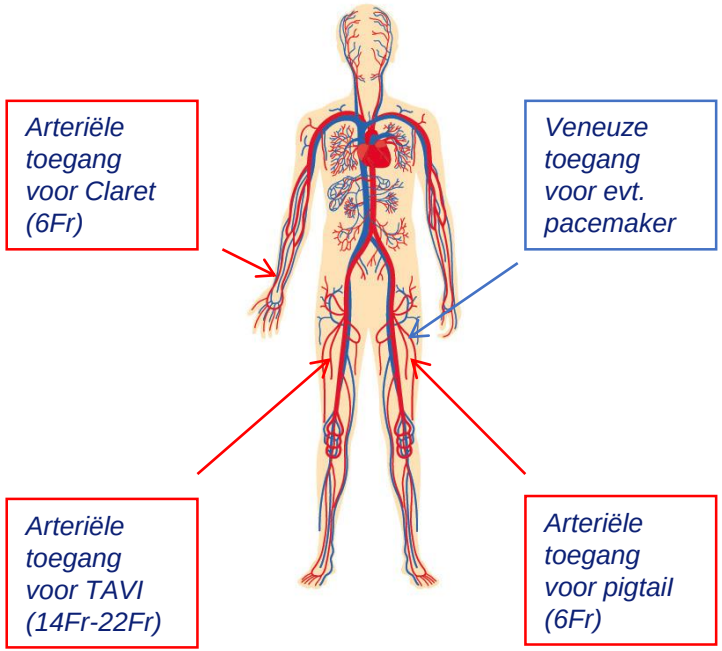
Rechts



Links

Erasmus MC

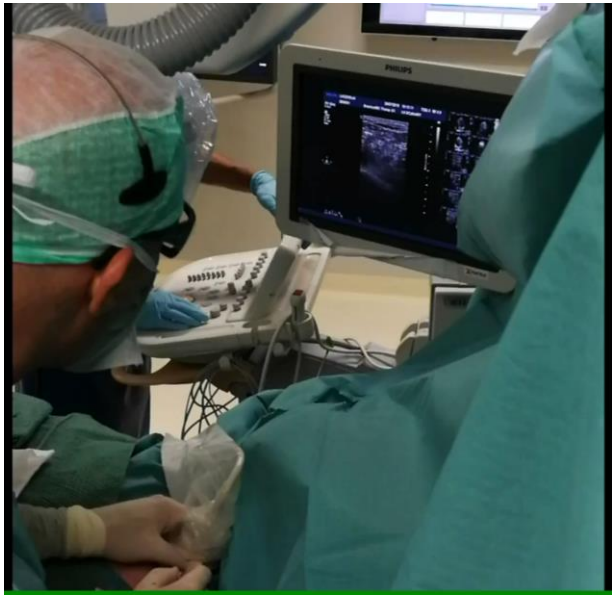
Toegangen

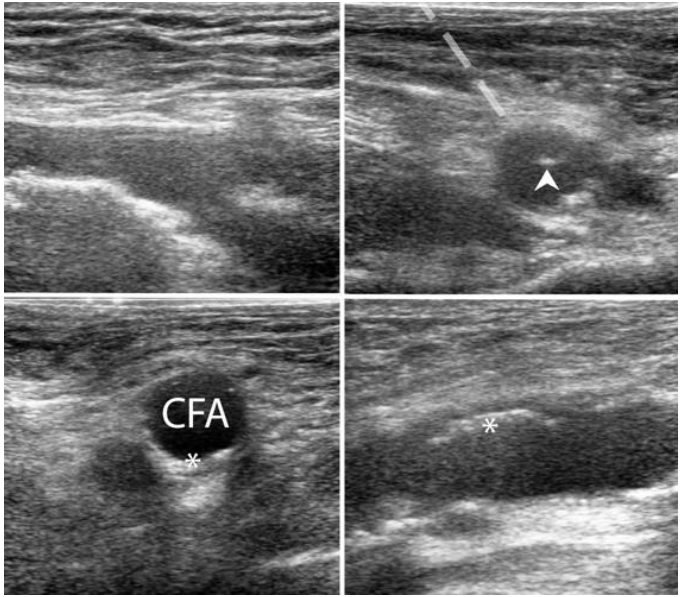


Benodigde toegangswegen

Erasmus MC

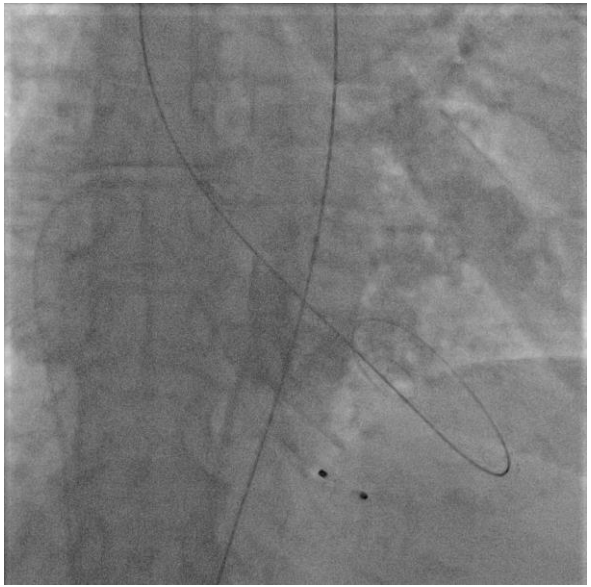
Echogeleid toegang





Echogeleid toegang

Pacemaker

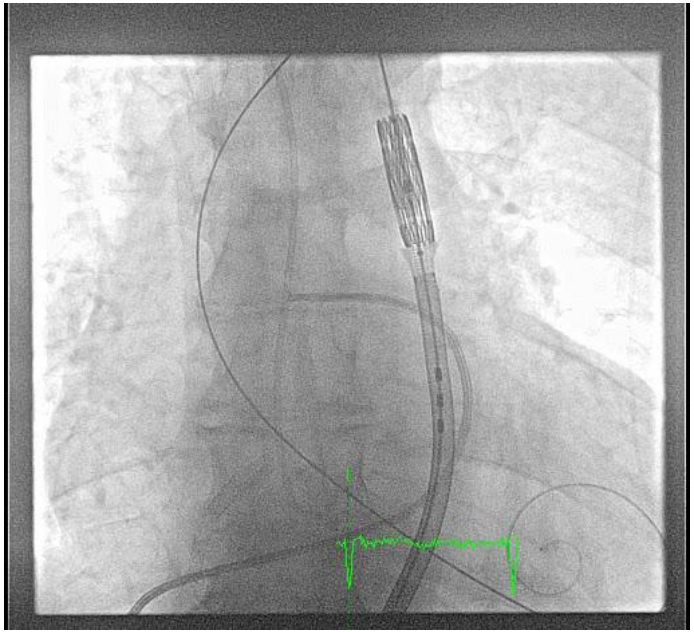


Pacen via tijdelijke draad

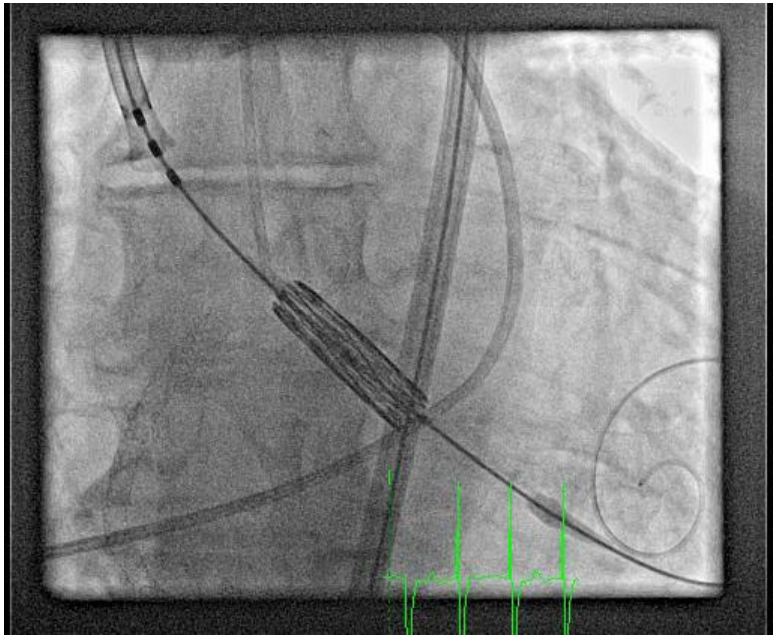
Pacen via tijdelijke draad

Erasmus MC

TAVI



Opvoeren van de klep (Sapien3 29)



Plaatsen van de klep

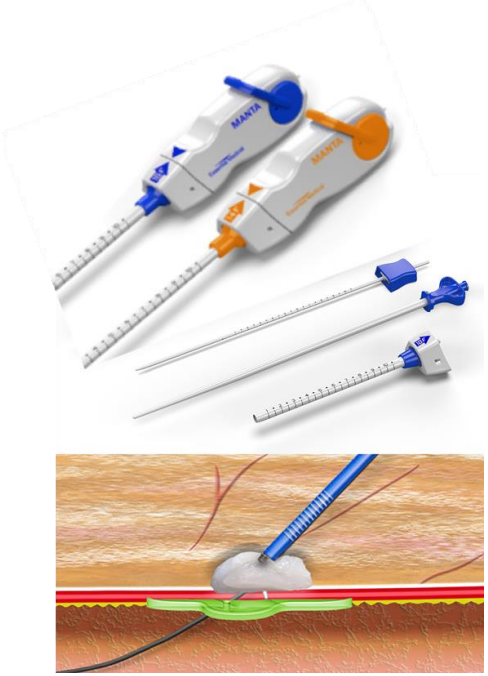
Erasmus MC

Resultaat

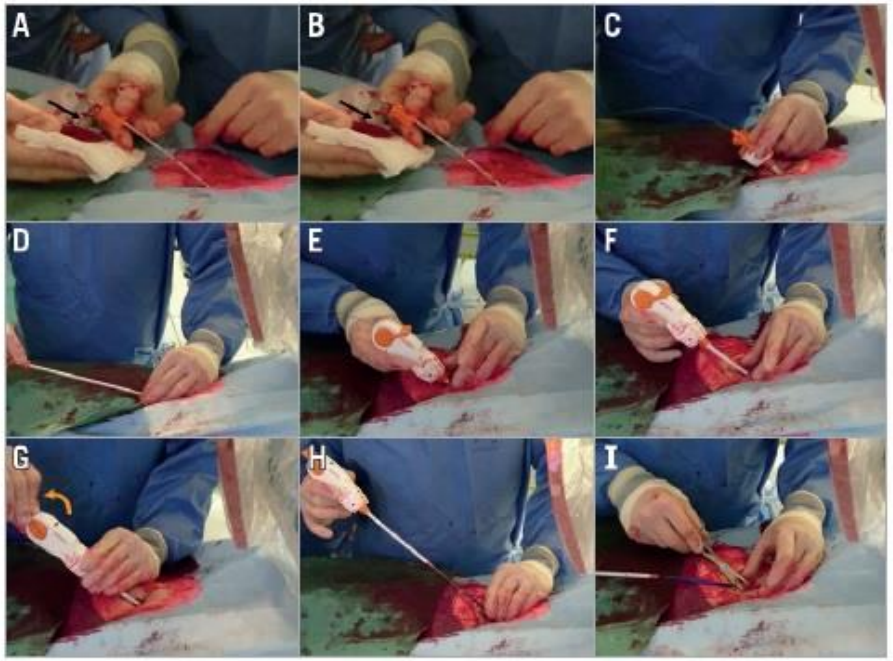
Geen PVL

Erasmus MC

Sluiting van de lies



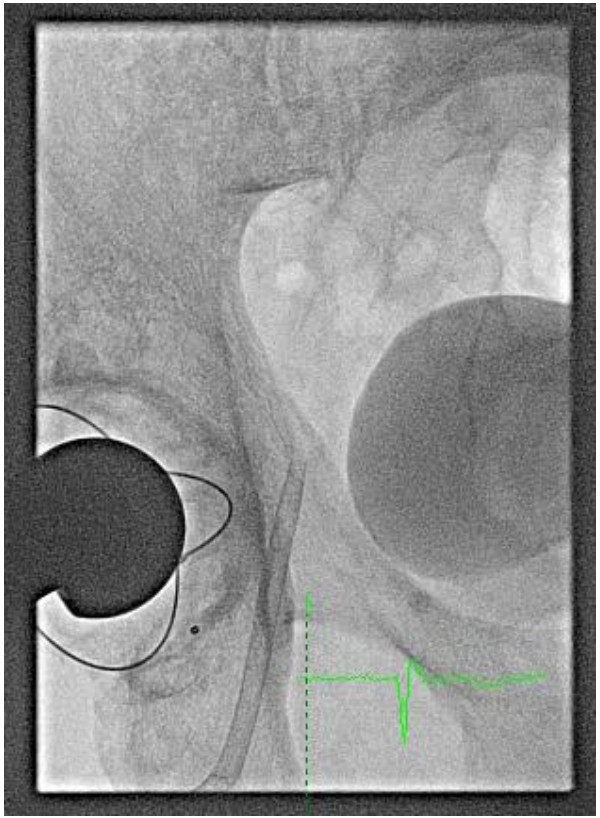
MANTA (plug)



Van Gils et al. EuroIntervention 2016;12:896-900

Erasmus MC

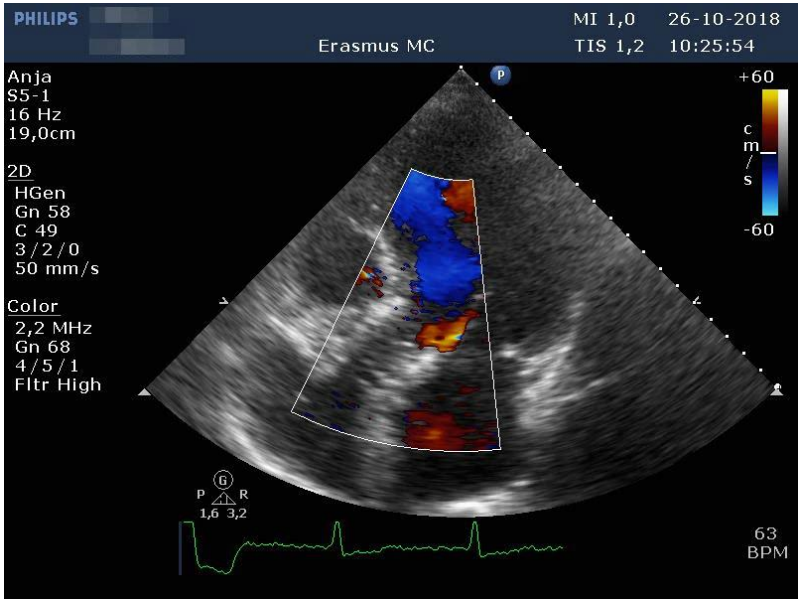
MANTA

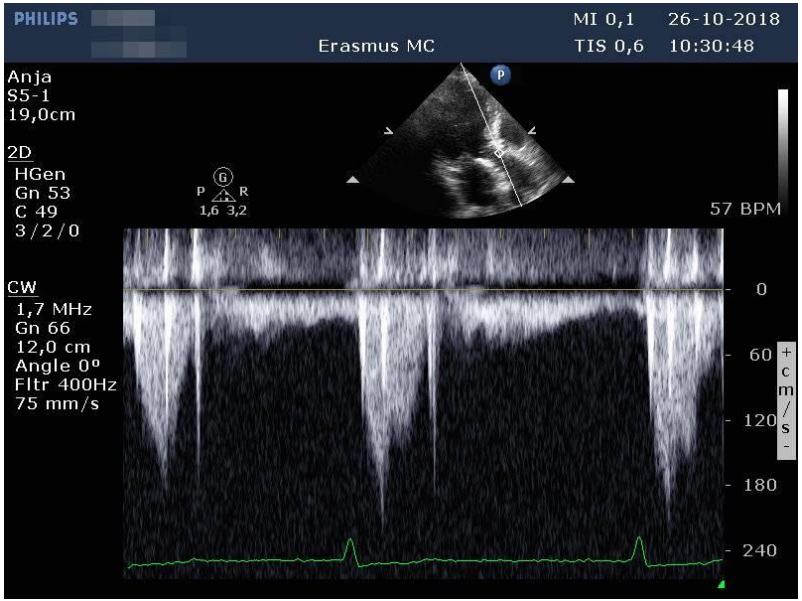


Angio na het sluiten

Erasmus MC

Resultaat na TAVI





Lichte PVL

Gradiënt 1.9 m/s

De patiënt

Procedure is ongecompliceerd verlopen

Controle na 1 maand

- NYHA 1
- Eetlust is weer toegenomen

Conclusie

- 25% van de 65+ ontwikkelt aortaklepsclerose
  - 16% van de mensen krijgt een stenose
  - Aortaklepstenose is een progressieve ziekte

- LV-dysfunctie treft bijna een kwart van de oudere populatie
  - Hartfalen treft 15% van de 70-80-jarigen
  - Opname voor hartfalen risico voor heropname of dood
  - Medische therapie voor groot deel gebaseerd op afterload reductie

- TAVI kan mogelijk zorgen voor afterload reductie in patiënten met systolisch hartfalen en matige aortaklepstenose
  - TAVR UNLOAD studie loopt momenteel (N=600)
  - Effectiviteit wordt beoordeeld op 1 jaar

Erasmus MC