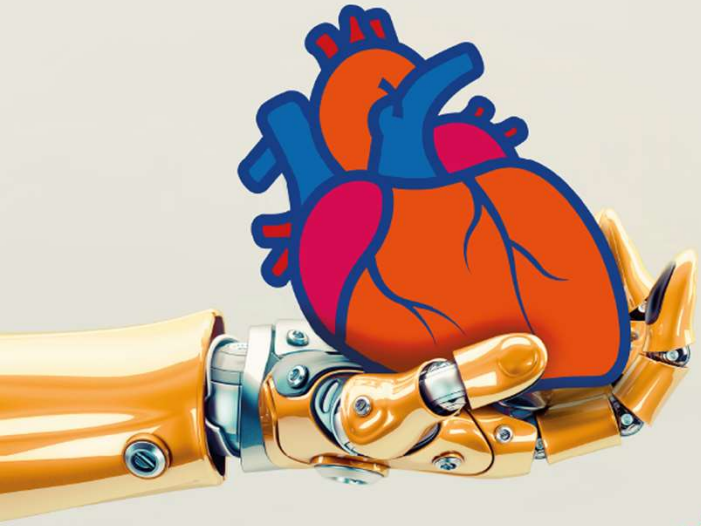

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Paravalvolar Leak: Diagnosis and Percutaneous Treatment

Giuseppe Santoro

Paediatric Cardiology and GUCH Unit
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IFC-CNR, Massa

Paravalvular Leak: Diagnosis and Percutaneous Treatment

* Paravalvular Leak (PVL) is an abnormal communication between cardiac chambers separated by a prosthetic valve through a gap along the valvular strut
* It has been reported in 2-17% of surgical AV replacement procedures and in 2.2-22% of MV replacement procedures
* It occurs in 2/3 of cases in the first year after surgery (due to anatomic or technical problems) and later in the remaining cases (due to endocarditis or prosthesis dehiscence)

Goel K. Curr Cardiol Rep 2018
Shah S. J Thorac Cardiovasc Surg 2019

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Paravalvular Leak: Diagnosis and Percutaneous Treatment

* Predisposing risk factors are tissue friability, annular calcification and infection
* Corticosteroid therapy and previous surgical valve replacements increase the risk of PVL formation
* Clinical relevant PVLs occur in 2-5% of patients
* Main indications for treatment are symptomatic hemolytic anemia, congestive heart failure or both
* Clinical PVLs have relevant impact in long-term prognosis

Paravalvular Leak: Diagnosis and Percutaneous Treatment

* PVL has been reported up to 10-25% of pts submitted to TAVI with the first generation valves and up to 2-5% of cases with the latest generation valves
* Aortic annulus calcification volume and use of self-expanding valves (vs balloon-expanding ones) are risk factors for PVL formation
* Clinical significant PVL is an independent risk factor for early (<30 day) and late mortality after TAVI

Goel K. Curr Cardiol Rep 2018
Pollari F. J Thorac Cardiovasc Surg 2019
Bhushan S. Curr Probl Cardiol 2022

Paravalvular Leak: Diagnosis and Percutaneous Treatment

PVL Treatment

- Surgery
- Trans-catheter
- "Hybrid" approach

Percutaneous vs surgical approach

* The occluding device fills the gap by a "stenting" mechanism different from the stitch traction of fragile peri-valvular tissues as in surgical approach

Paravalvular Leak: Diagnosis and Percutaneous Treatment

*** Based on the number of re-interventions, surgical treatment shows increasing morbidity (recurrence of PVL from 15% after 1st re-do to 35% after 3rd re-do) and mortality (from 13% after 1st re-do to 37% after 3rd re-intervention)**

Echevarria JR, Eur J Cardiothorac Surg 1991
Pate GE, CCI 2006
Shah S, J Thorac Cardiovasc Surg 2019

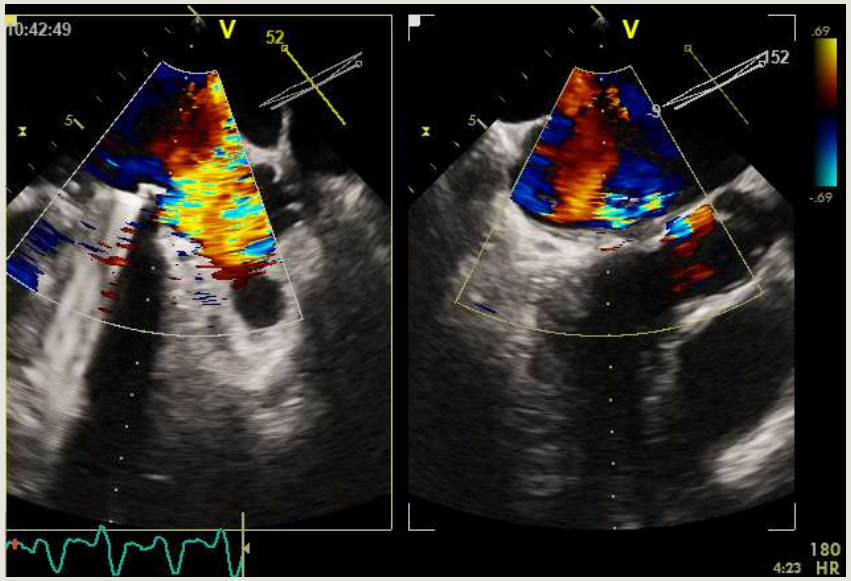
Indication to percutaneous treatment

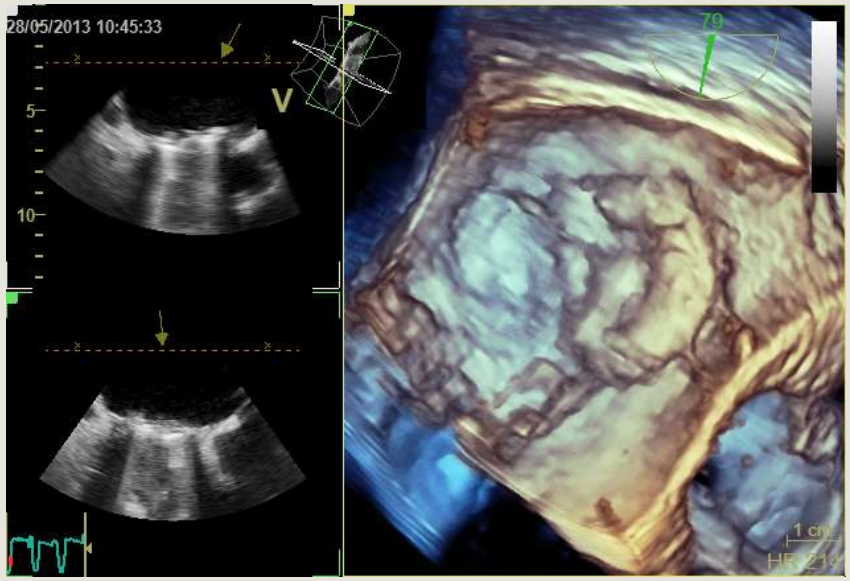
* Hemodynamic and clinical relevance !!!!
* Surgical indication
- "compassionate" in high-risk pts
- "alternative" to surgery
* "Predicted" surgical indication in significant PVL without clinical relevance (early phase)

Paravalvular Leak: Diagnosis and Percutaneous Treatment

Contraindications

* Active endocarditis
* Leak >30% of prosthesis (valvular instability and "rocking")





Endovascular Treatment

* No standard rules
* Deep knowledge of the anatomic details of the PVL
* Procedure technical tricks, some sort of «imagination» in techniques and deep knowledge of dedicated or off-label devices

Paravalvular Leak: Diagnosis and Percutaneous Treatment

Diagnostic Tools

* Echocardiography
* CT scan
* 3D imaging & printing technology

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Echocardiography in PVL treatment

* Grading the functional impact of regurgitation
* Imaging size, shape, number and position of PVLs
* Guiding the transcatheter approach
* Evaluating the post-procedure results and complications

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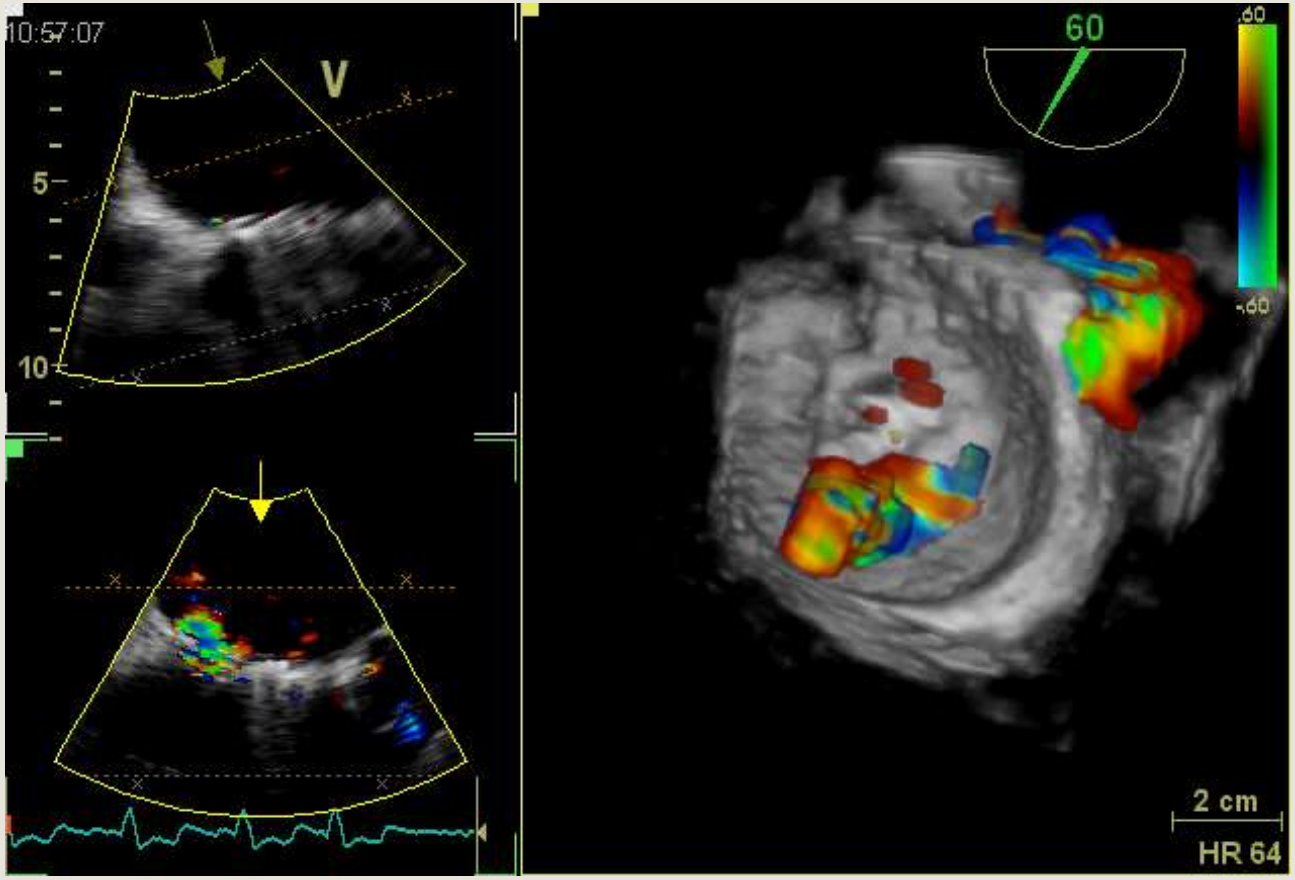
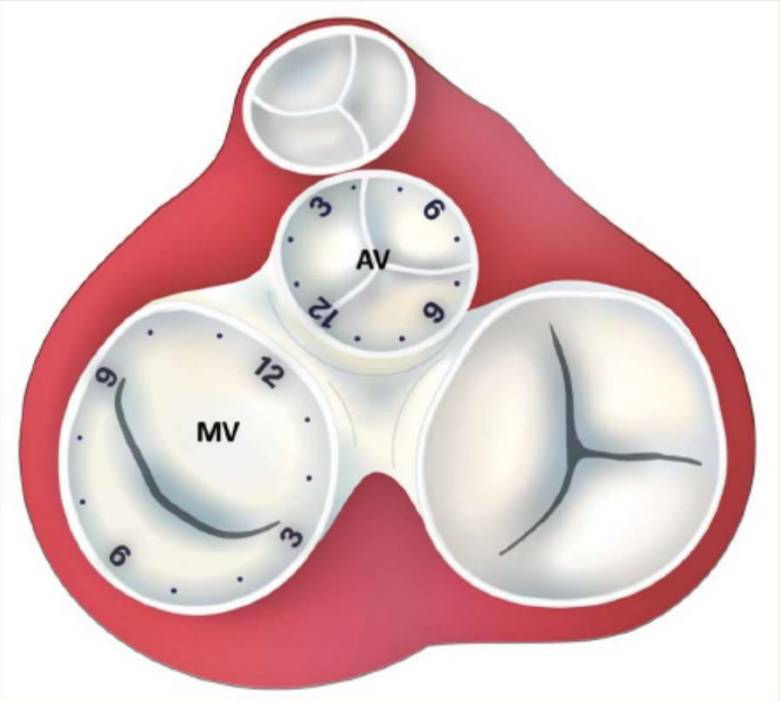


Paravalvular Leak: Diagnosis and Percutaneous Treatment



«Clockwise» format from surgical view

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CT scan

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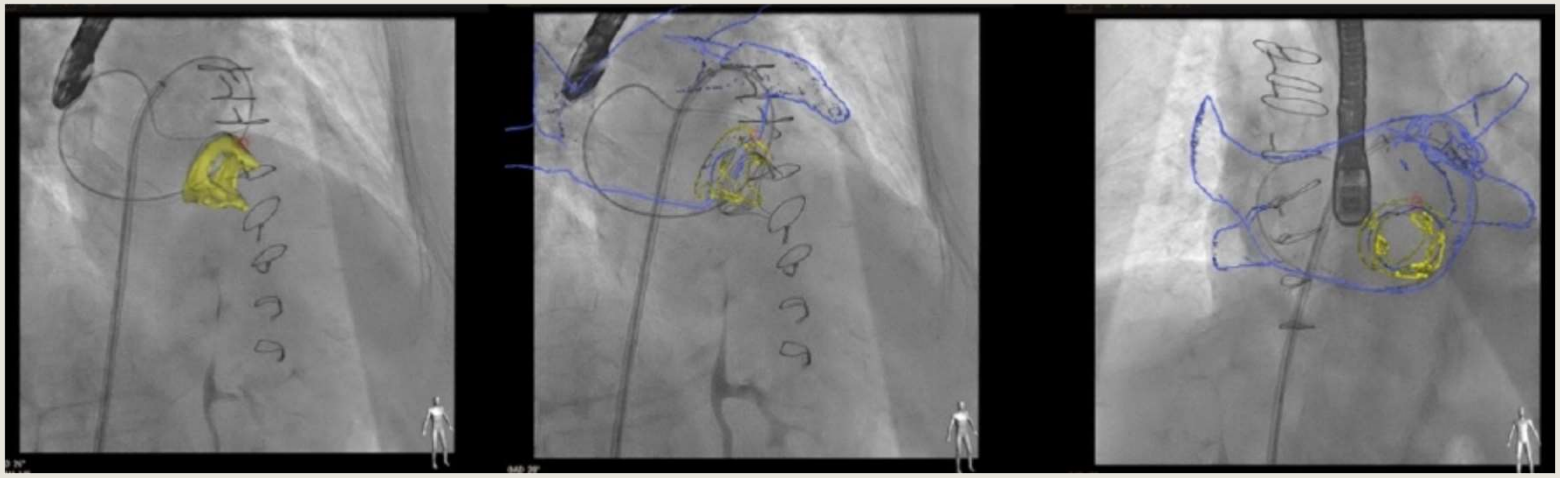

Paravalvular Leak: Diagnosis and Percutaneous Treatment

Mitral PVL

- Often echocardiographically-guided without angiography
- More challenging to occlude and with a higher failure rate

Aortic PVL

- Often angiographically-guided (echocardiography useful in biological prosthesis without cage and radio-opaque markers)
- Less difficult and risky to approach
- Higher success rate

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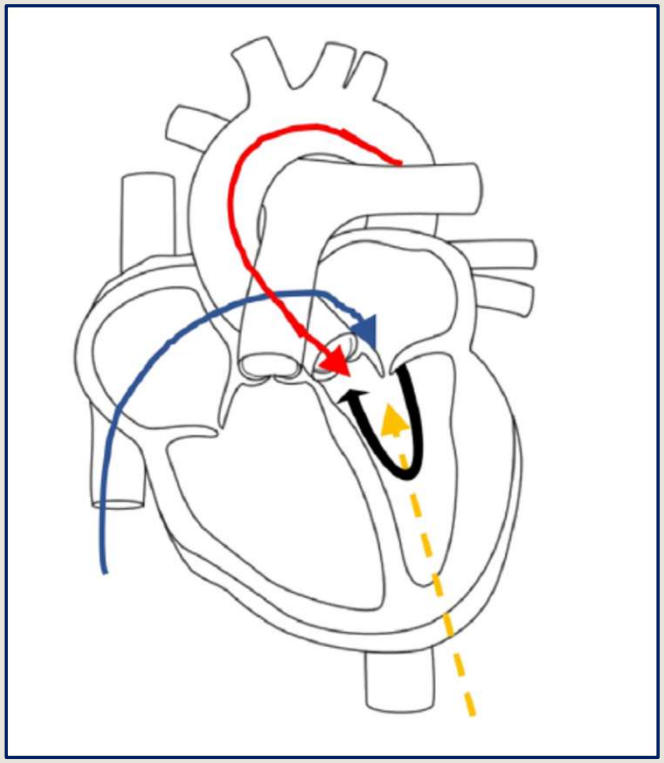


Paravalvular Leak: Diagnosis and Percutaneous Treatment

Mitral PVL Technique

* Antegrade transeptal approach → 12h and 9h PVLs (higher puncture for lateral and posterior PVLs, lower puncture for septal PVLs)

* Retrograde trans-aortic approach (or trans-apical approach) → 6h and 3h PVLs

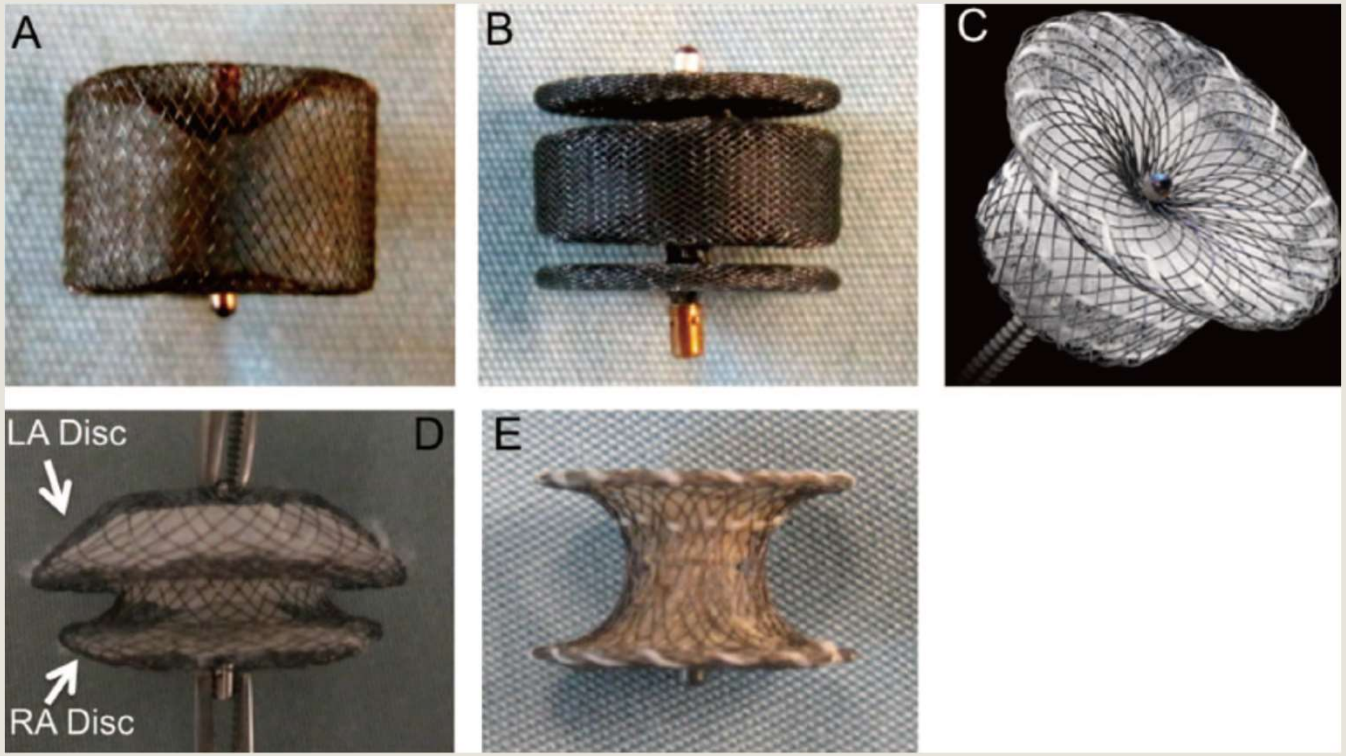
Paravalvular Leak: Diagnosis and Percutaneous Treatment

Aortic PVL Technique

* Retrograde trans-aortic approach (very often)
* Antegrade transeptal approach or trans-apical approach (rare)
* Need for coronary artery check during the procedure for PVLs close to coronary artery origin

Paravalvular Leak: Diagnosis and Percutaneous Treatment

* "Off-label" devices based on shape and size of PVL



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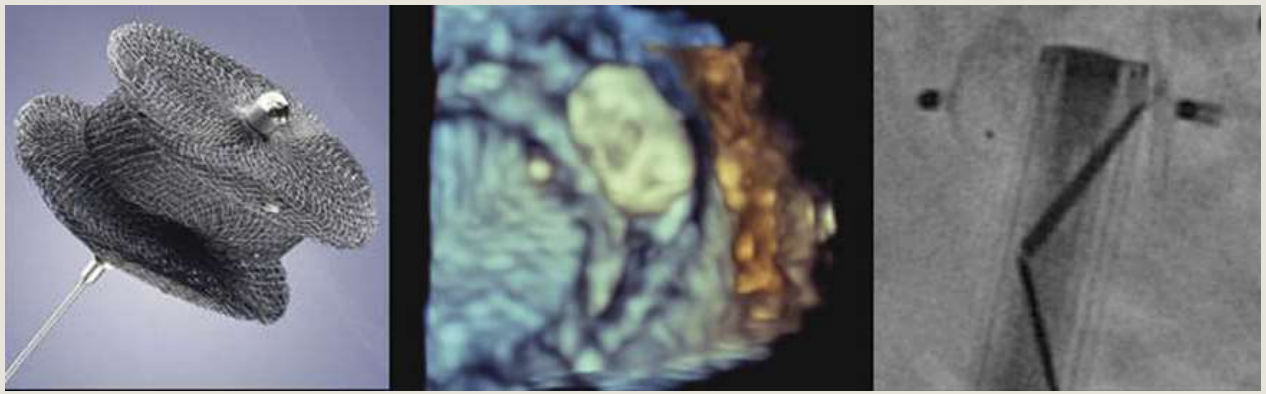
Dedicated devices



Paravalvular Leak: Diagnosis and Percutaneous Treatment

Mitral PVL treatment (procedure steps)

- Transeptal access (the site depends on leak position)
- Antegrade probing (telescopic ensamble with steerable sheath±catheters±standard/hydrophilic/stiff guidewire)
- Retrograde or trans-apical probing
- +/- AV rail formation
- Device selection and deployment

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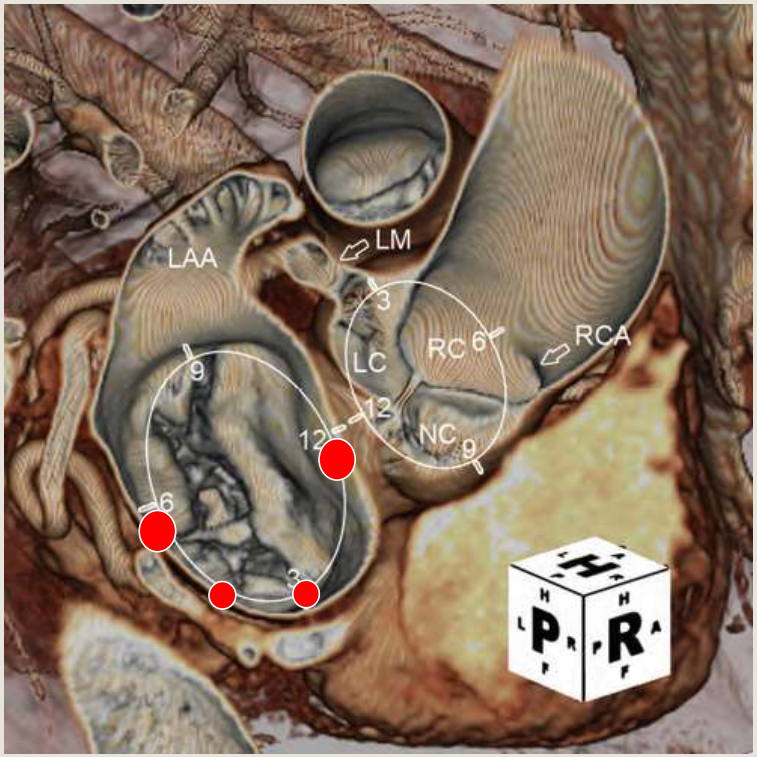

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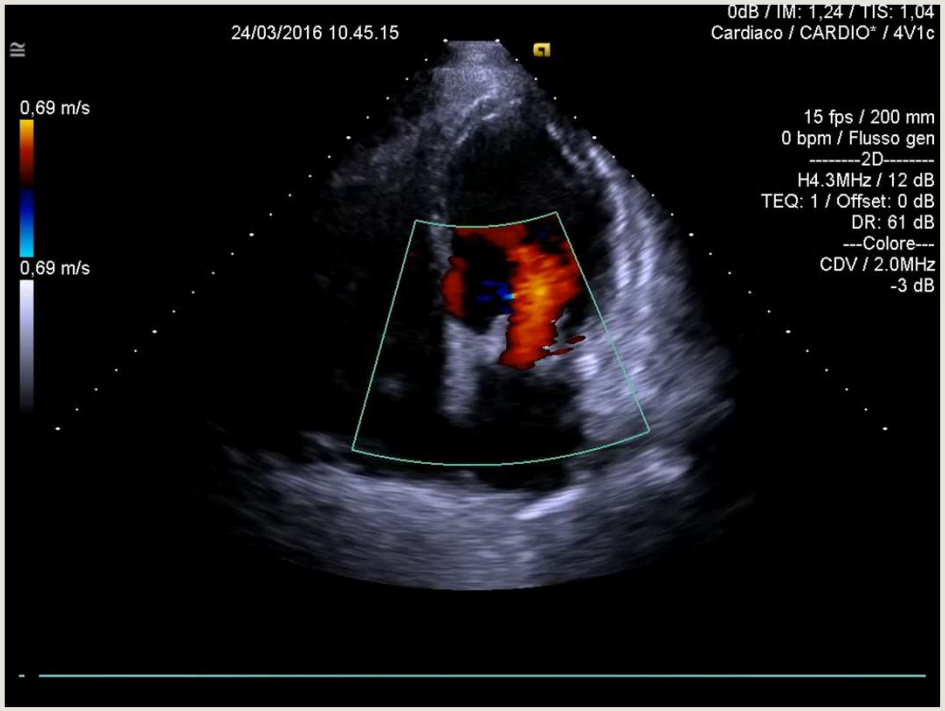

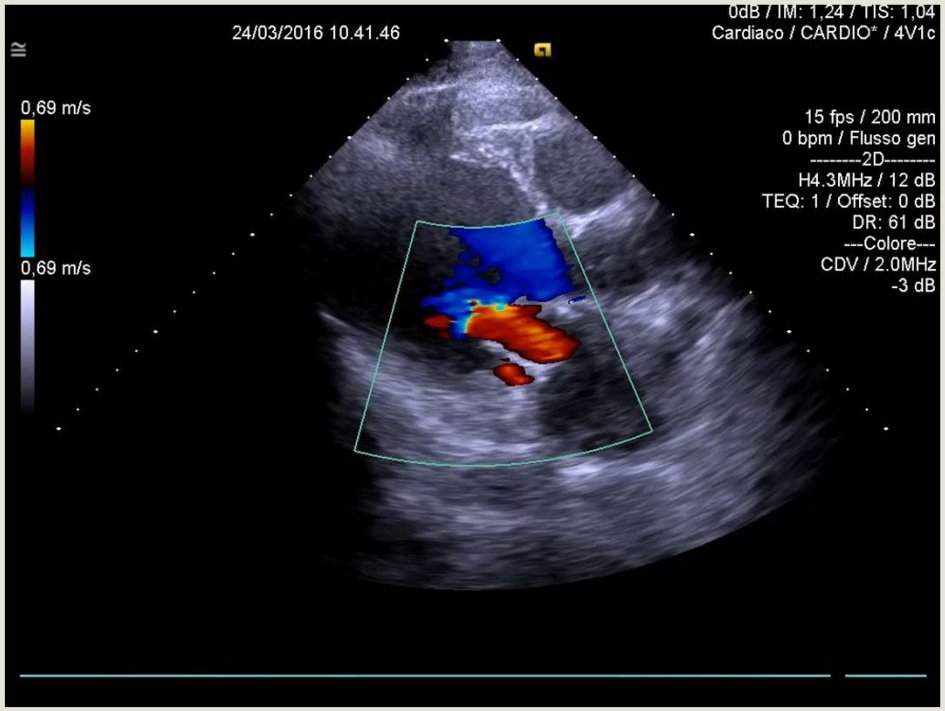

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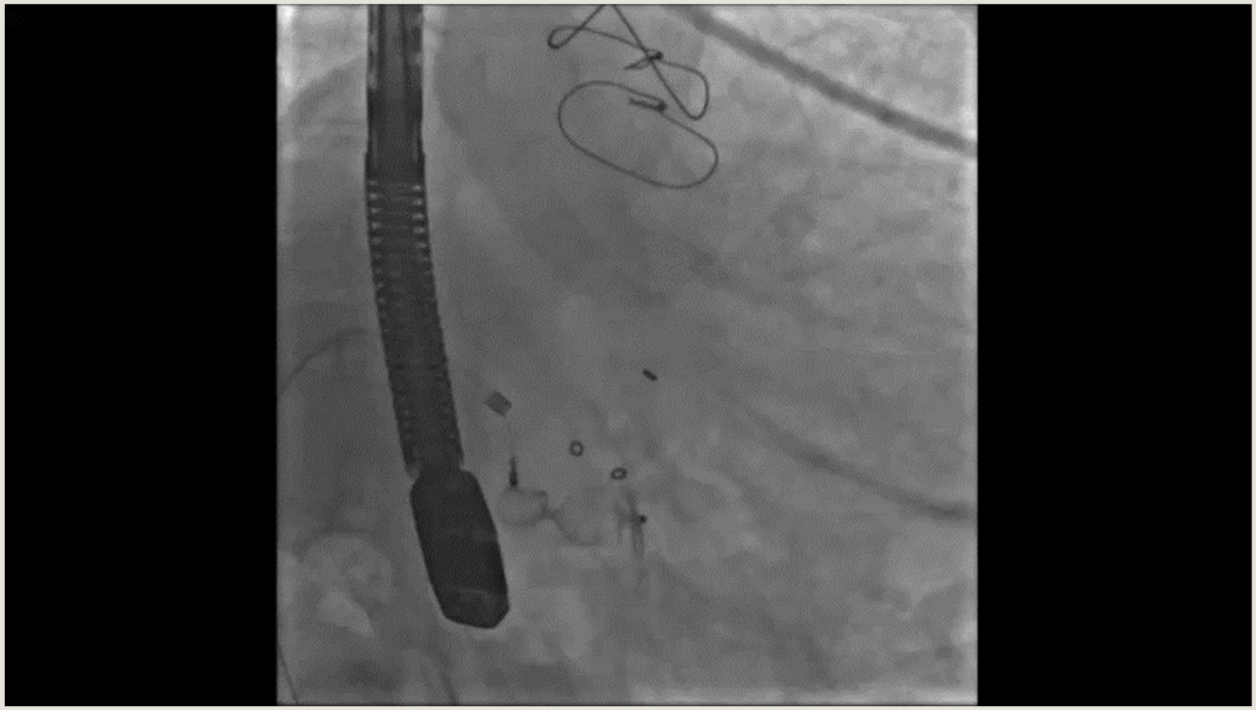
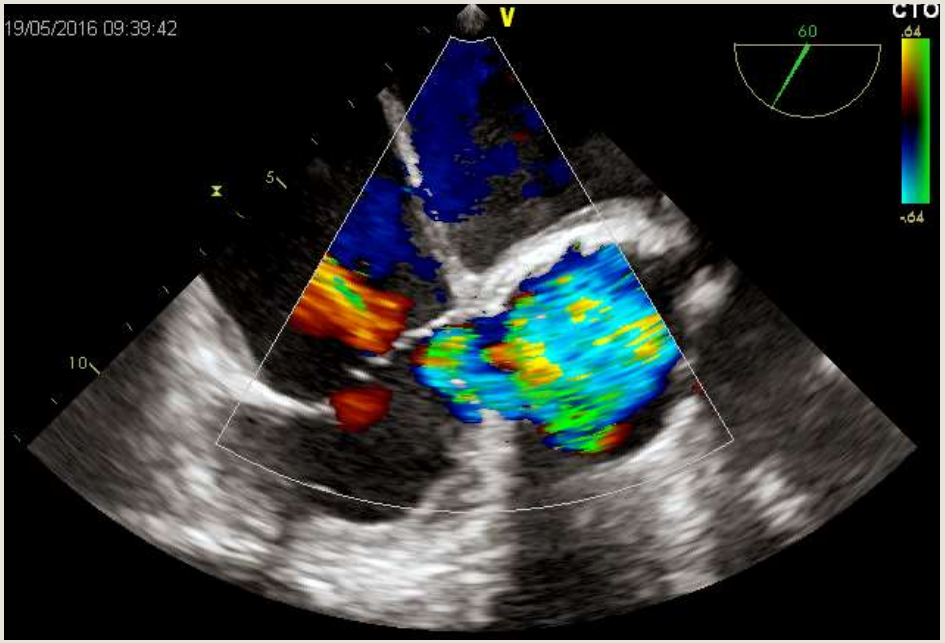


Paravalvular Leak: Diagnosis and Percutaneous Treatment

Aortic PVL treatment (procedure steps)

- Aortic angiography
- Retrograde probing (catheters±hydrophilic/stiff guidewire)
- Antegrade probing (transeptal or trans-apical access and AV rail creation)
- Device selection and deployment

Paravalvular Leak: Diagnosis and Percutaneous Treatment



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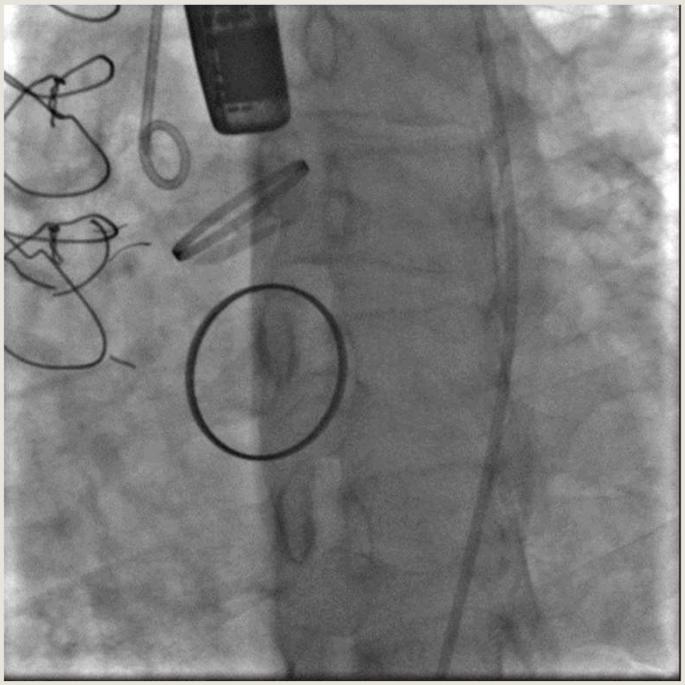
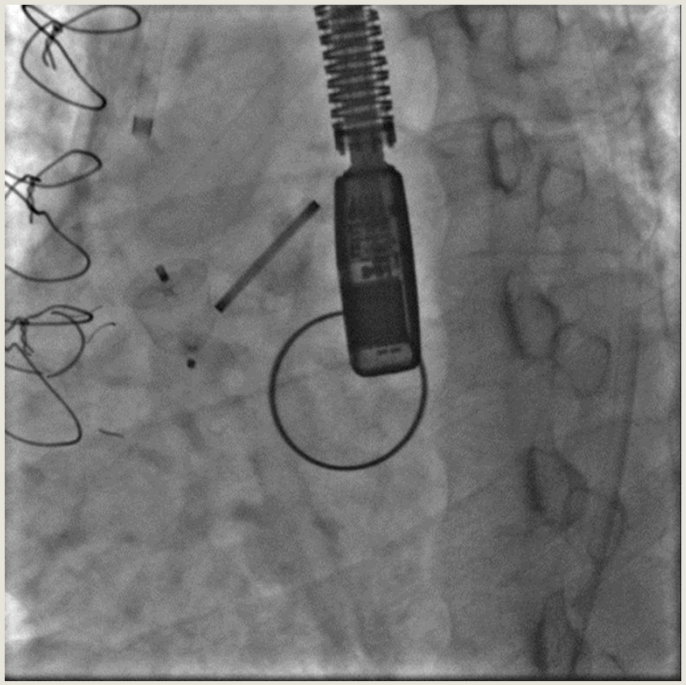
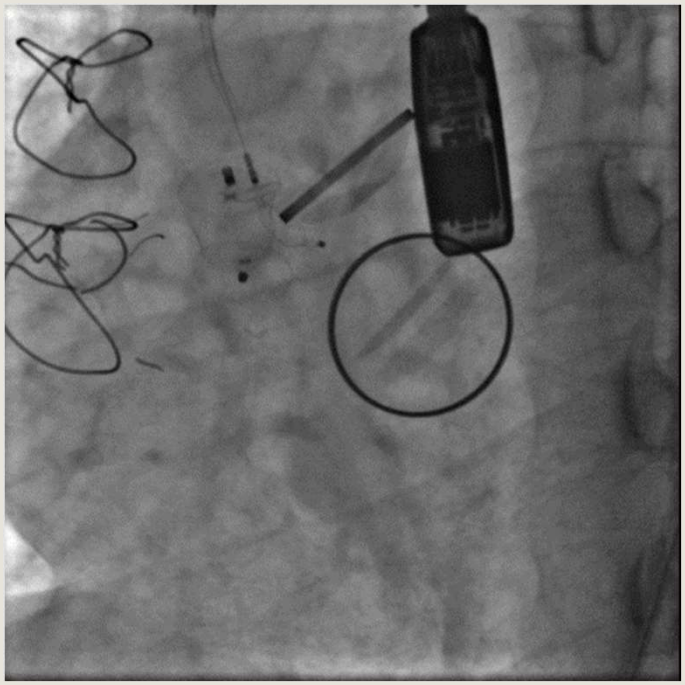

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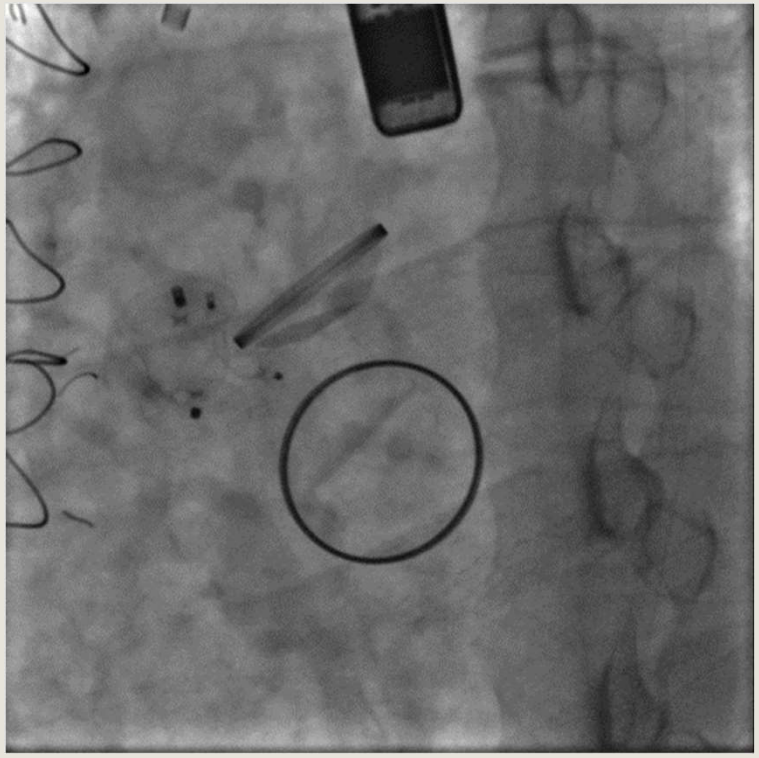

Aortic & Mitral PVL treatment (procedure steps)

- Simultaneous retrograde and antegrade approach
- Sequential retrograde and antegrade probing
- Device selection and deployment

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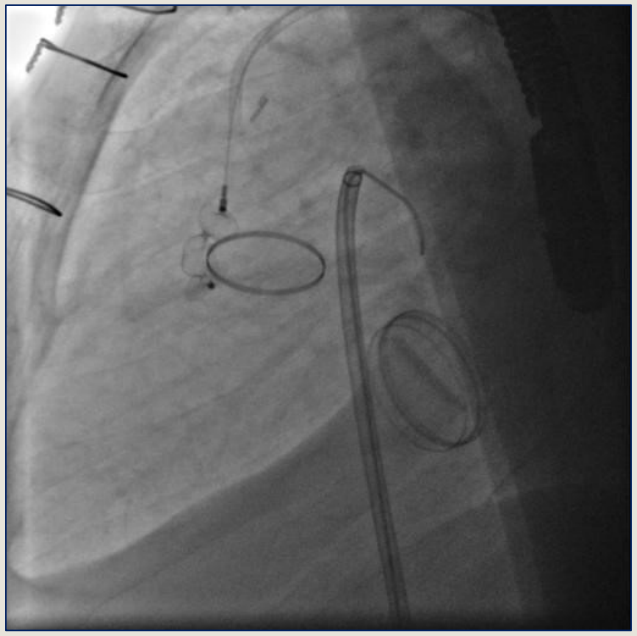

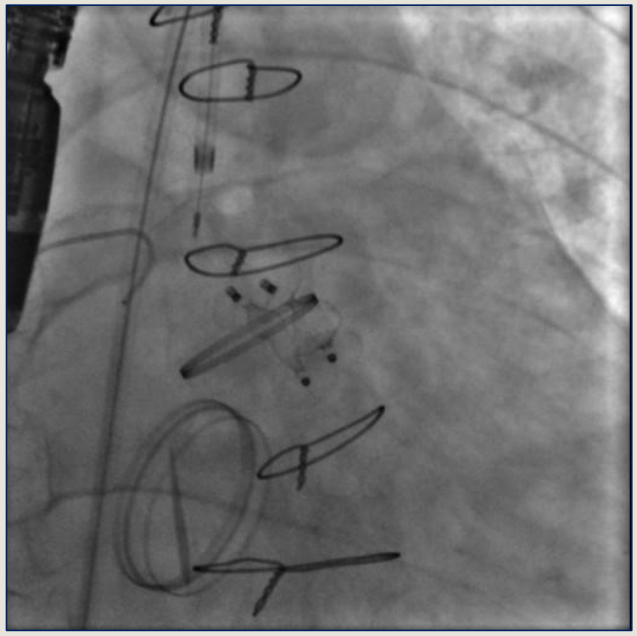

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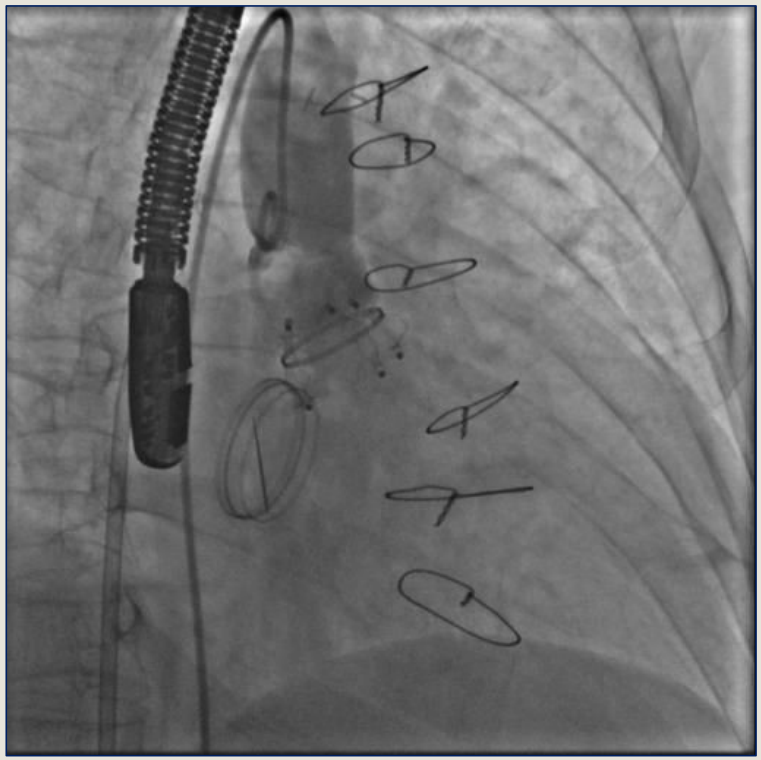

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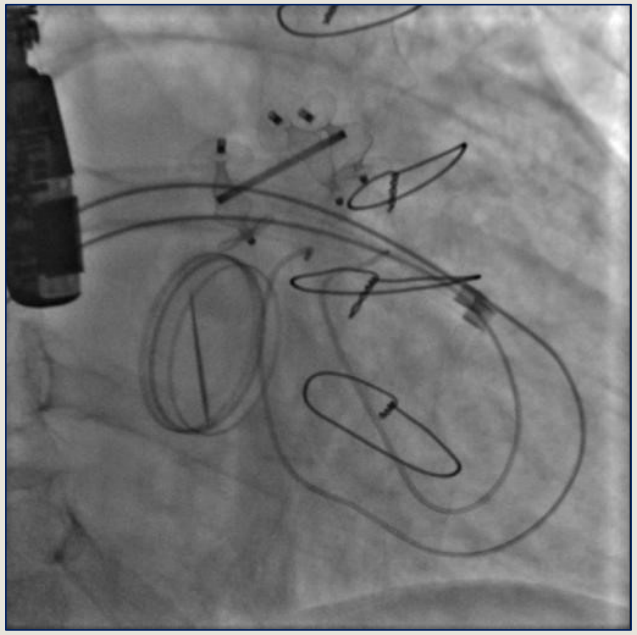

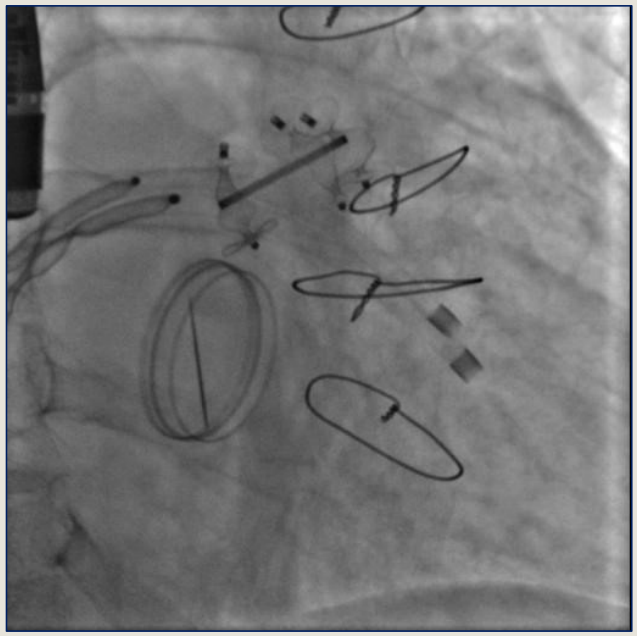

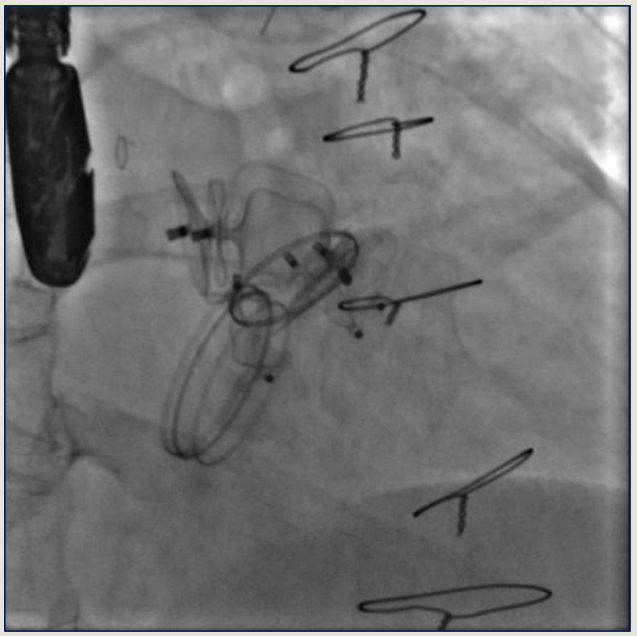

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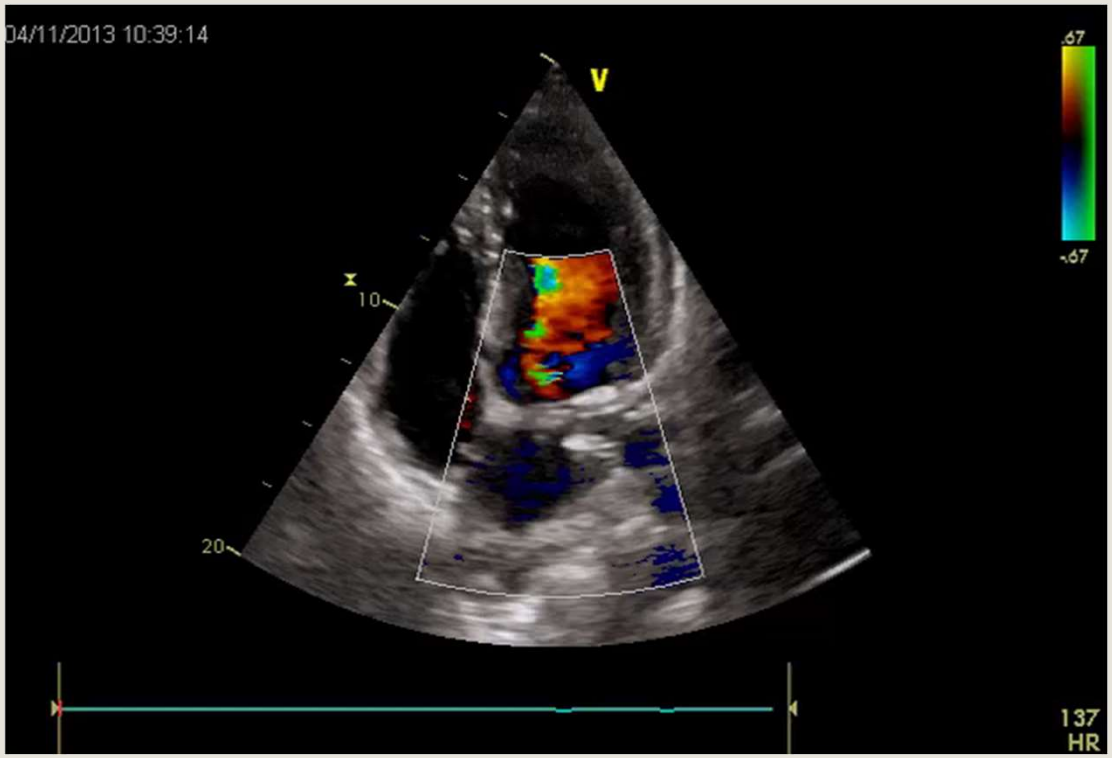

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Paravalvular Leak: Diagnosis and Percutaneous Treatment

Percutaneous Device Closure of Paravalvular Leak: Combined Experience from the United Kingdom and Ireland

Patrick A Calvert, PhD, FACC[1,2,3], David B Northridge, MB, FRCP[4], Iqbal S Malik, PhD, FRCP[5], Leonard Shapiro, MD, FRCP[1], Peter Ludman, MD, FRCP[2], Shakeel A Qureshi, BMBCh, FRCP[6], Michael Mullen, MB, BS, MD, FRCP[7], Robert Henderson, DM, FRCP[8], Mark Turner, MD[9], Martin Been, MD, FRCP[10], Kevin P Walsh, MD, FRCPI[11], Ivan Casserly, BMBCh[1,2], Lindsay Morrison, MD, FRCP[1,3], Nicola L Walker, PhD, MRCP[14], John Thomson, MD, FRCP[15], Mark S Spence, MD, FRCP[16], Vaikom S Mahadevan, MD, FRCP[17], Angela Hoye, PhD, FRCP[18], Philip A MacCarthy, MBChB, BSc, PhD, FRCP[19], Matthew J Daniels, PhD, MRCP[20], Paul Clift, MD[2], William R Davies, PhD, MRCP, MRCS[1], Philip D Adamson, MBChB[3], Gareth Morgan, MD[6], Suneil K Aggarwal, MBBS, MRCP[13], Yasmin Ismail, MD[9], Julian O M Ormerod, PhD, MRCP[20], Habib R Khan, MD[8], SujaySubash Chandran, MD[21], Joseph de Giovanni, MD, FRCP, FRCPH[2], Bushra S Rana, MD, FRCP[1], Oliver Ormerod, DM, FRCP[20], and David Hildick-Smith, MD, FRCP[21]

Circulation. 2016 September 27; 134(13): 934–944

Paravalvular Leak: Diagnosis and Percutaneous Treatment

Results—308 PVL closure procedures were attempted in 259 patients in 20 centers (2004-2015). Patient age was 67±13 years; 28% were female. The main indications for closure were heart failure (80%) and hemolysis (16%). Devices were successfully implanted in 91% of patients, via radial (7%), femoral arterial (52%), femoral venous (33%) and apical (7%) approaches. 19% of patients required repeat procedures. The target valve was mitral (44%), aortic (48%), both (2%), pulmonic (0.4%) or TAVR (5%). Pre-procedural leak was severe (61%), moderate (34%) or mild (5.7%) and was multiple in 37%. PVL improved post-procedure ($p<0.001$) and was none (33.3%), mild (41.4%), moderate (18.6%) or severe (6.7%) at last follow up. Mean NYHA improved from 2.7±0.8 pre-procedure to 1.6±0.8 ($p<0.001$) after a median follow-up of 110 [7-452] days. Hospital mortality was 2.9% (elective), 6.8% (in-hospital urgent) and 50% (emergency), ($p<0.001$). MACE during follow-up included death (16%), valve surgery (6%), late device embolization (0.4%) and new hemolysis requiring transfusion (1.6%). Mitral PVL was associated with higher MACE (HR=1.83, p=0.011). Factors independently associated with death were the degree of persisting leak (HR=2.87, p=0.037), NYHA (HR=2.00, p=0.015) at follow up and baseline creatinine (HR=8.19, p=0.001). The only factor independently associated with MACE was the degree of persisting leak at follow up (HR=3.01, p=0.002).

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Outcomes and predictors of success and complications for paravalvular leak closure: an analysis of the SpanisH real-wOrld paravalvular LEaks closure (HOLE) registry

Eulogio García[1], MD; Dabit Arzamendi[2], MD, PhD; Pilar Jimenez-Quevedo[3], MD, PhD; Fernando Sarnago[4], MD; Gerard Martí[5], MD; Angel Sanchez-Recalde[6], MD; Garikoit Lasa-Larraya[7], MD; Manuel Sancho[8], MD, PhD; Andres Iñiguez[9], MD, PhD; Javier Goicolea[10], MD; Koldobika Garcia-San Roman[11], MD; Juan Horacio Alonso-Briales[12], MD; Eduardo Molina[13], MD; Jose Calabuig[14], MD; Xavier Freixa[15], MD; Alberto Berenguer[16], MD, FESC; Mariano Valdes-Chavarri[17], MD, PhD; Nicolas Vazquez[18], MD; Jose Francisco Diaz[19], MD; **Ignacio Cruz-Gonzalez**[20]*, MD, PhD

EuroIntervention 2017;12:1962-1968

Methods and results: A total of 514 first-attempt percutaneous PVL closure in 469 patients were included at 19 centres. Technical and procedural success was achieved in 86.6% and 73.2% of the patients, respectively. In multivariate analysis, the independent predictors for procedural success in mitral lesions were the type of device used (AMPLATZER AVP III vs. others, HR 2.68 [1.29-5.54], p=0.008) and the number of procedures performed at the centre (top quartile vs. others, HR 1.93 [1.051-3.53], p=0.03). For aortic leaks the only predictor of procedural success was the leak size (≥10 mm vs. <10 mm, HR 3.077 [1.13-8.33], p=0.027). The overall major adverse events rate (death or emergency surgery or stroke) at 30 days was 5.6%; the only predictor for combined adverse events was New York Heart Association functional Class IV (HR 4.2 [1.42-12.34], p=0.009).

Paravalvular Leak: Diagnosis and Percutaneous Treatment

Conclusions

- Transcatheter treatment of PVLs is a complex but highly effective approach at lower risk than surgical re-do
- Clinical outcome is often better than technical and instrumental results
- Tight cooperation between "imaging" cardiologist, invasive cardiologist, anesthetists and cardiac surgeons is crucial to achieve effective closure

Paravalvular Leak: Diagnosis and Percutaneous Treatment

- **Knowledge of local anatomy, the use of dedicated and "off-label devices and some sort of "imagination" are crucial for the final success of the procedure**