5TH AZERBAIJAN INTERVENTIONAL CARDIOLOGY MEETING

12-14 October 2023

Badamdar Hotel
Former Pullman Hotel Baku

Azerbaijan Society of Cardiology

Prof. Dr. Cem Barçın
Sağlık Bilimleri Üniversitesi
Kardiyoloji AD Ankara

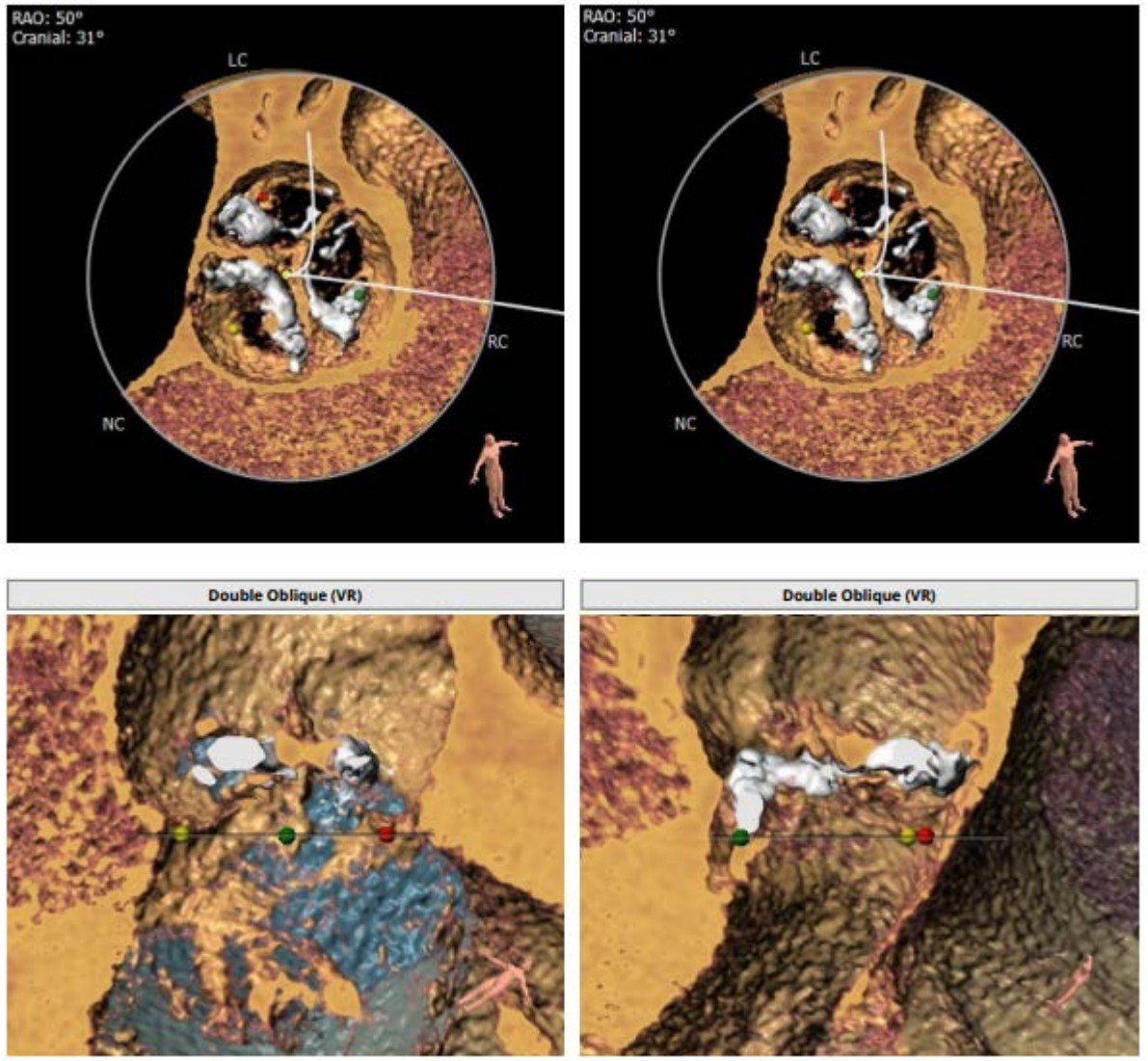
MÖVZU

TAVI in heavily calcified aortic disease
How to choose the proper treatment strategy

Ağır kalsifik Ciddi Aort Darlığında TAVİ
Doğru strategiyanı necə seçək

Aortik kalsifikasyon:
Dost mu düşman mı ?

- **Homojen**
- **Simetrik**
- **Küçük**
- **Uzantıları olmayan**



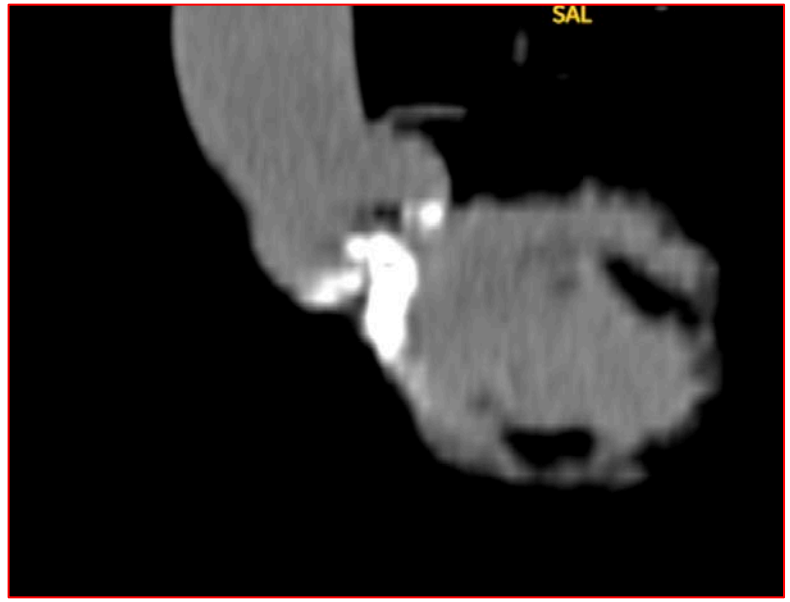
TAVİ’de İleri kalsifikasyonun komplikasyonları

- Paravalvüler yetmezlik
- Anüler rüptür
- İleti bozuklukları / yüksek pil oranları
- Koroner oklüzyon
- İnme
- Kapak migrasyonu

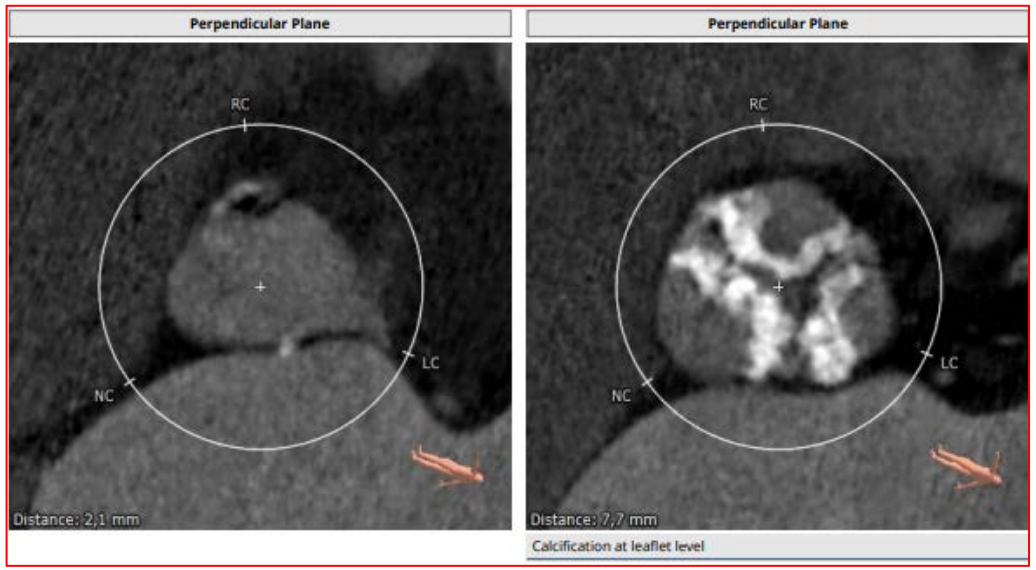
Predilatasyon / postdilatasyon oranları yüksek

Aort Kapak Kalsifikasyonları Sınıflandırılması

Grade	Kalsifikasyon
Grade 1	Yok
Grade 2	Hafif kalsifikasyon (küçük,izole,noktasal)
Grade 3	Orta kalsifikasyon (çok büyük noktalar)
Grade 4	Tüm cusplara uzanan ağır kalsifikasyonlar

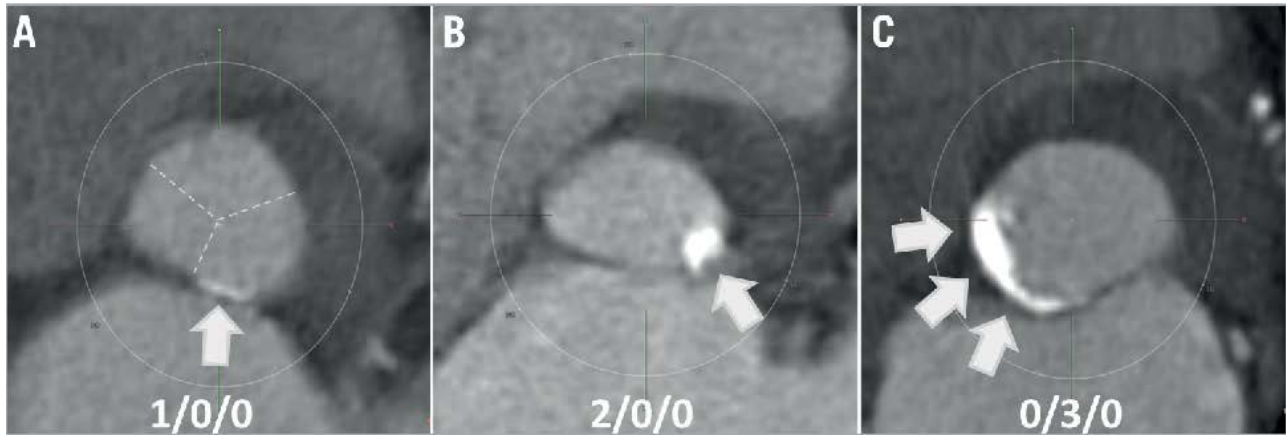


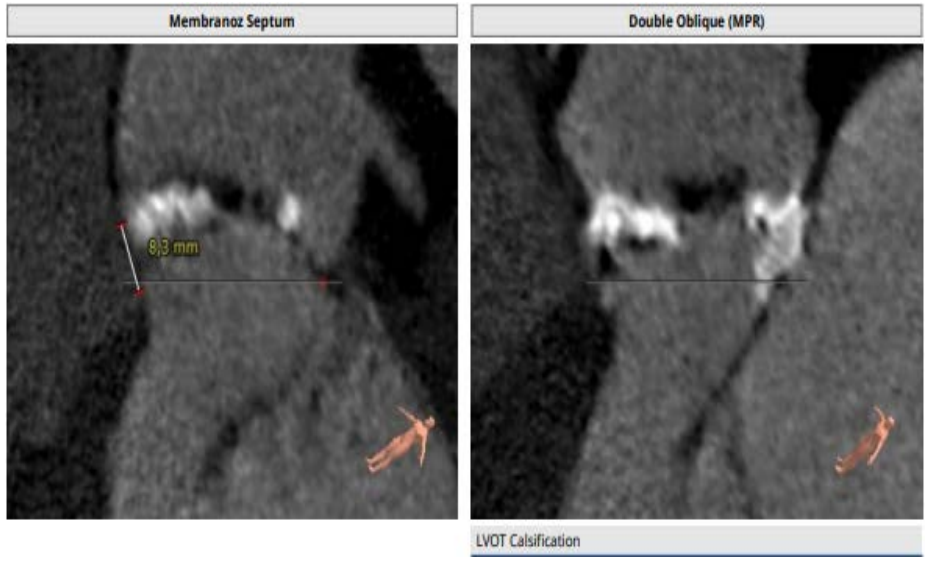
LVOT kalsifikasyonu



Kalsifikasyon Özellikleri

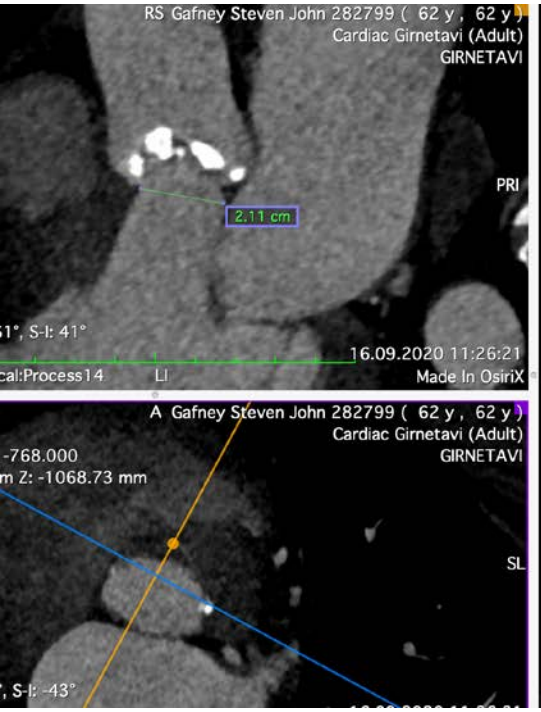
- **Lokasyon *(Ao cusp, Root ve LVOT)***
- **Uzantısı**
- **Asimetrik**
- **Komşuluğu**
- **Şekli (düz, ay şeklinde,çıkıntılı)**
- **Miktarı**

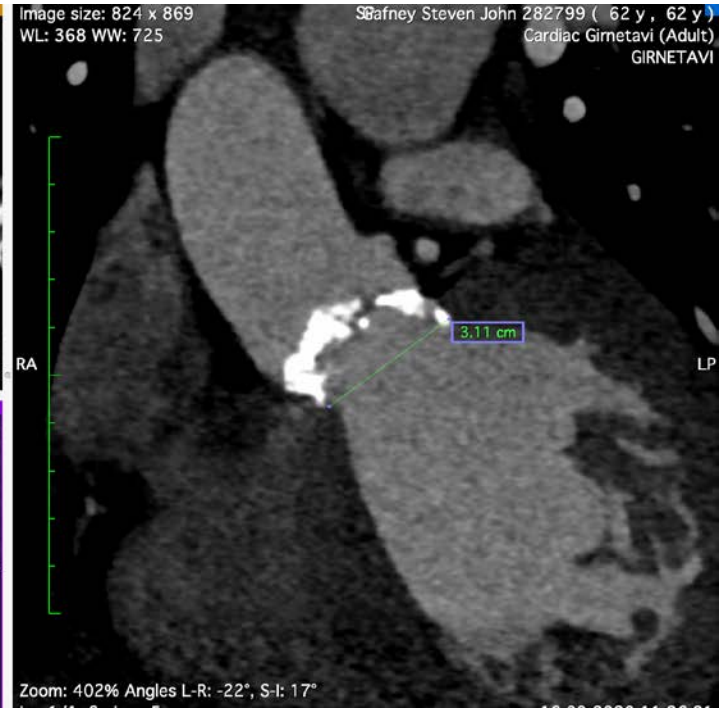


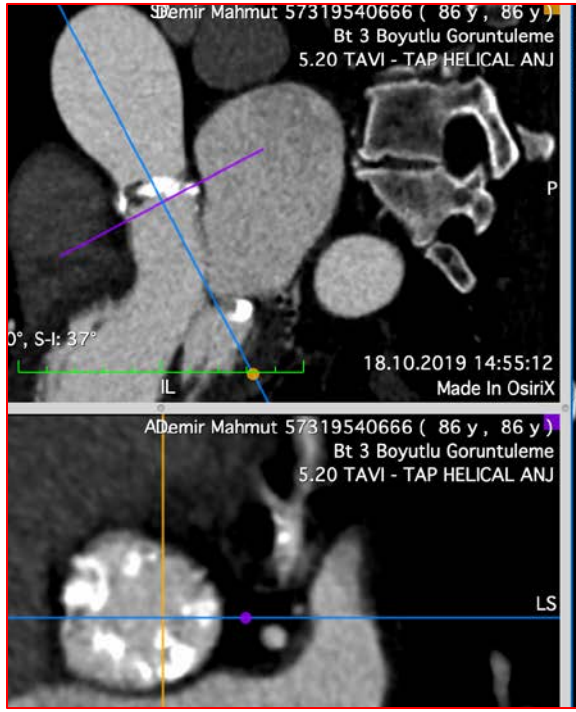


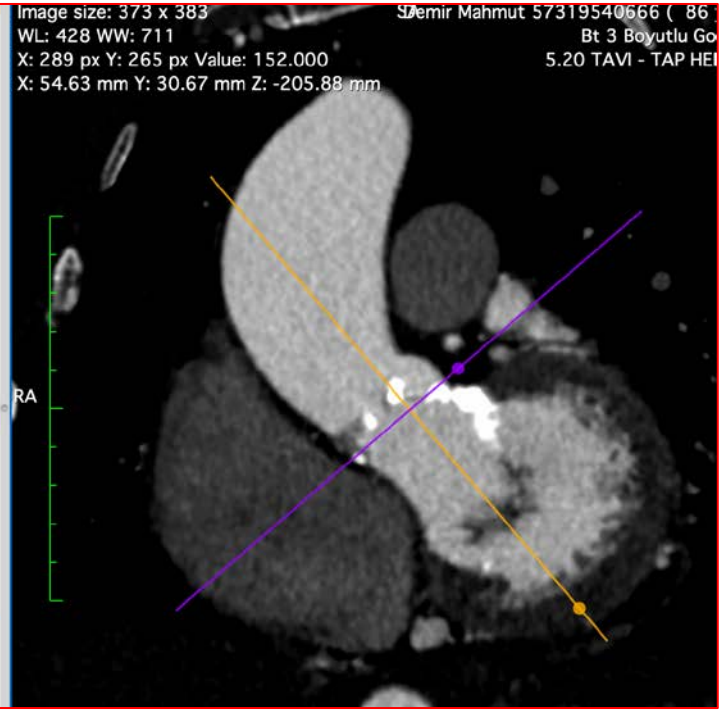
Nodüler kalsifikasyon ve LVOT kalsifikasyonu özellikle önemli

Bilgisayarlı tomografi



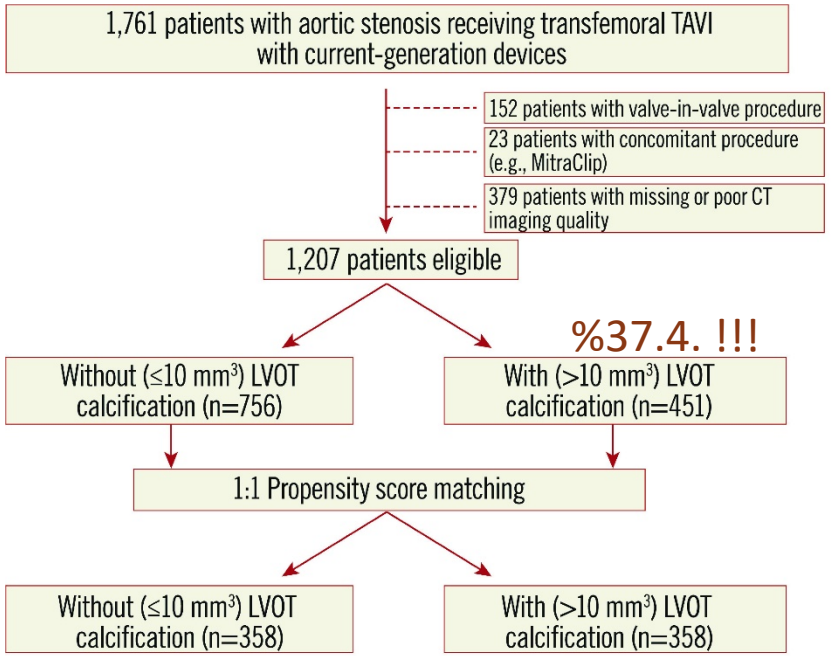


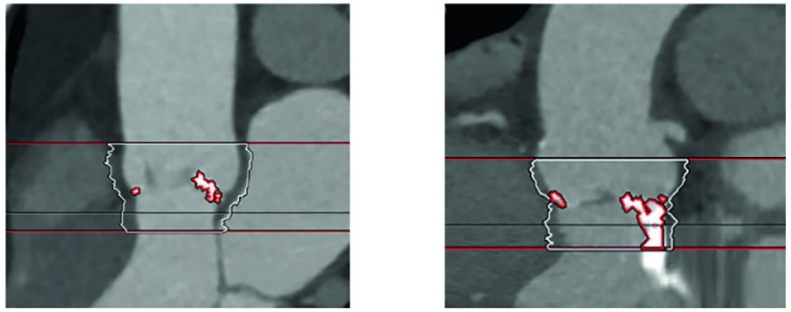




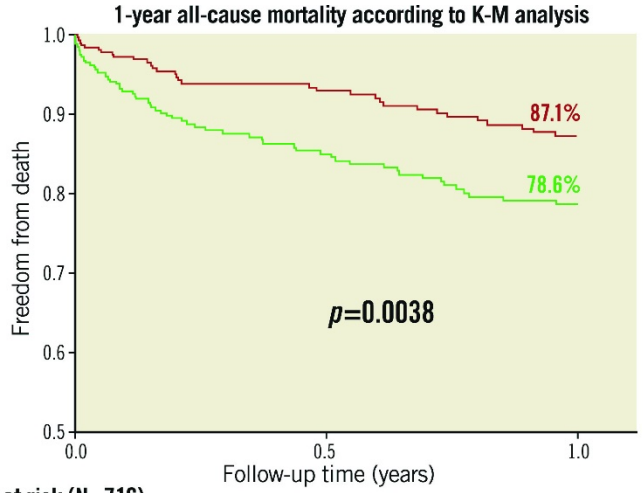
Kalsifikasyon ile ilgili parametrelerin değerlendirilmesinde en değerli yöntem

LVOT kalsifikasyonunun prognostik önemi





Measurement of LVOT calcium volume from contrast-enhanced MSCT images using 3mensio Structural Heart software

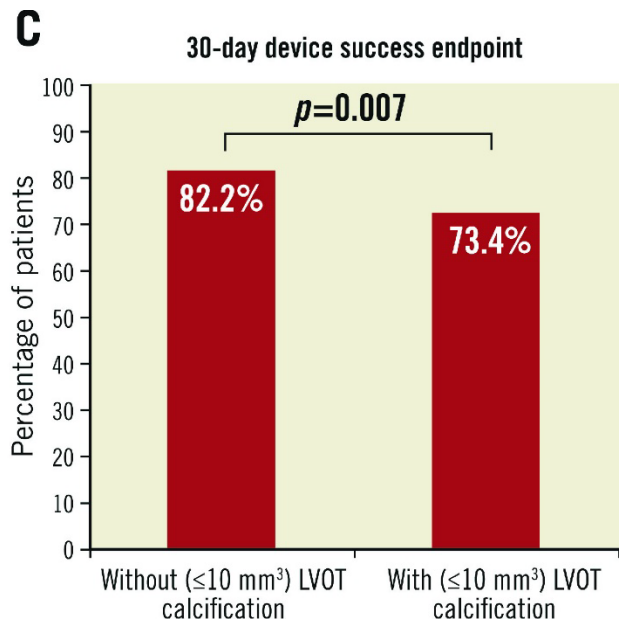


Patients at risk (N=716)

Without	358	206	159
With	358	195	155

	Without* LVOT calcification (n=358)	With** LVOT calcification (n=358)	*p*-value
Outcome at 30 days according to VARC-3			
All-cause mortality	10 (2.8)	22 (6.1)	0.05
Disabling or non-disabling stroke	9 (2.5)	21 (5.9)	0.04
Type 2-4 bleeding	14 (3.9)	15 (4.2)	1.00
Kidney injury (AKIN 3)	2 (0.6)	7 (2.0)	0.18
Major access-site complication	24 (6.7)	22 (6.1)	0.88
MI requiring revascularisation	2 (0.6)	1 (0.3)	1.00
P mean >20 mmHg	4 (1.2)	8 (2.4)	0.34
PVL > mild	10 (2.9)	20 (6.0)	0.08
Permanent PM implantation	55 (15.4)	56 (15.7)	0.99

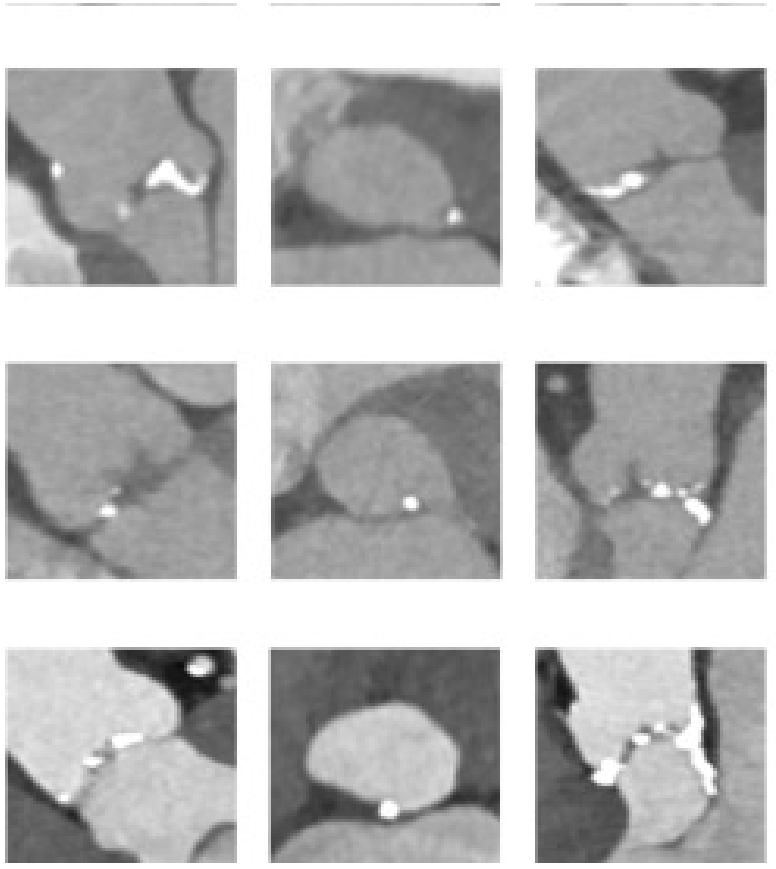
*Without ≤10 mm³, **With >10 mm³ calcium volume. Values n (%). AKIN: Acute Kidney Injury Network; LVOT: left ventricular outflow tract; MI: myocardial infarction; PM: pacemaker; PVL: paravalvular leakage; VARC: Valve Academic Research Consortium



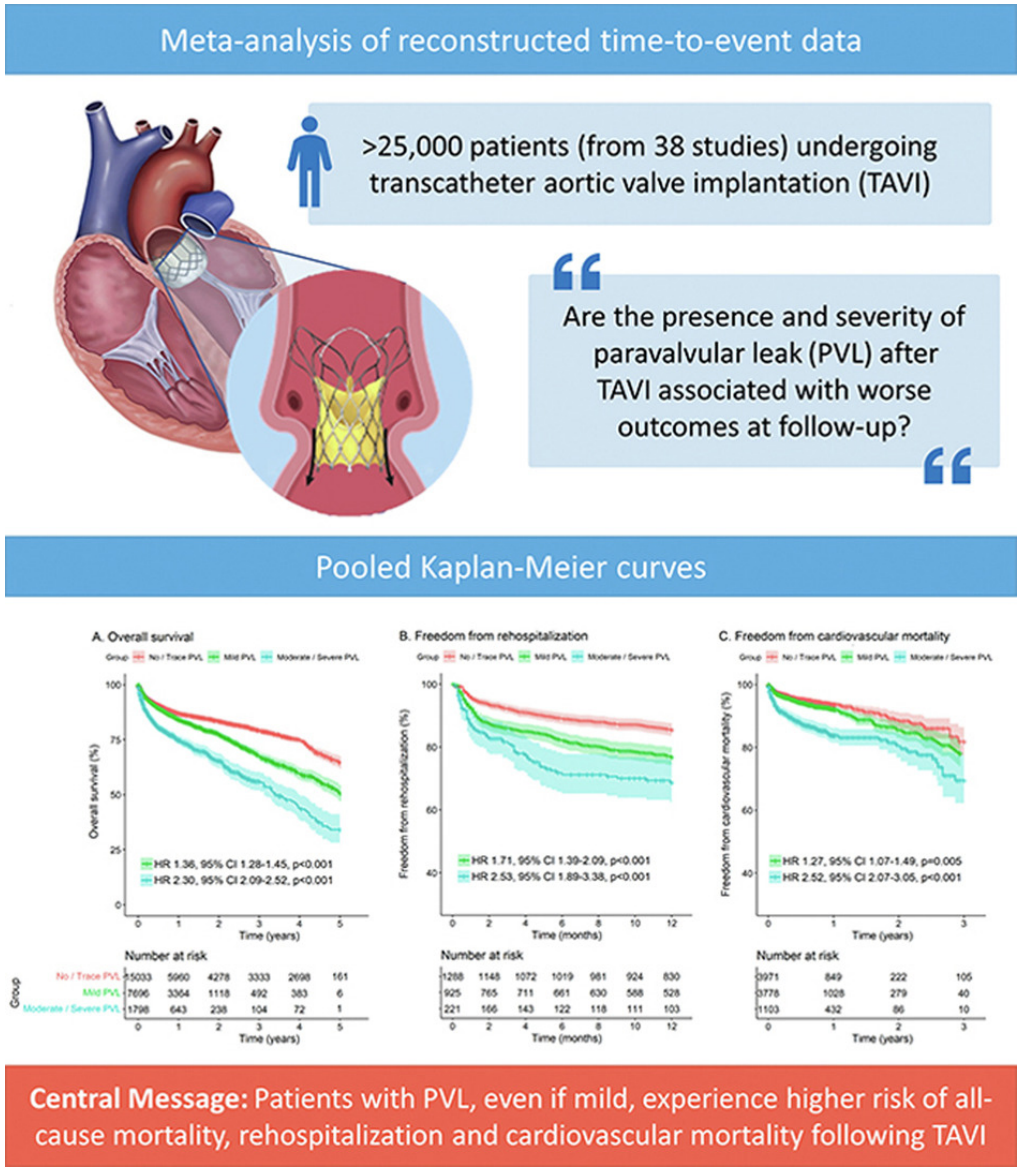
Waldschmidt L, et al. EuroIntervention. 2022 Apr; 17(17): e1417–e1424.

LVOT Kalsifikasyon Değerlendirilmesi

Derece	Kalsifikasyon
Hafif	1 nodül uzantısı <5mm, LVOT çevresinin %10 azını kapsıyor
Orta	2 nodül kalsifikasyon veya 5 mm büyük veya LVOT çevresinin %10 dan fazlasını kapsıyor
Ciddi	Tek focusta 1 cm den büyük veya LVOT çevresinin %20 den fazlasını kapsıyor



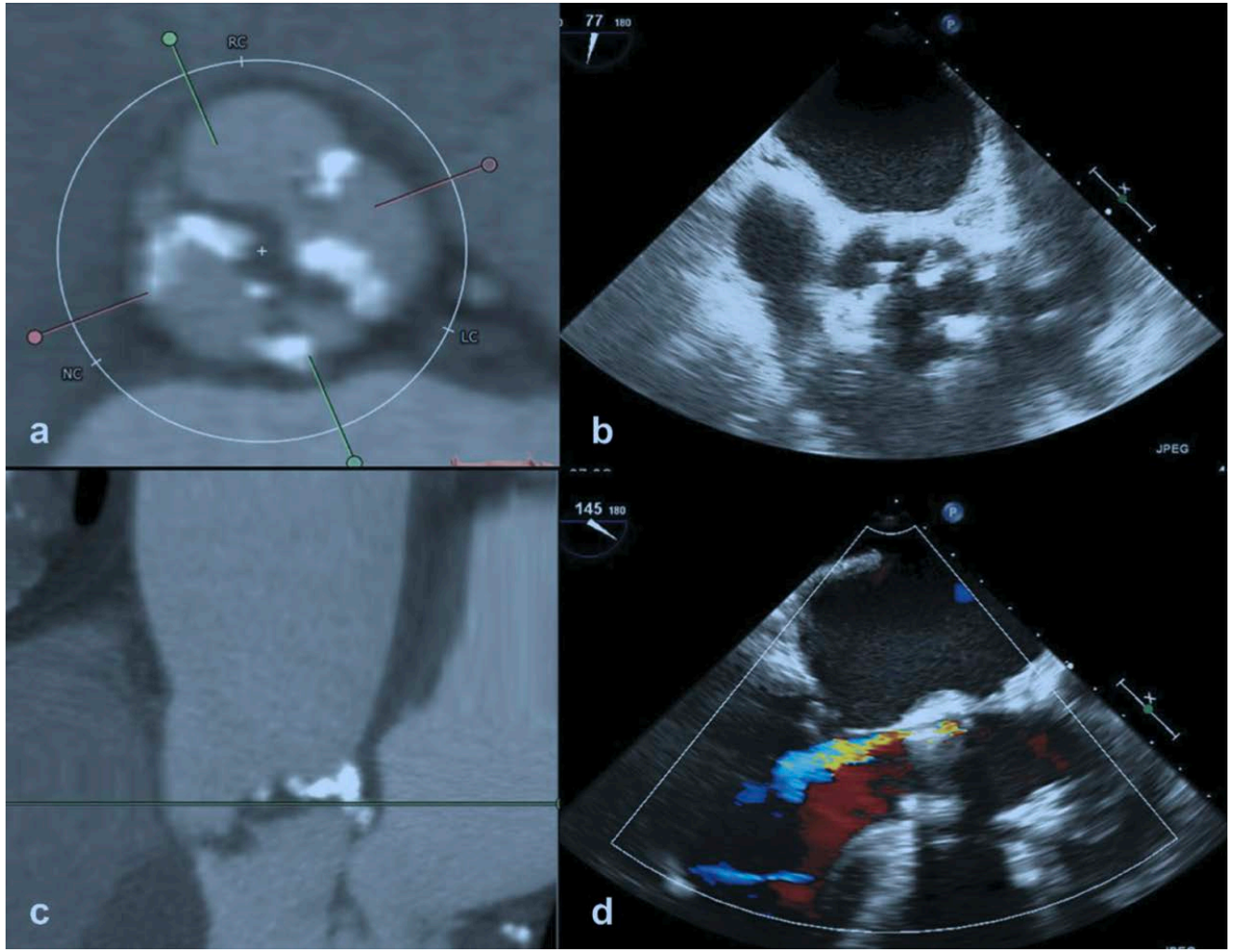
Paravalvüler kaçakların prognostik önemi



Pompeo et al. Structural Heart 2023

«Paravalvüler kaçaklar «hafif» olsa bile KV ölüm, tüm sebeplere bağlı ölüm ve hastaneye yatışları artırmaktadır»

Kalsifikasyon – PVL İlişkisi



Kalsifik kitlenin boyutu ve lokalizasyonu PVL derecesi ve bölgesi ile ilişkilidir

Self-expandable kapaklarda PVL daha fazladır

Yeni jenerasyon « etekli» kapak kullanılanlarda kapaklar arasında (SE/BE) ve kalsifikasyon derecesinin (az/çok) önemi yoktur.

Yeni jenerasyon güçlendirilmiş eteği olan kapaklarda PVL daha düşüktür

Edwards S3 -> S3ULTRA/S3UR

SAPIEN 3 Stent Frame & Leaflets
- Balloon-expandable, cobalt-chromium
- Bovine pericardial leaflets
- Open cell design for coronary access

Enhanced Outer Sealing Skirt
- Textured PET material
- 40% increase height of the outer skirt

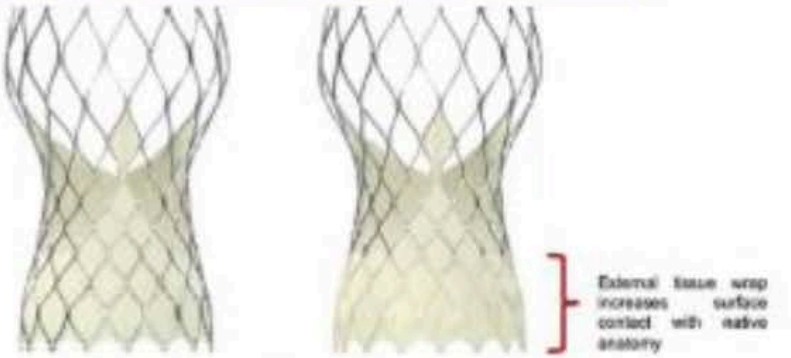
Ultra

SAPIEN 3

MyVal

Abbott Portico -> Navitor

Medtronic E-R -> Evolut-PRO

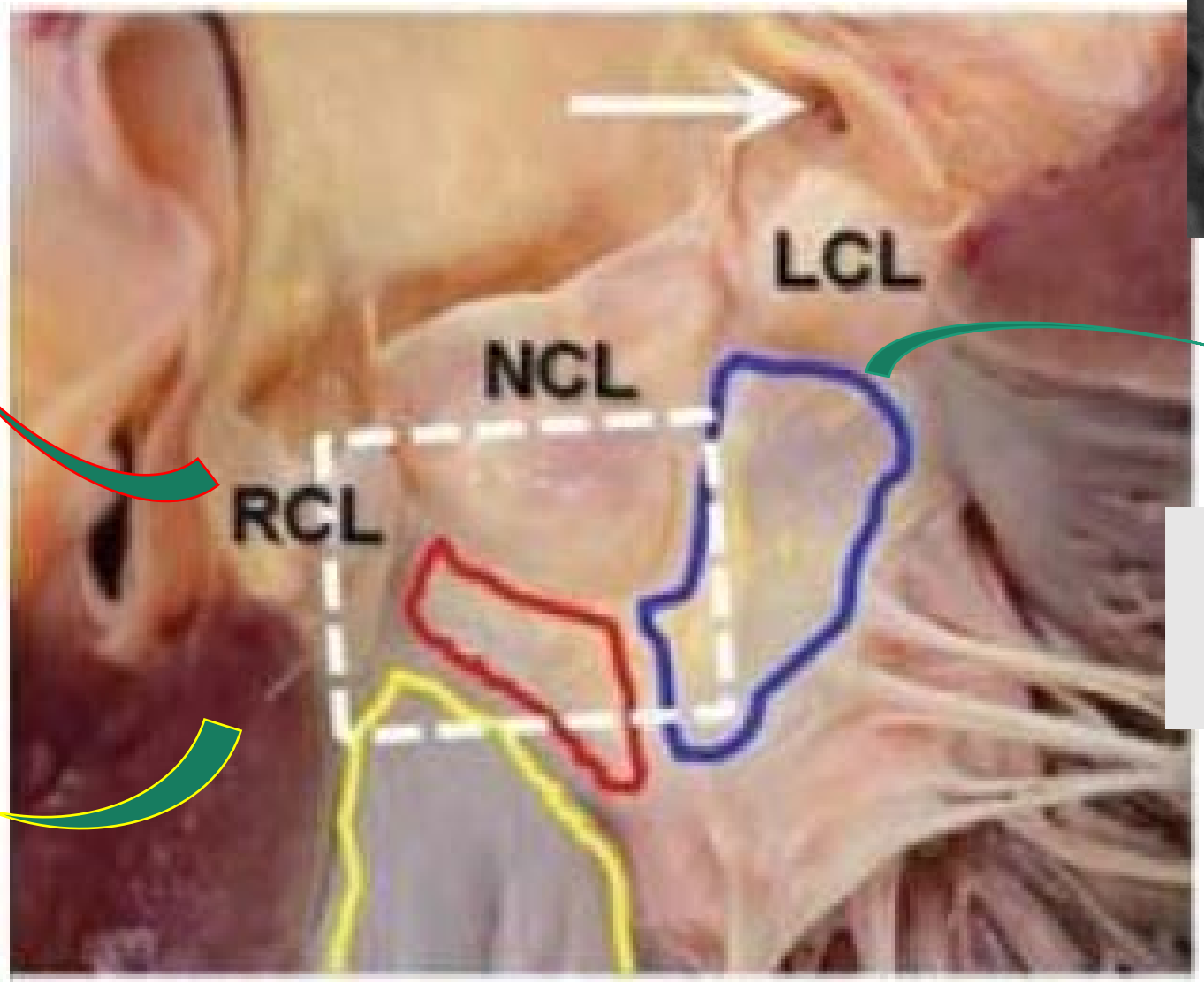


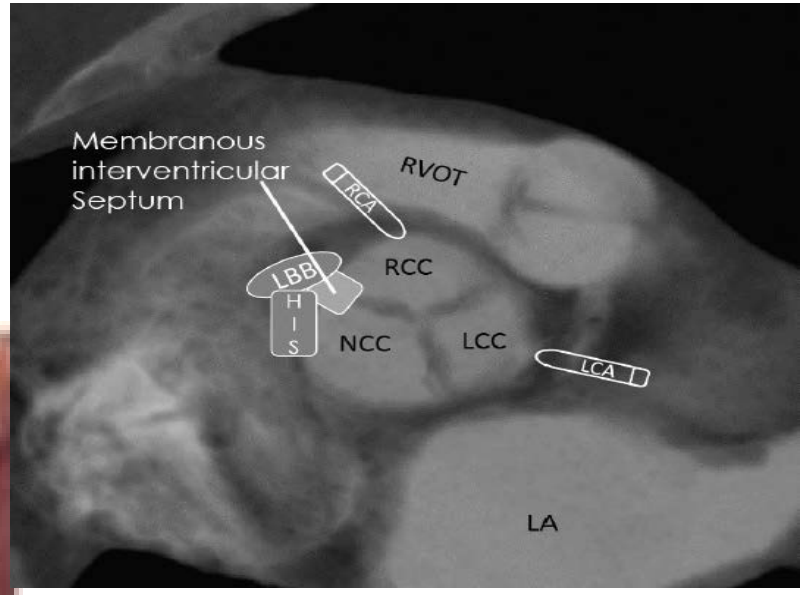
Evolut-R → Evolut-Pro

Kalıcı kalp pili / kalsifikasyon ilişkisi

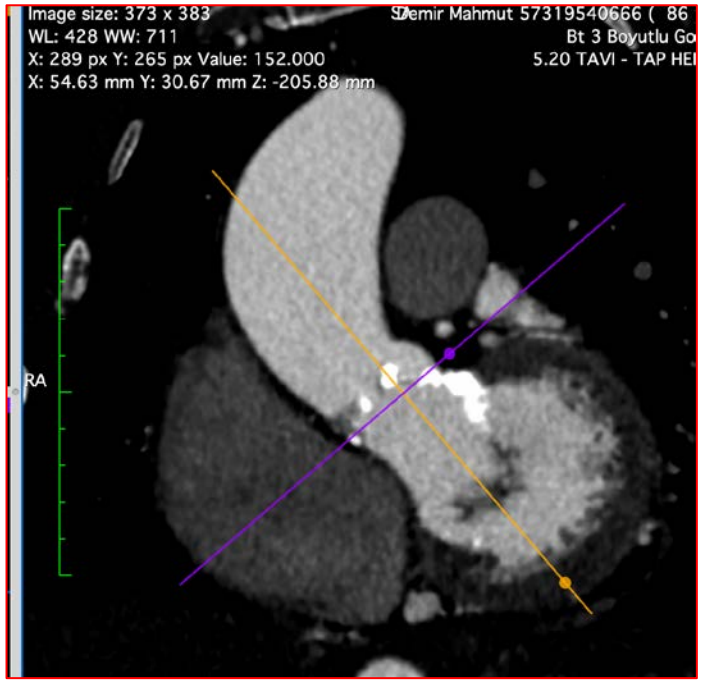
Membranöz septum

Müsküler septum

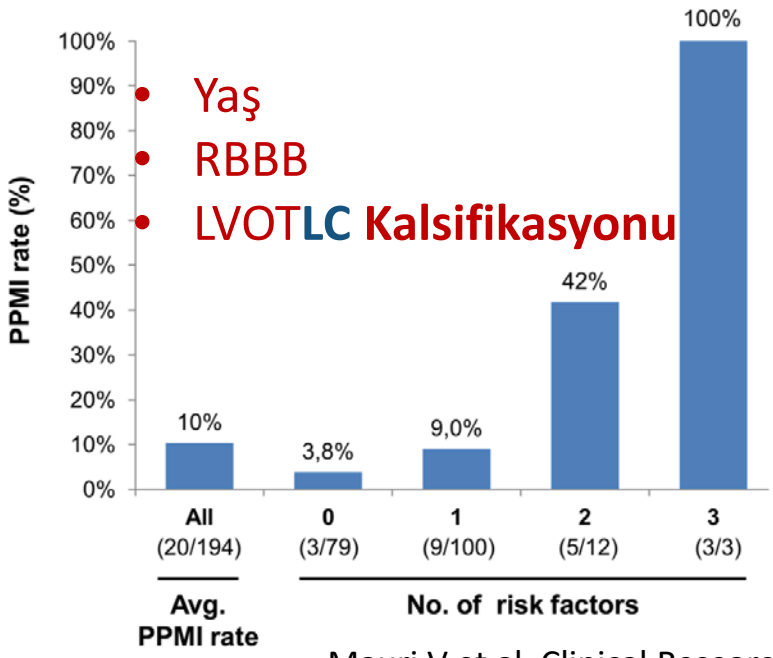




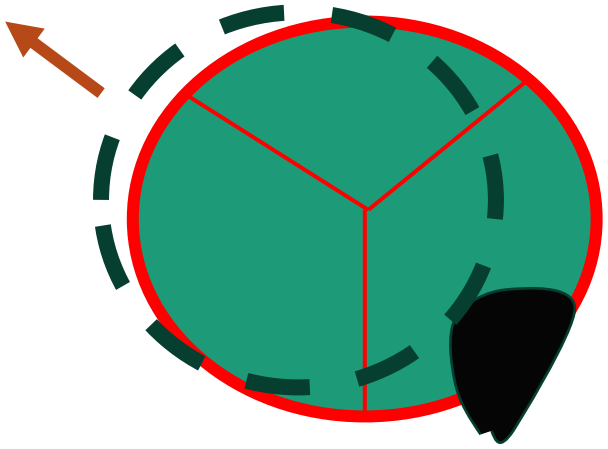
Mitral-aort arası fibroz bölge “curtain”

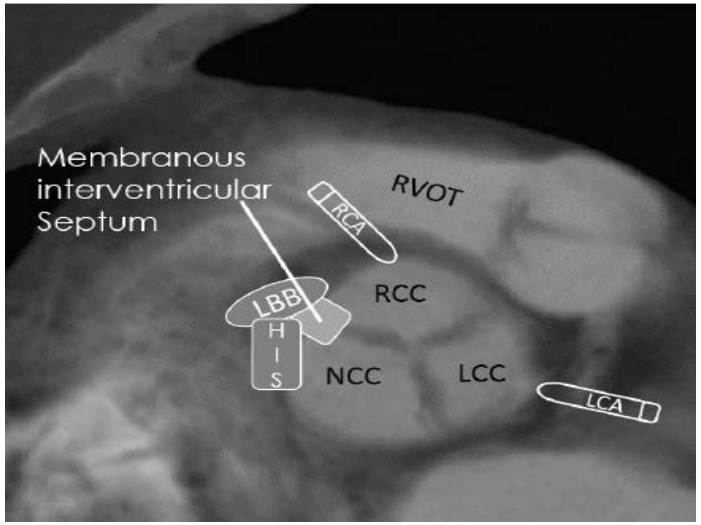


Özellikle sol koroner cusp tarafındaki asimetrik kalsifikasyon PPM açısından daha riskli !!?



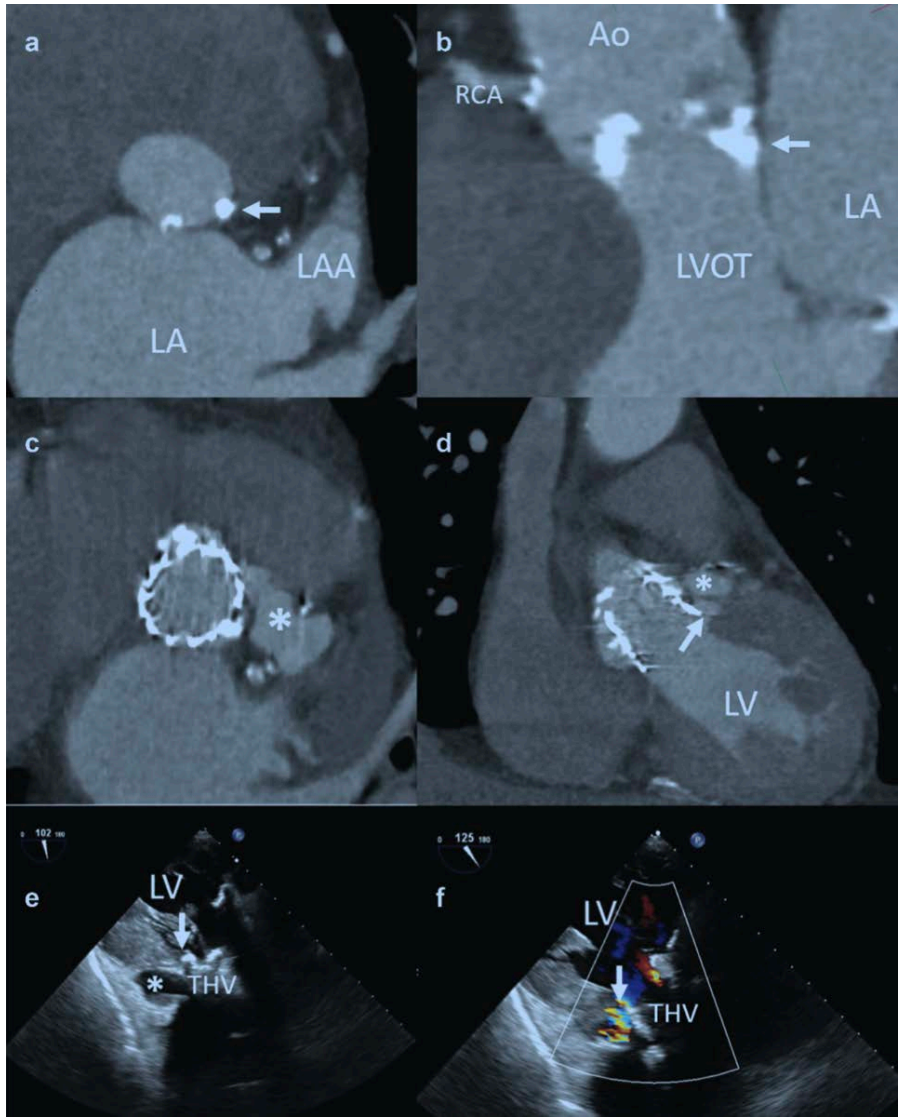
- Yaş
- RBBB
- LVOTLC Kalsifikasyonu





Mauri V et al. Clinical Research in Cardiology 2018

Aortik Rüptür



LCC-RCC komissural bölgesi dış destek az

Balon expandable kapaklar risk yüksek

Pio SM et al, XPERT REVIEW OF MEDICAL DEVICES 2020

Sonuç -1

İleri derece kalsifikasyon TAVİ'de kötü progostik göstergedir

Kalsifikasyon yeri, dağılımı, boyutu gelişebilecek sorunların öngördürücüsü olabilir

Bu konuda «standart» yaklaşım stratejileri bulunmamaktadır

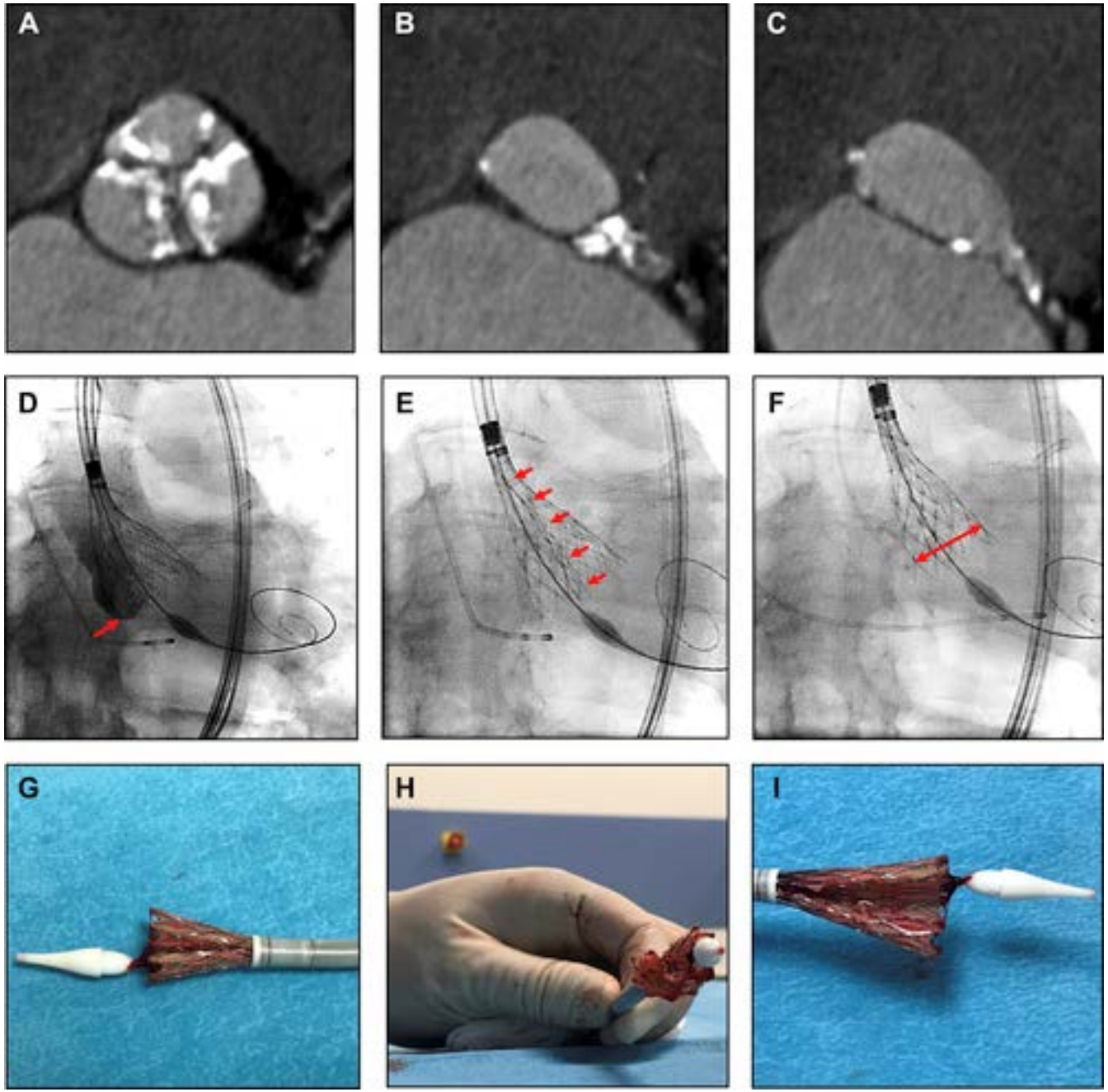
Self expandable kapaklar daha çok tercih edilmektedir

Sonuç -2

- **Balon ile genişletilen kapaklar**
  - Aortik ark ve ascenden aortada daha rahat navigasyon
  - Apozisyonları daha iyi (PVL daha düşük)
  - Post-dilatasyon ihtiyacı yok / az
  - Anüler rüptür nispeten fazla
  - Overdilatasyondan kaçınılmalı (balona 1-2 cc eksik SF konulabilir)
  - Yerleştirme «yavaş» ve «iki-aşamalı» yapılabilir

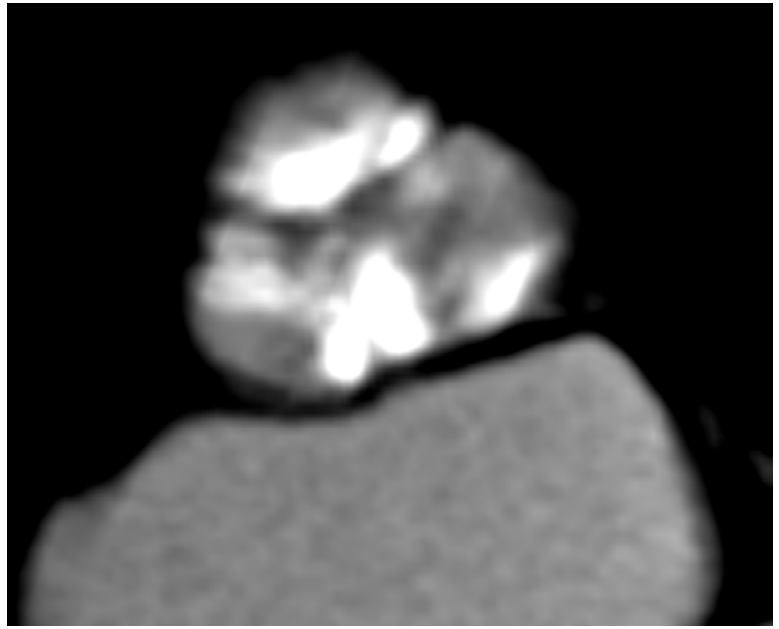
Sonuç -3

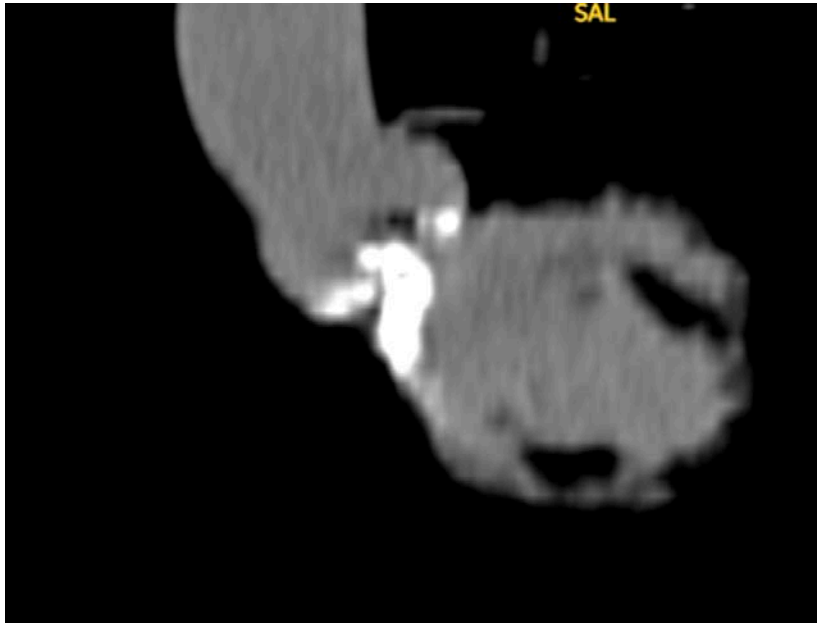
- **Kendiliğinden genişleyen kapaklar**
  - Arcus aorta dönüşü daha zor
  - Rüptür riski çok daha az (balon pre/post dilatasyona bağlı)
  - Predilatasyon mutlaka yapılmalı (ne kadar agresif ???)
  - Postdilatasyon gereklilik oranı yüksek
  - PVL daha yüksek (ancak yeni chazlarda arada fark yok)



Infolding

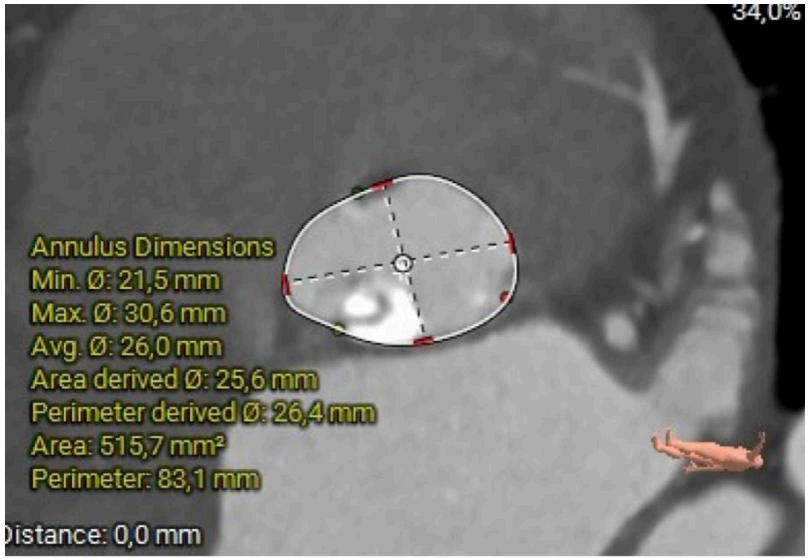
Self exp kapaklarda ileri asimetrik kalsifikasyon / kalsifik raphe varlığında dikkat





93 yaşında erkek hasta

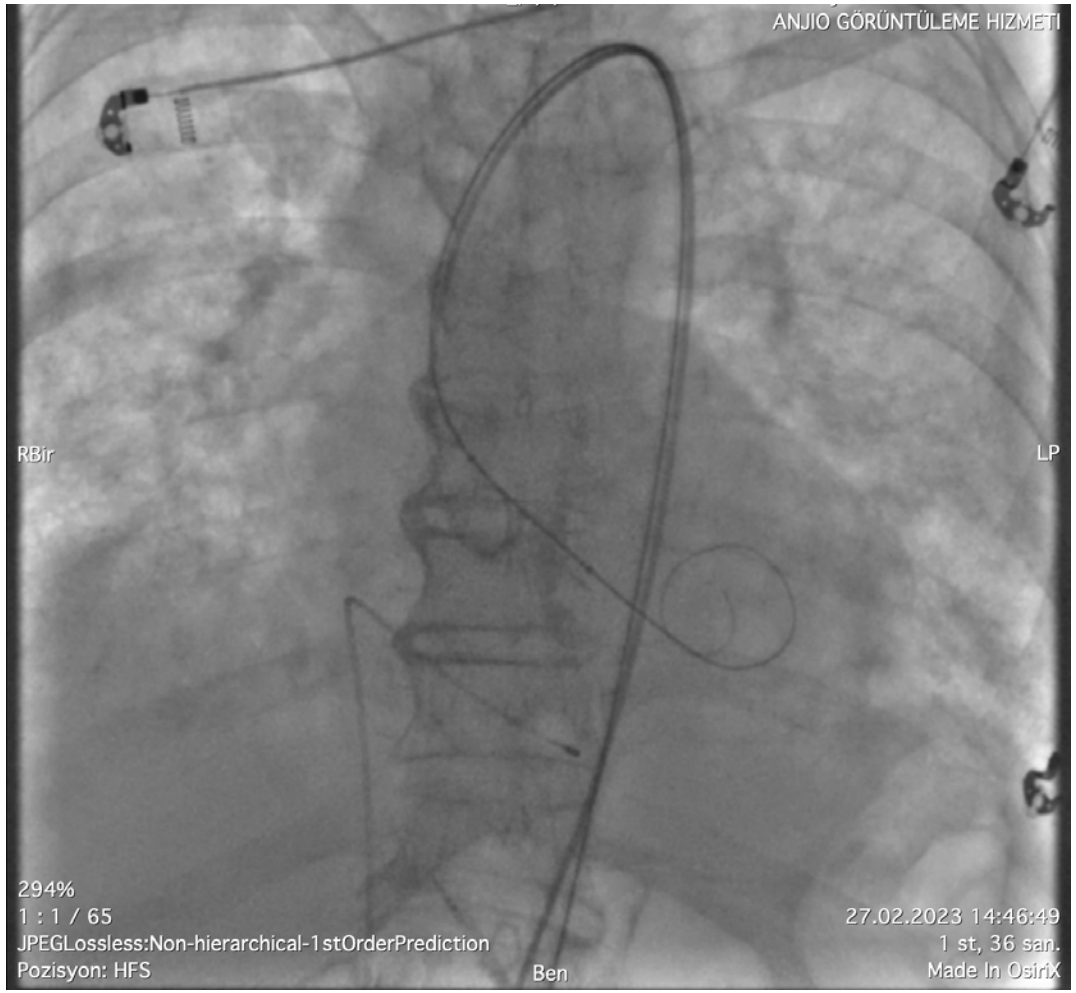
AVA: 0,5 cm2
Max PG 95 mmHg
Mean PG 65 mmHg

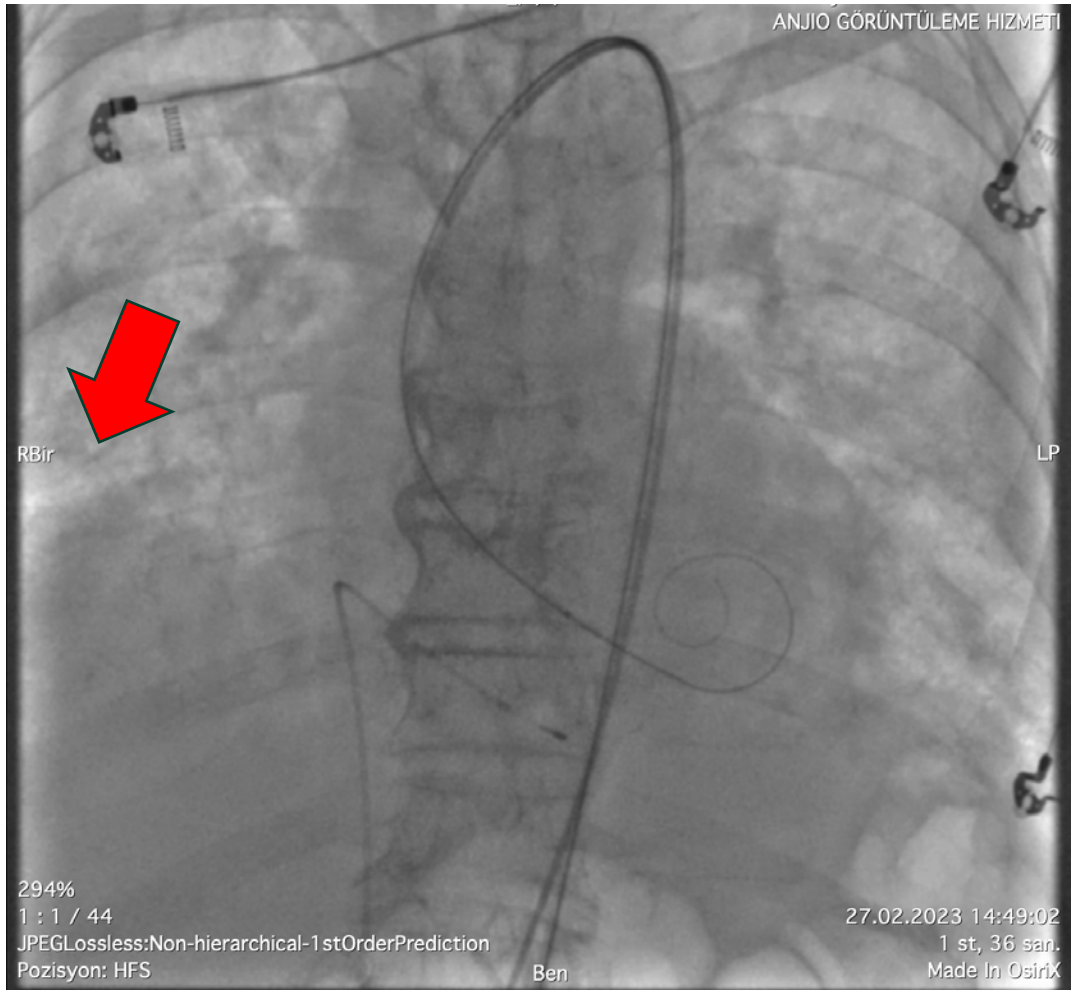


ANNULUS

Diameter (mm)	21,5	x	30,6	,	26,0
	Min		Max		Mean
Perimeter (mm)	83,1	, Derived Ø (mm)			26,4
Area (mm²)	515,7	, Derived Ø (mm)			25,6

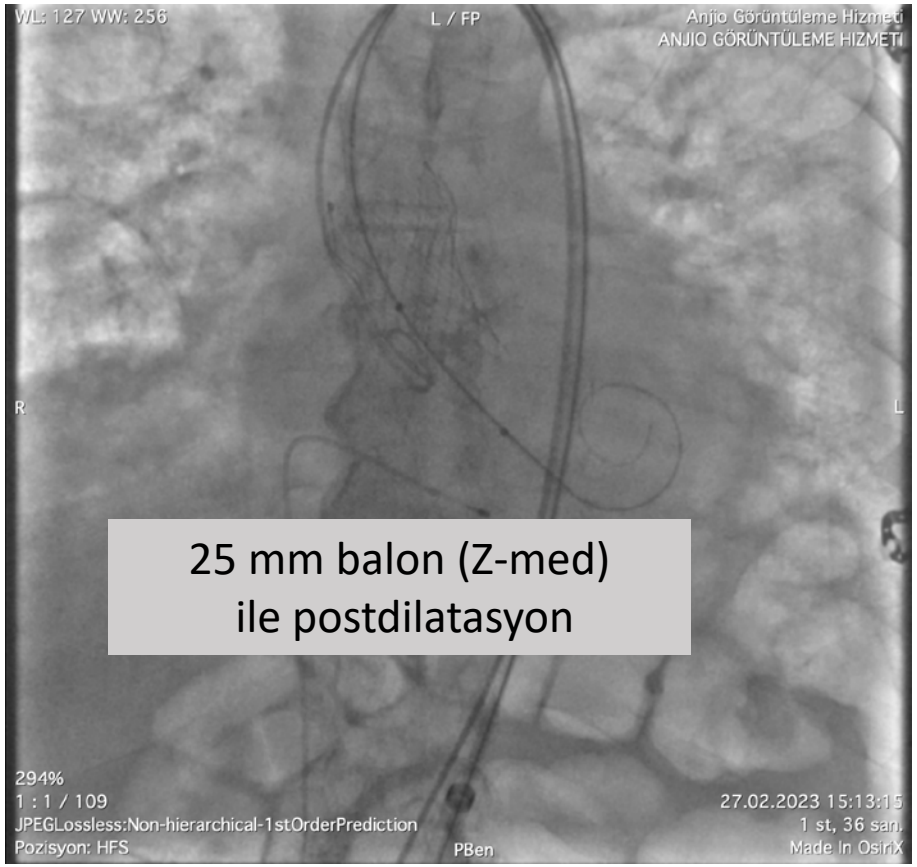
EvolutR 34 mm





23 mm balon (Z-med)
ile predilatasyon

EvolutR
34 mm yerine 29 mm



25 mm balon (Z-med)
ile postdilatasyon

Sonuç:
Basınç Gradienti
21 / 10 mmHg

Hafif PVL (1-2/4)

Case: 71-year-old woman. Shortness of breath esp. in the last 6 months. NYHA Class III. Obesity (BMI 32 kg/m^2). Normal coronary arteries.

Calcified critical aortic stenosis, probable BAV

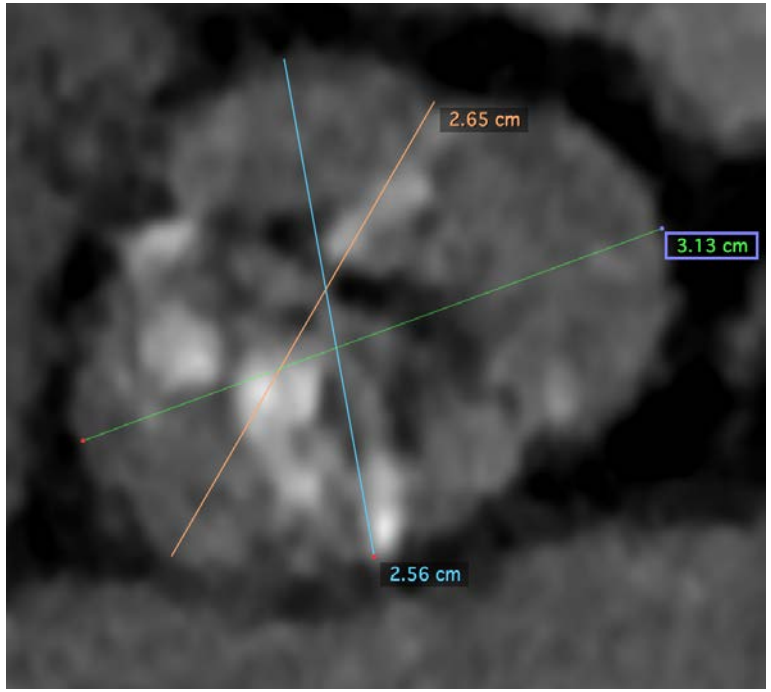
Max PG= 128 mmHg
Mean PG = 80 mmHg
AVA= 0,3 cm 2

Mild aortic regurgitation
Mild mitral regurgitation
Pulmonary artery systolic pressure= 45 mmHg

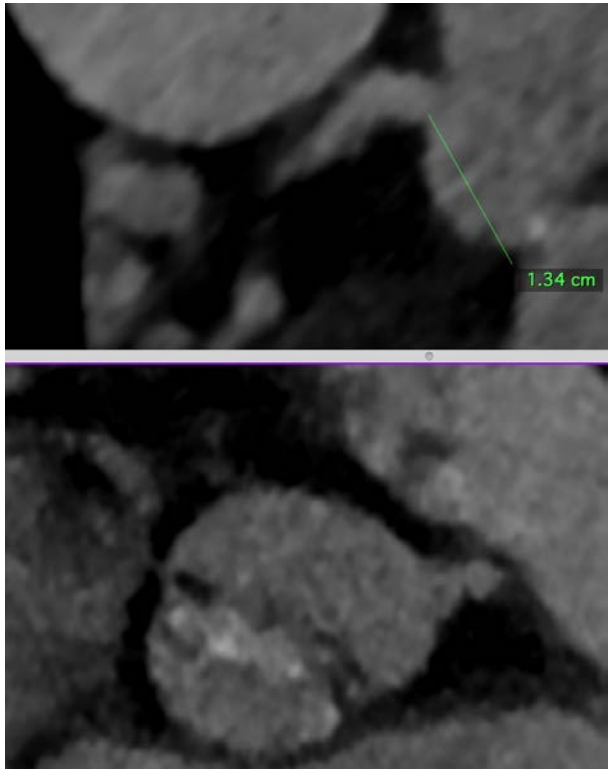
LVEF = 70 %

Case: SoV width, coronary heights

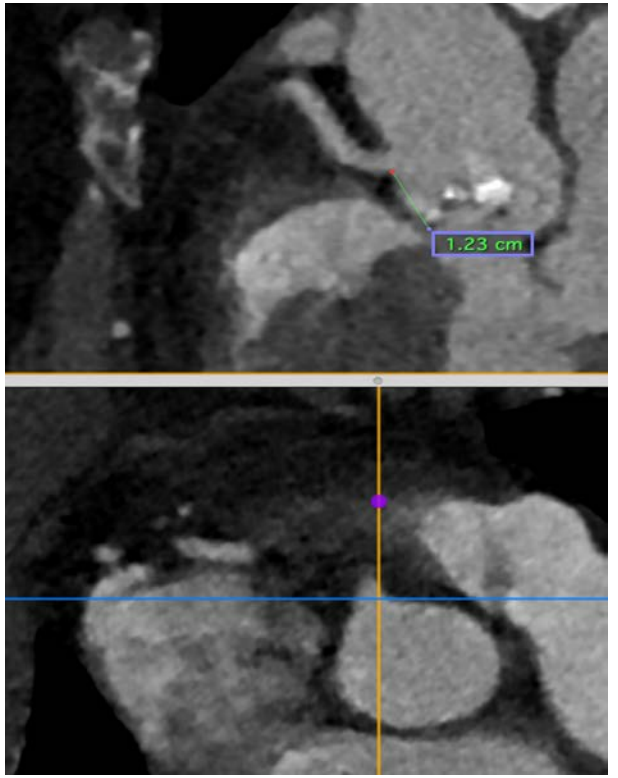
Sinus valsalva diameters



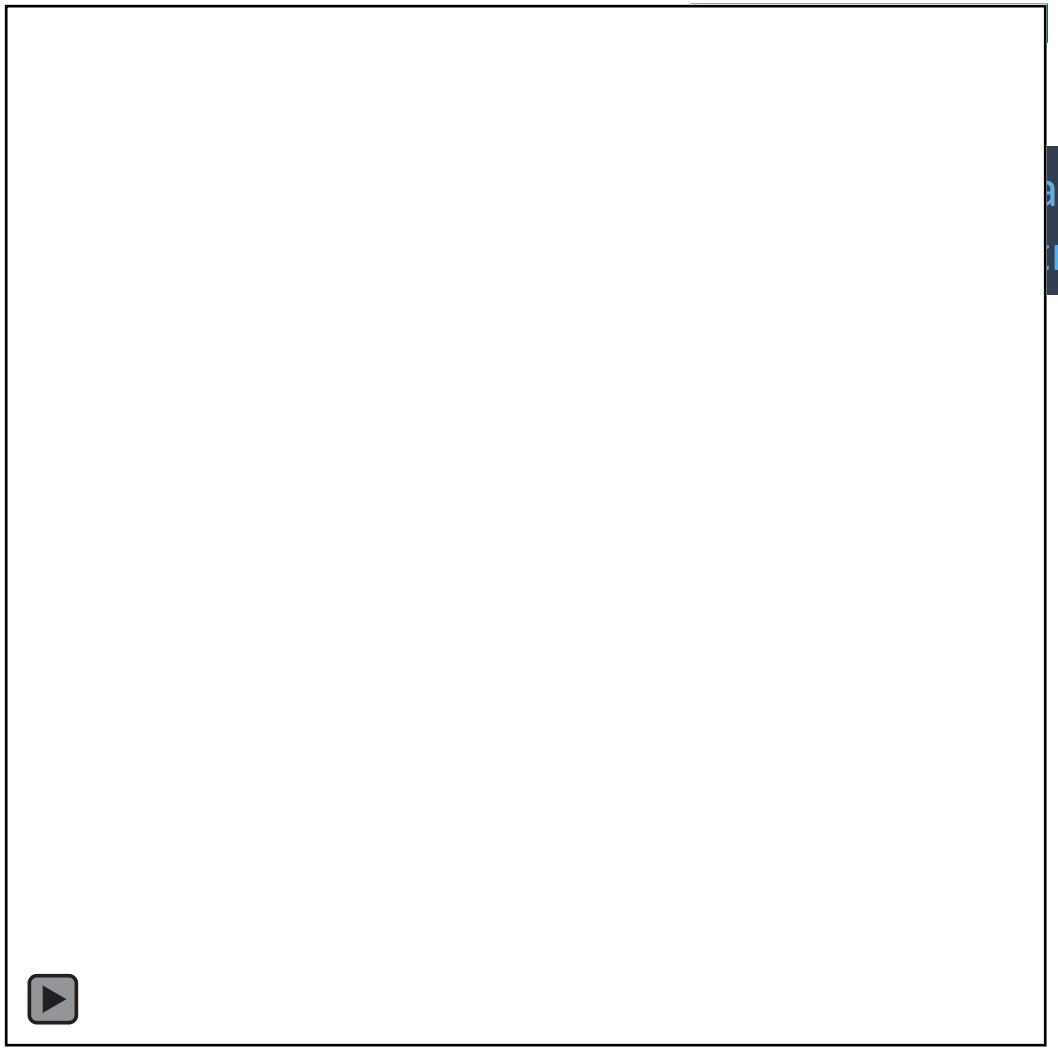
LC Ostium



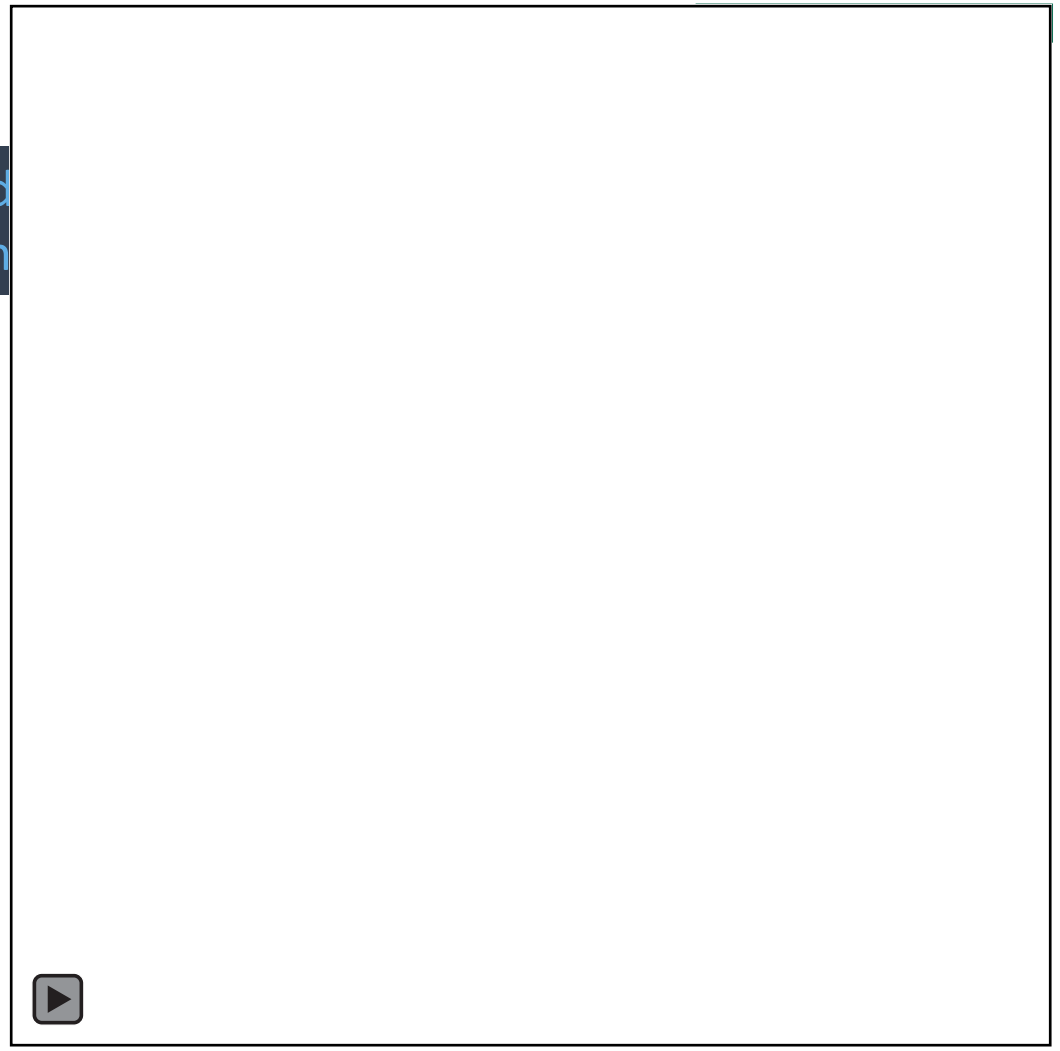
RC Ostium



Co-planner and near-cusp views

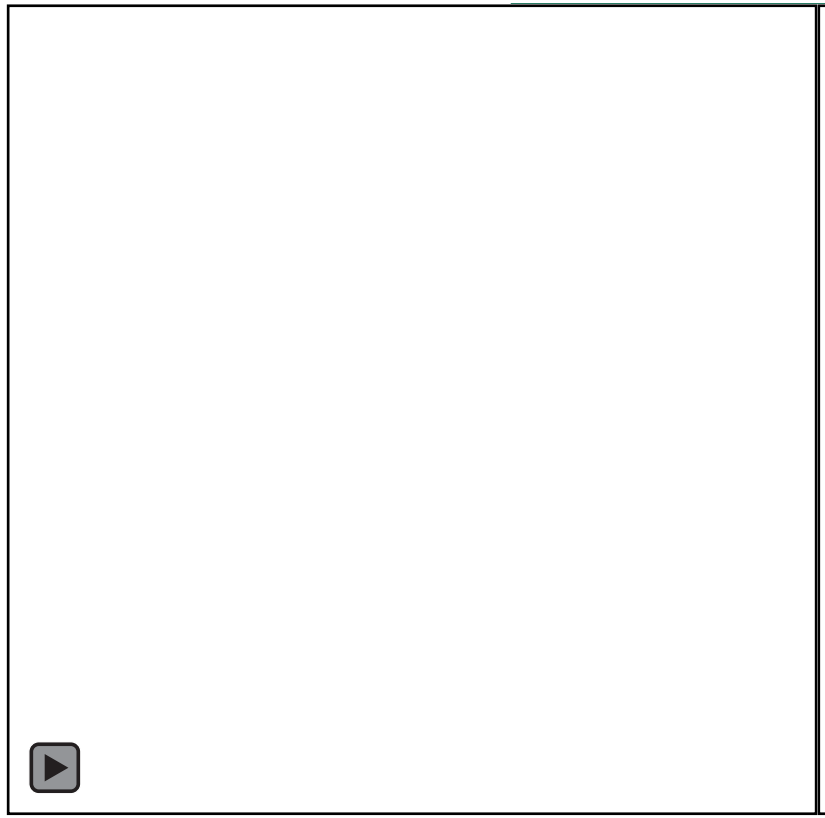


Co-planner view

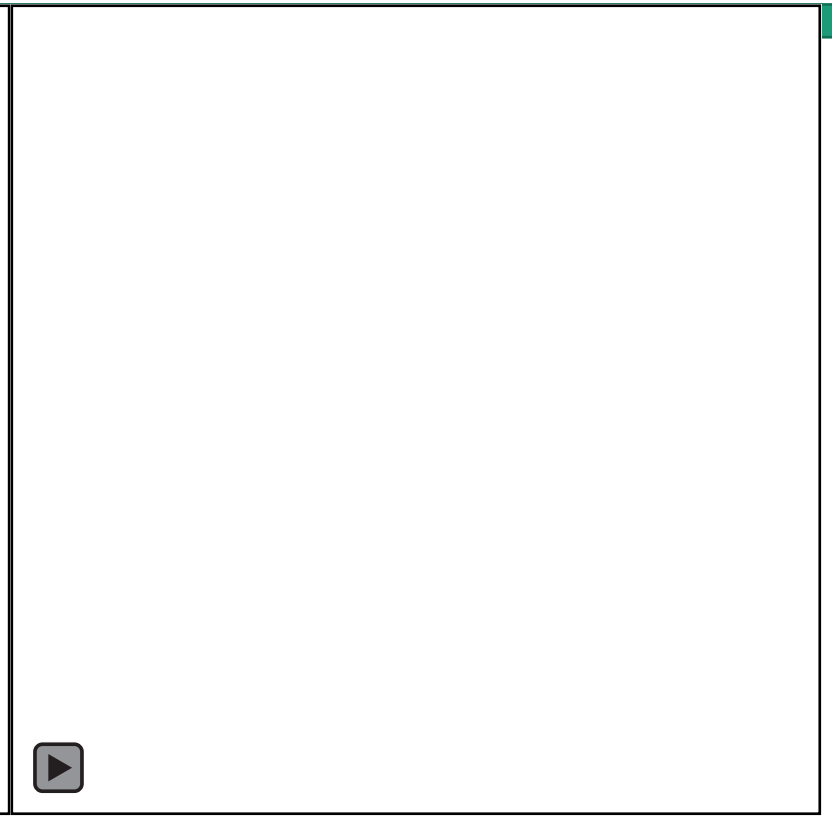


Near cusp overap view

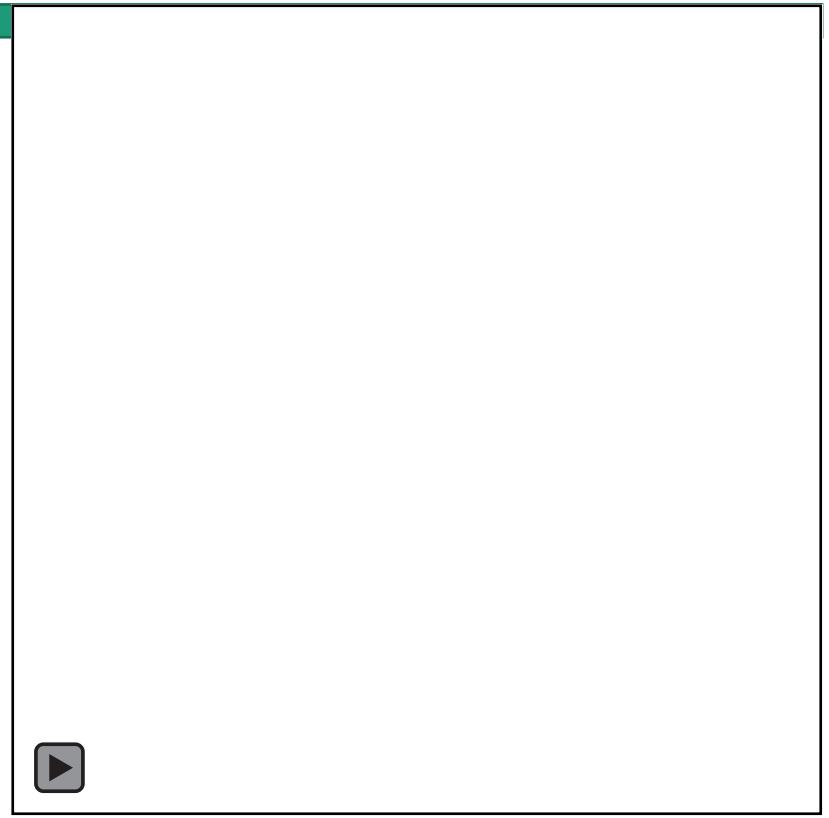
Passing the Aortic valve antegradely



Atrial septostomy

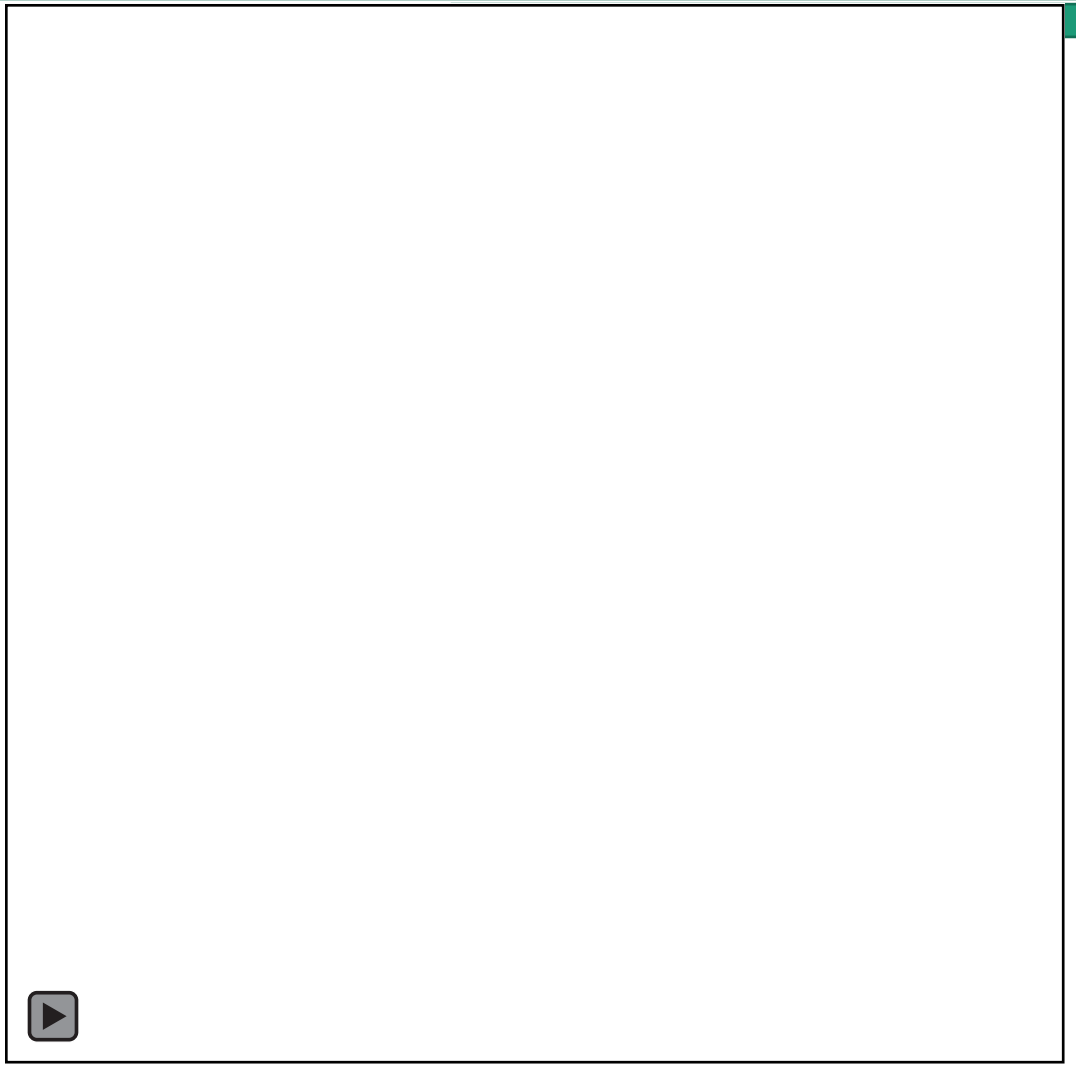


Passing the valve antegradely with a noodle wire

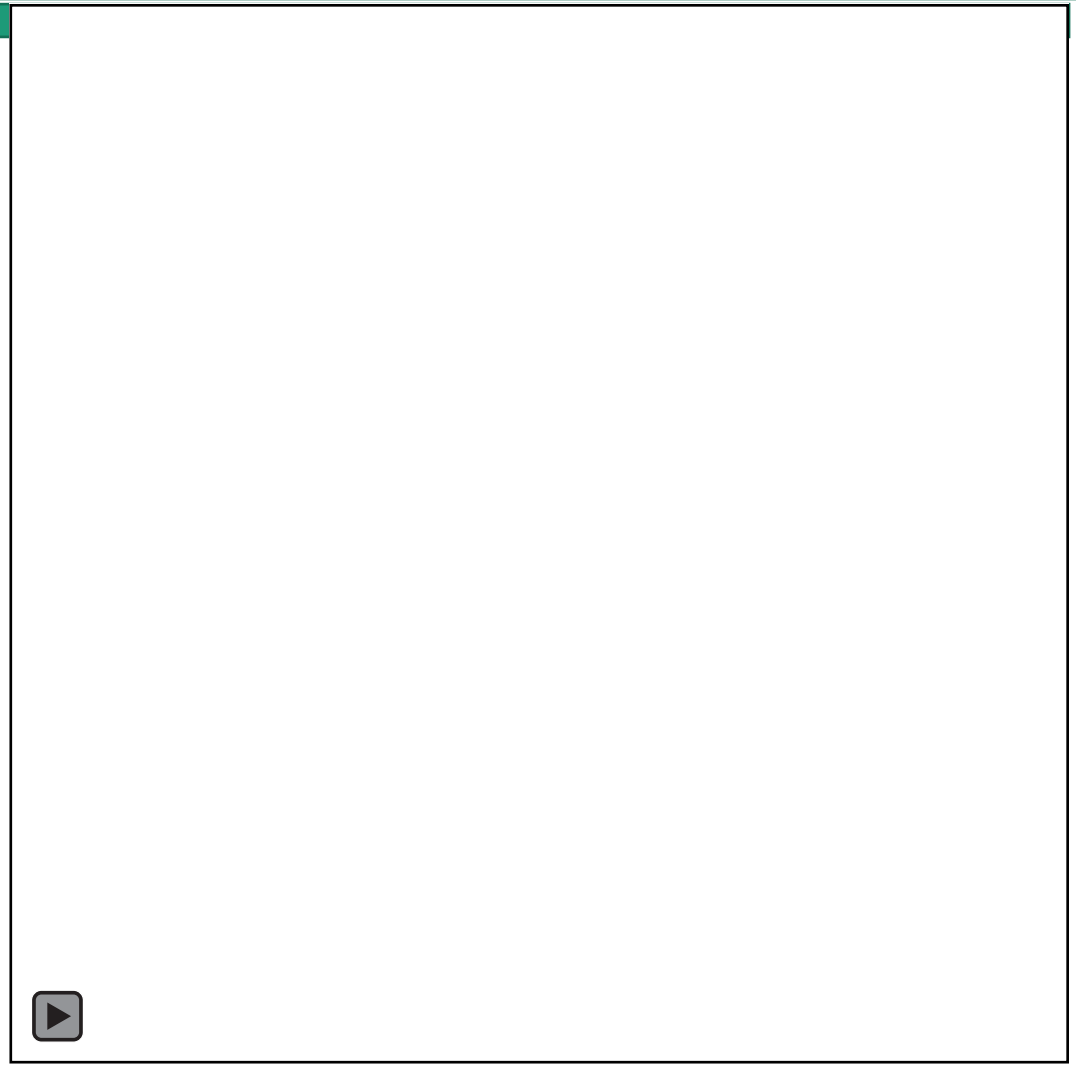


Snaring the wire and making arterio-venous loop

Predilation – Adjustment of implantation depth

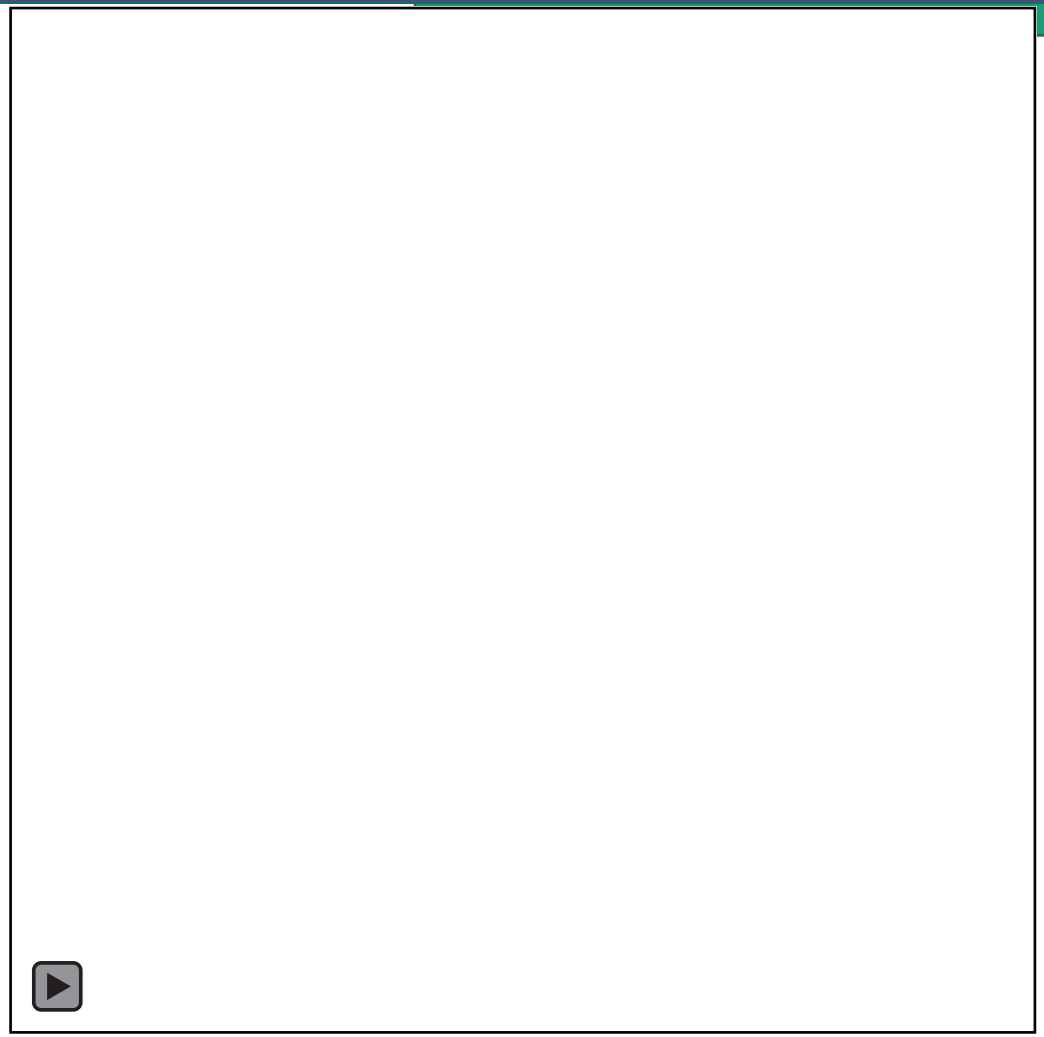


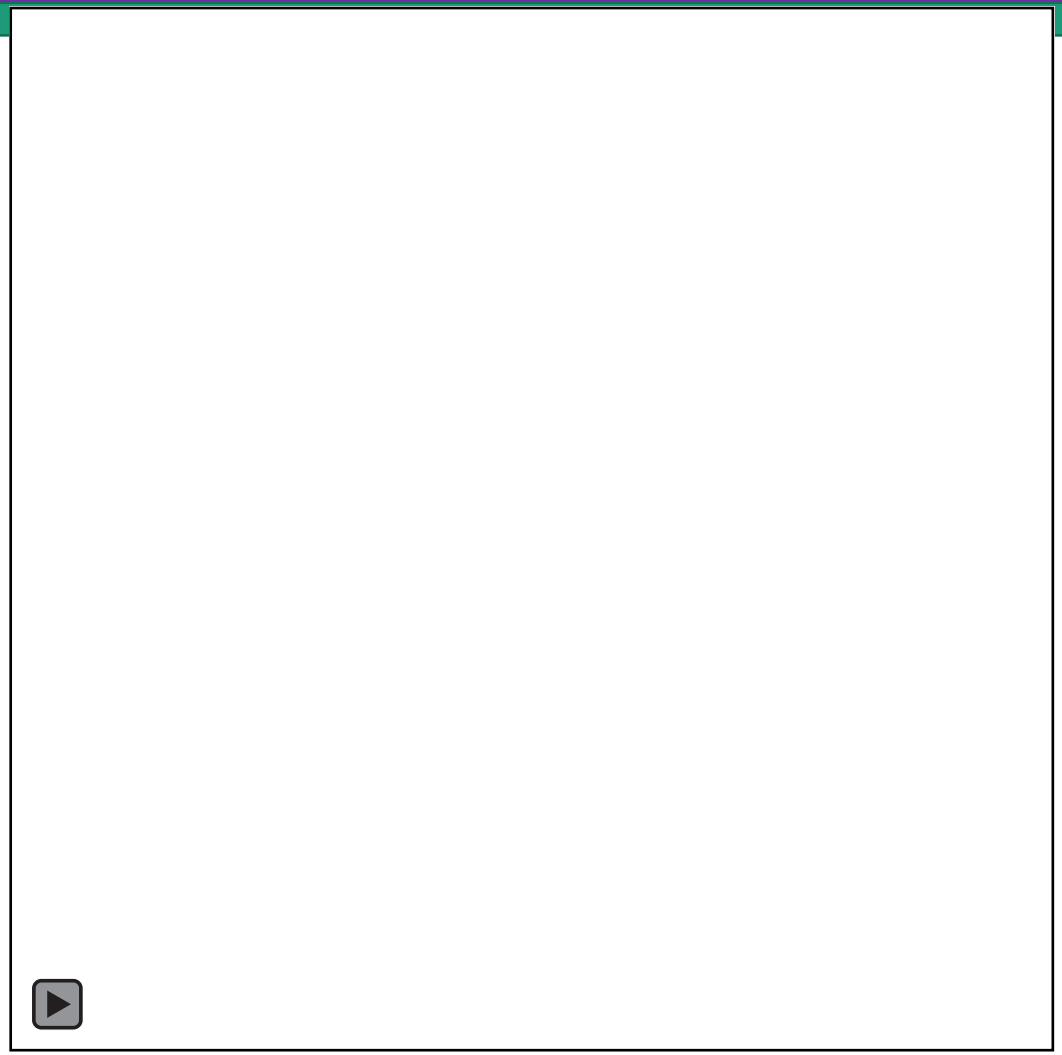
Predilatation with 16 mm balloon



View from RAO-Cau

Predilation – Adjustment of implantation depth





Implantation of the THV (LAO 25 Cau 5)

Post dilatation

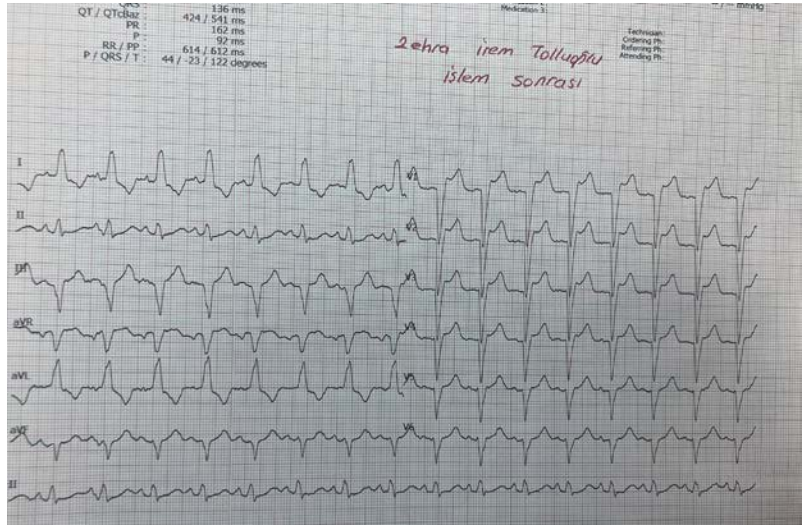
After implantation

Peak-to-peak
PG 40 mmHg

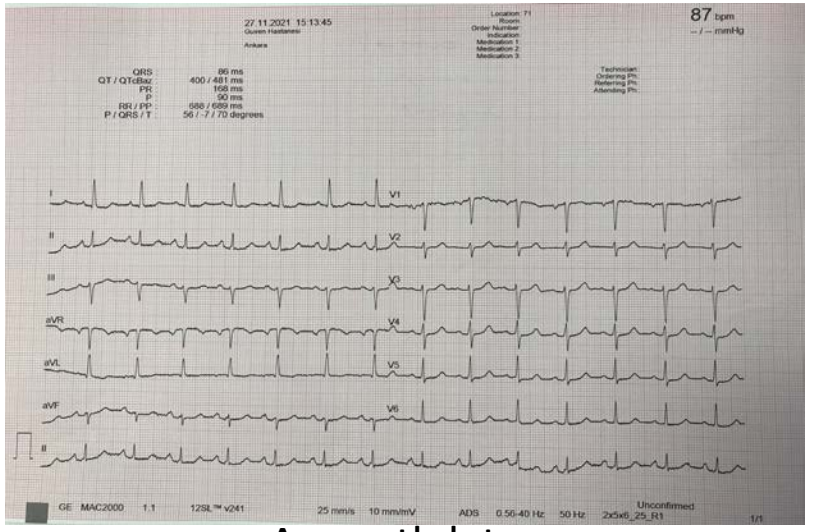
Post dilatation with 20 mm balloon

After post-dilatation

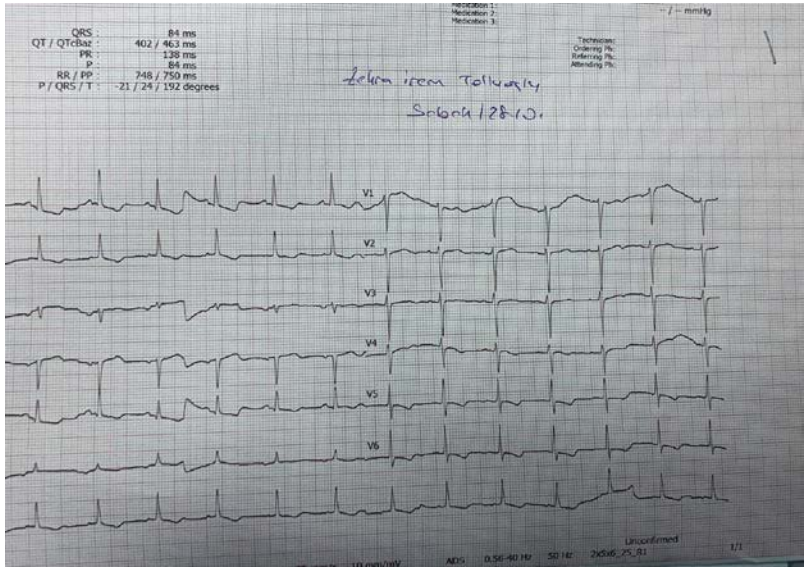
ECG and Echocardiography after the procedure



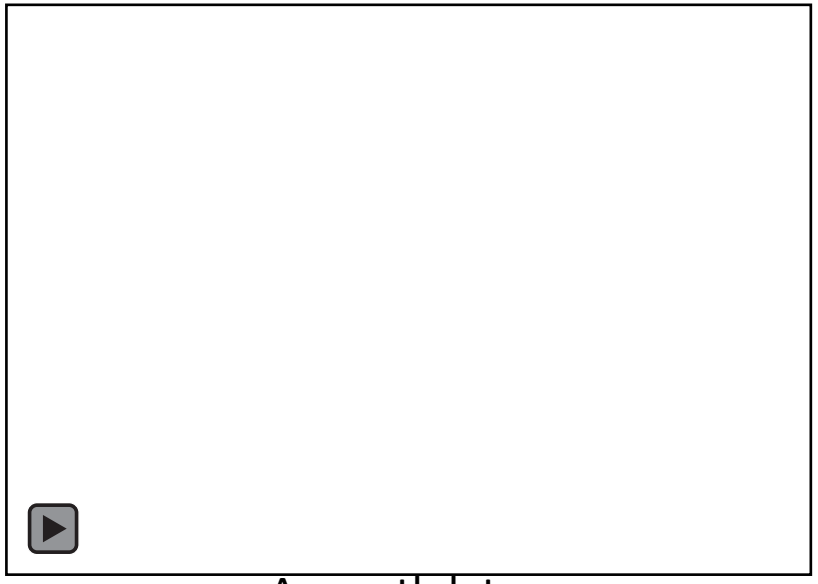
Immediately After the procedure



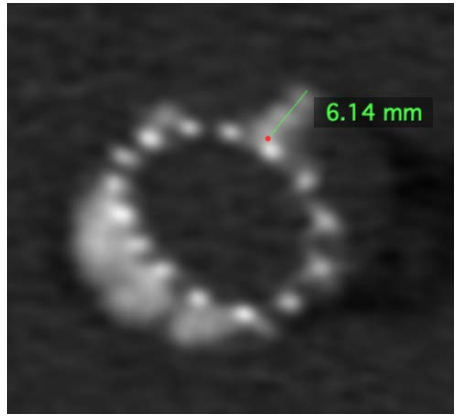
A month later

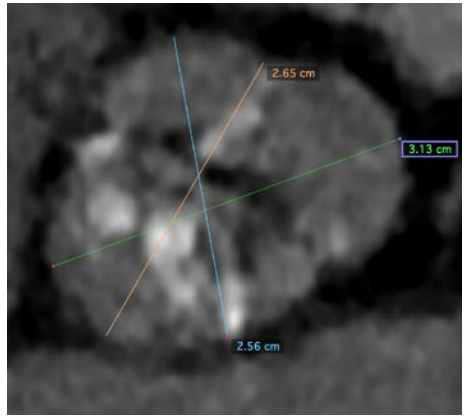


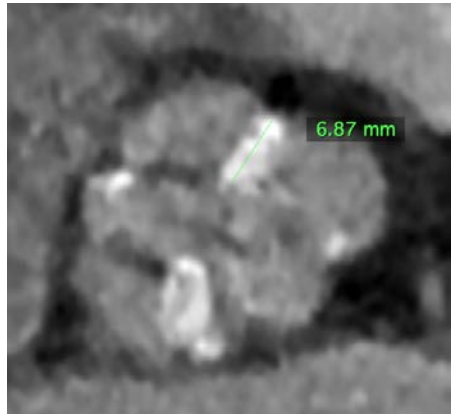
Following morning

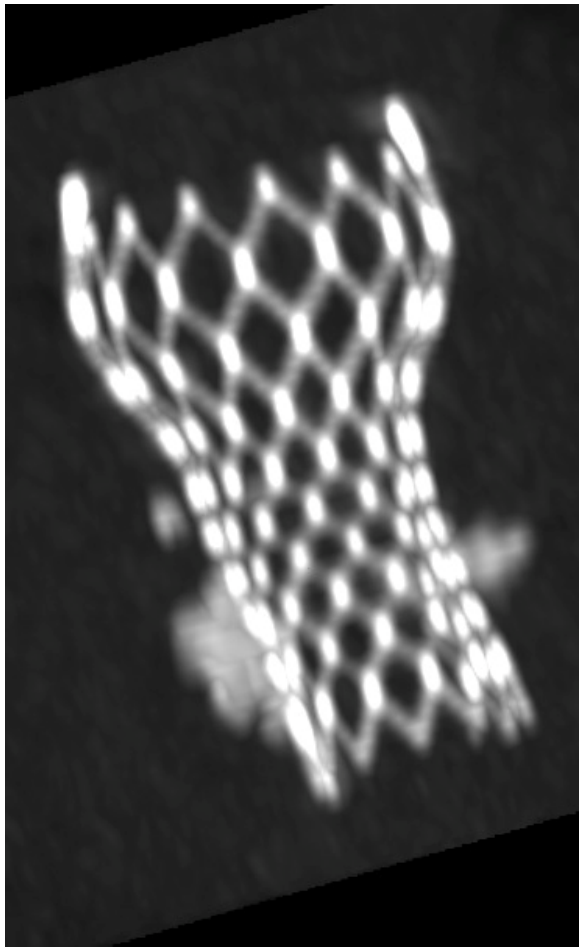


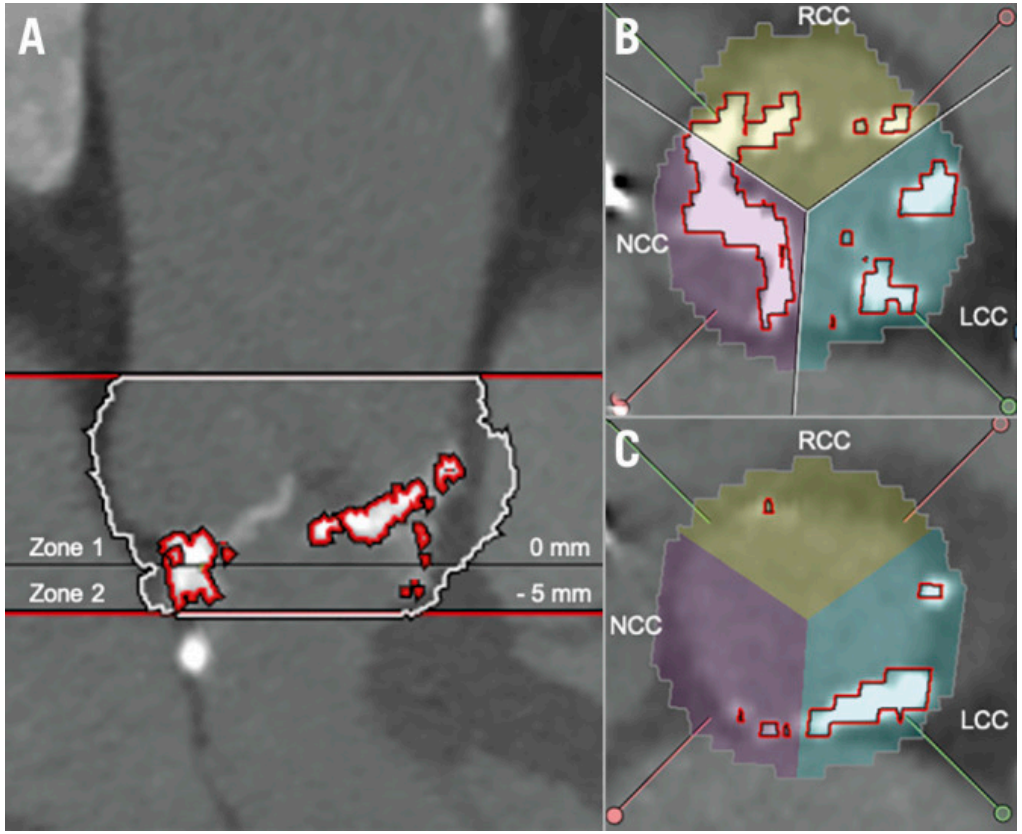
A month later


6.14 mm


2.65 cm
3.13 cm
2.56 cm


6.87 mm





Waldschmidt L, et al. EuroIntervention. 2022 Apr; 17(17): e1417–e1424.

Kapak migrasyonu

- Ciddi kalsifikasyonlarda undersising kalması
- Genelde işlem sonrası
- Nadiren self kapaklarda işlem sonrası
- Spontan
- Ciddi komplikasyon nadir oluşturur
- Kalsifikasyon olmadığı için oluşan migrasyon daha tehlikeli
- PVY önemli bir nedeni

Paravalvüler yetmezlik

- En sık komplikasyon
- Ciddi kalsifikasyon kapağın tam ve simetrik açılımını önler
- Non-koroner ve sol cusp kalsifikasyonlarında daha fazla izlenir
- Kalsifikasyon miktarı ile artar
- Balon kapaklarda daha az selflerde daha fazla
- Yeni jenerasyonlarda daha az
- Partner 1 çalışmasın da %12 iken Partner 2 de %3.8
- Kapak teknolojileri ve operatör deneyimi

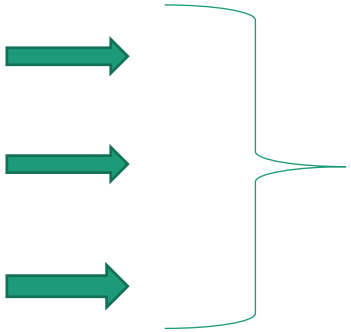
Anüler rüptür

- Balon eksbandbl kapaklarda daha fazla
- %83 subanüler bölgede
- Genelde agresif veya tekrarlayan postdilatasyon
- En fazla
  - İleri kalsifik biküspit (tip-2)
  - Sirküler anüler kalsifikasyon
  - LVOT uzanan kalsifikasyon

Kapağı ne kadar şişirelim? Ekspanse edelim?

Kapak tipi	Kapak ölçüm şekli	Sistol-diyastol değişim oranı	Max artış oranı
Balon EK	Alan bazlı	%0-10	<%20
Self EK	Perimetre(circumference)	%10-25	<25

- Ciddi kalsifik biküspit kapak
- Sirküler anüler kalsifikasyon
- LVOT uzanan kalsifikasyon



Slow-two-step

E AND HEART FAILURE

ular outflow tract calcification on clinical outcomes of patients with severe aortic stenosis undergoing

Thomas Kurz[4,5], MD; Hans-Josef Feistritzer[2,3], MD, PhD; Philipp Hartung[2,3], MD; Ingo Eitel[4,5], MD; Holger Nef[6], MD; Oliver Doerr[6], MD; Alexander Lauten[7], MD; Ulf Landr
nn School of Medicine at Mount Sinai, New York, NY, USA; 2. Department of Internal Medicine and Cardiology, Heart Center Leipzig, University of Leipzig, Leipzig
as been associated with worse outcomes in patients undergoing transcatheter aortic valve implantation (TAVI) and may influence the selection of prosthetic val
outcomes after TAVI with a self-expanding valve (SEV) versus a balloon-expandable valve (BEV).
rds SAPIEN 3 or Medtronic Evolut R, were divided according to LVOT calcification into no/mild (≤1 calcium nodule extending <5 mm and covering <10% of the LVO
fication was present in 143 (34.4%). Moderate/severe LVOT calcification was associated with significantly longer fluoroscopy time and higher rates of pre- and pos
d with longer fluoroscopy time and an increased need for pre- and post-dilation, but not with a higher incidence of early and mid-term adverse clinical outcomes

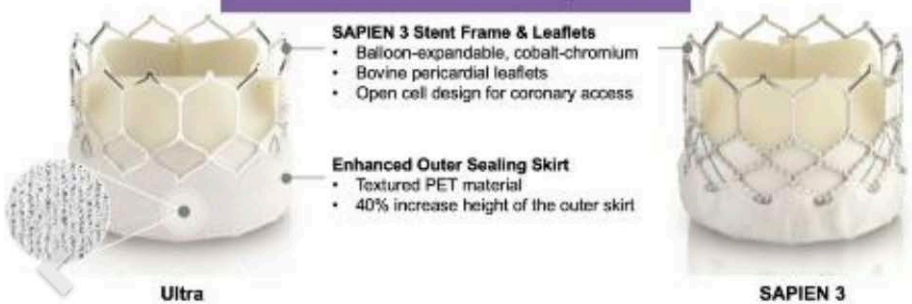
Chen[7*]

SYSTEMATIC REVIEW article
Front. Cardiovasc. Med., 24 May 2023
Sec. Heart Surgery
Volume 10 - 2023
| https://doi.org/10.3389/fcvm.2023.1170979
This article is part of the Research Topic
Reviews in Transcatheter Aortic Valve Implantation
View all 3 Articles

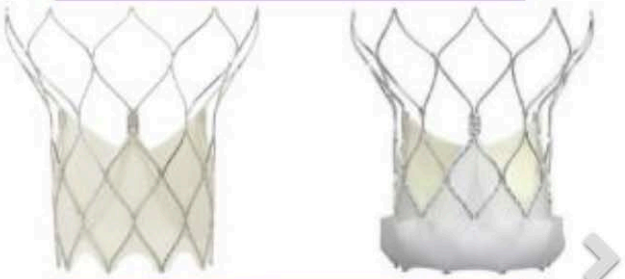
Quantity and location of aortic valve calcification predicts paravalvular leakage after transcatheter aortic valve replacement: a systematic review and meta-analysis

Minimizing PVL – sizing and choice of device

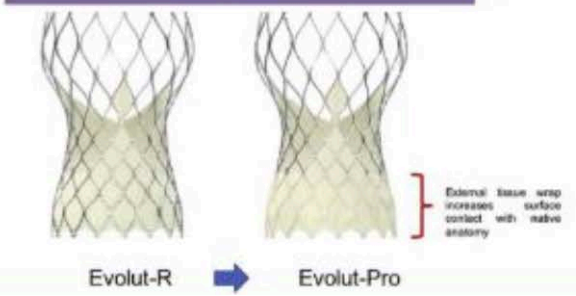
Edwards S3 -> S3ULTRA/S3UR



Abbott Portico -> Navitor



Medtronic E-R -> Evolut-PRO



Industry standard of sealing skirt/cuff at the annular level has reduced severity of moderate or severe PVL

Conclusion

- There is some data to suggest even mild PVL lead to worse outcomes.
- Greater than moderate PVL is not acceptable; ?greater than trivial for younger patients?
- Newer generation THV devices have reduced the incidence moderate and severe PVL.
- In the future, perhaps truly hostile anatomy – i.e. likelihood of moderate + PVL or inability of TAVi-in-TAVI – may be the strongest contraindication for TAVI.

İleti bozuklukları

- %4-47
- Self E> Balon E
- Ciddi kalsifikasyon
- Önceki ileti defekti
- Kapak tipi ve yerleşimi
- Non-koroner ve sol cuspda ciddi asimetrik kalsifikasyon

Koroner ostium tıkanması

- Sıklık <%1
- Kalsifikasyon yeri ve büyüklüğü
- Lmca
- BEK %0.81 SEK %0.34
- %80 kadınlarda
- Aortik root <28mm ve ostiyum yüksekliği <10 mm

Stroke

- Peri-prosedürel AF ve kalsifik aort daha sık
- Sağ koroner cusp ve LVOT kalsifikasyonunda fazla
- Kapaklar arasında strok açısından fark yok
- Aortik kalsifikasyondan bağımsız

Ciddi kalsifikasyon var hangi kapağı takalım?

- SOLVE –TAVİ Trial

Table 3 **Primary endpoint and its components**

	Self-expanding valve (Evolut R)	Balloon-expandable valve (Sapien 3)	Rate difference (90% CI)	*P*-value equivalence
Composite primary endpoint,[a] % (*n*/total)	28.4 (62/218)	25.9 (56/216)	-2.51 (-9.56 to 4.53)	0.04
All-cause mortality, % (*n*/total)	3.2 (7/217)	2.3 (5/219)	-0.94 (-4.79 to 2.91)	<0.0001
Stroke, % (*n*/total)	0.5 (1/210)	4.7 (10/214)	4.2 (0.11 to 8.28)	0.003
Moderate or severe prosthetic valve regurgitation,[b] % (*n*/total)	3.4 (7/208)	1.5 (3/207)	-1.92 (-5.88 to 2.05)	0.0002
Permanent pacemaker, % (*n*/total)	23.0 (49/213)	19.2 (41/214)	-3.85 (-10.4 to 2.72)	0.06

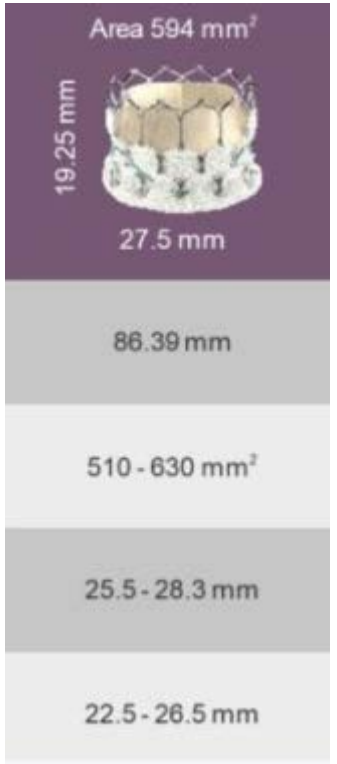
Results are displayed for the prespecified hierarchical testing against the equivalence margin 10% for the primary endpoint and its components.

[a]Composite of all-cause mortality, stroke, moderate or severe prosthetic valve regurgitation; permanent pacemaker implantation at 30-day follow-up.

[b]Moderate or severe paravalvular leak (PVL) based on core laboratory assessment.

Nasıl yapardım?

- Çift proglide
- En az 23 mm balon ile predilatasyon ama self kullanacaksam en az 25 mm balon
- Balon expandbl
- Kapağı 2 basamaklı açmayı tercih ederdim (anüler rüptürden kaçınmak için)



- Operatörün en deneyimli olduğu kapak
- Over-under size kaçınmak
- Tekrarlayan postdilatasyondan kaçınmak

- Teşekkürler