

Katetrizační intervence mitrální chlopně – možné komplikace

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II. interní klinika

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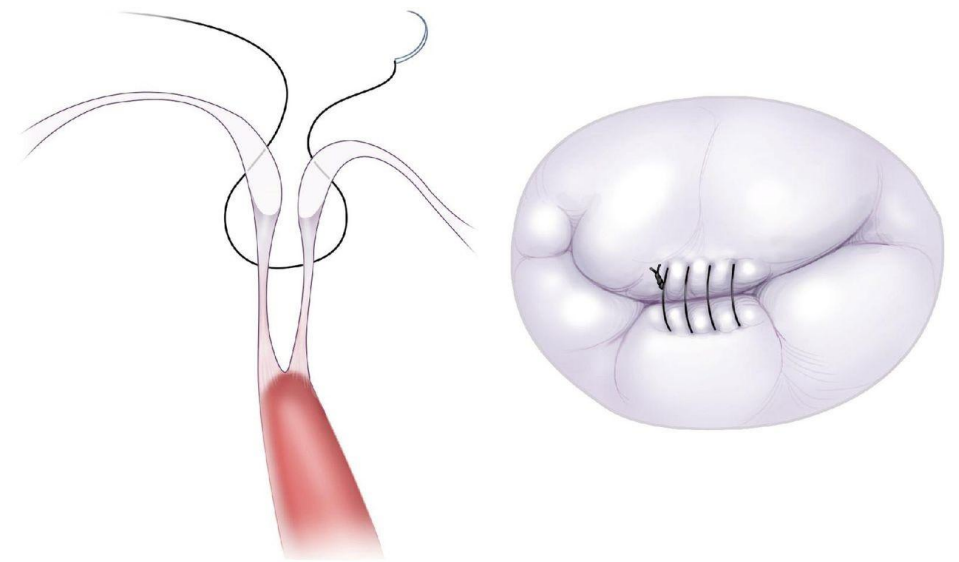
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Katetrizační „edge-to-edge“ plastika mitrální chlopně

„transcatheter edge-to-edge repair (TEER) mitrální chlopně

- vychází z chirurgické techniky Alfieriho spočívající ve vytvoření dvou ústí
- princip katetrizační intervence:
 - transeptální přístup
 - jícnové 3-D ECHO
- největší zkušenosti MitraClip (EVEREST I, EVEREST II, COAPT, MITRA-FR, RESHAPE HF 2)
- menší zkušenosti Pascal (CLASP IID)



O’Gara P et al. JACC 2008

Komplikace TEER mitrální chlopně

Komplikace procedury

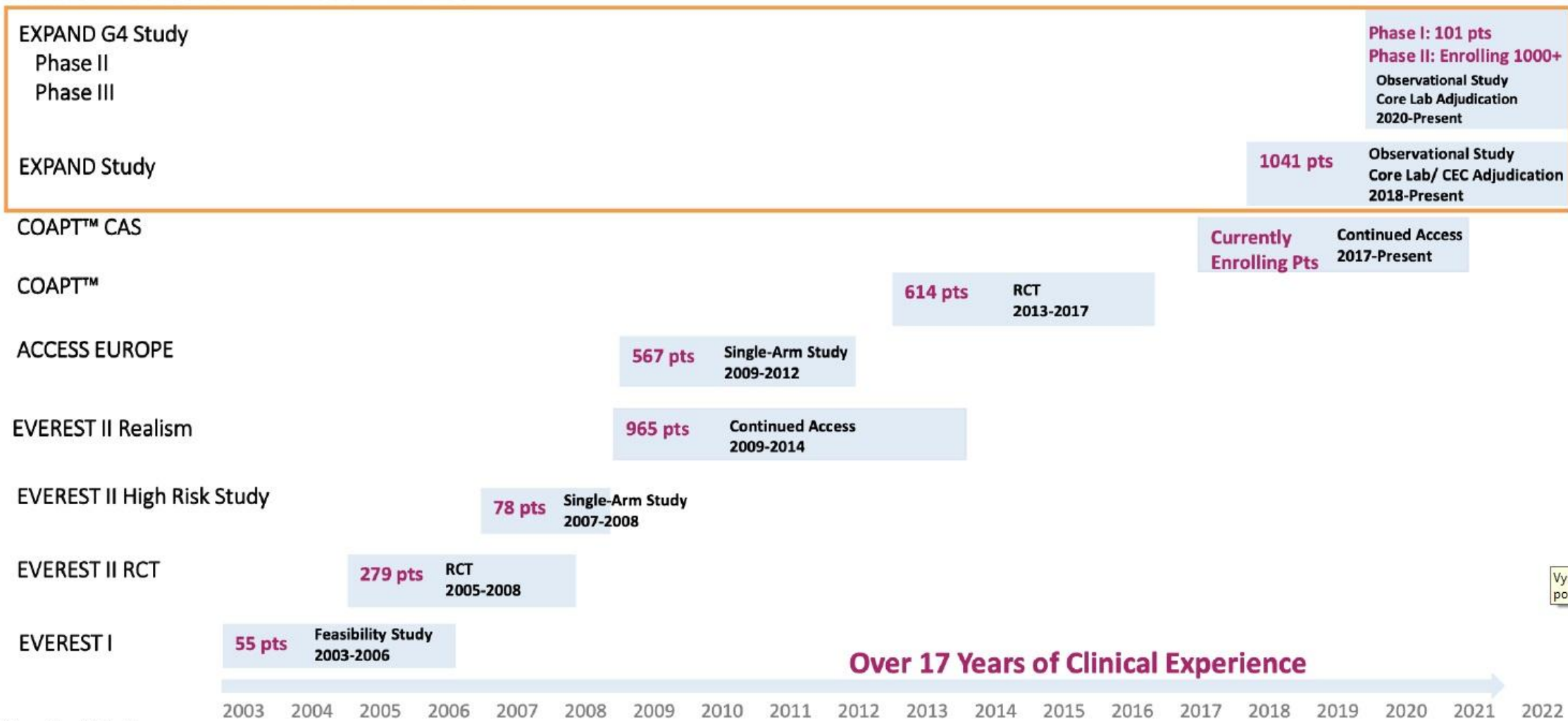
- Úmrtí
- Cévní mozková příhoda
- Tamponáda
- Krvácení do třísla
- Fibrilace síní
- Srdeční selhání
- Komplikace anestézie

Komplikace chytání cípů

- Embolizace klipu
- SLDA („single leaflet device attachment“)
- Stenóza mitrální chlopně
- Perforace cípů
- Ruptura závěsného aparátu
- Rekurence mitrální regurgitace



INCREASING MITRACLIP CLINICAL EXPERIENCE WITH EXPANDED REAL-WORLD EVIDENCE



Vyp pod

Data on file at Abbott.



Goel SS TCT 2022

Komplikace TEER mitrální chlopně

Procedure-related	Access-site vascular	Major vascular complications (significant bleeding, perforation, rupture, dissection)	1.4%-4.0% ¹²⁰
	Cardiac structural damage	Pericardial effusion or tamponade	0%-0.5% ¹²⁰
		Haemodynamically relevant interatrial septal defect	Not consistently defined
	Bleeding	Severe bleeding requiring blood transfusion. Possible bleeding locations: access site, pericardial effusion, gastrointestinal, urinary tract	0%-17% ¹²⁰
	Thromboembolic	Myocardial infarction	0%-3% ¹²⁰
		Stroke	0%-1% ¹²⁰

Category		Complication	Rate (references)
Device-related	Structural failure	Single leaflet device attachment	1.5%-5.1% ^{33,34}
		Device embolisation	0.05%-0.70% ^{33,119}
		Leaflet injury	0%-2% ^{14,15}
	Functional impairment	Residual MR >2+	3.4%-17.0% ^{14,15}
		Transmitral gradient >5 mmHg	Up to 15% ¹⁵



Komplikace TEER mitrální chlopně

30 Day Adverse Events

	EXPAND G4 (N=529)	EXPAND ¹ (N=1041)	TVT Registry ² (N=2,952)	ACCESS-EU ³ (N=567)
All-cause Death	1.5% (7)	2.3% (24)	5.2% (96)	3.4% (19)
Myocardial Infarction	0.0% (0)	0.0% (0)	0.2% (3)	0.7% (4)
Stroke	0.0% (0)	1.2% (8)	1.0% (17)	0.7% (4)
Ischemic	0.0% (0)	1.0% (6)	0.6% (11)	NA
Non-elective CV surgery for device related complication	0.8% (4)	1.1% (11)	NA	NA
Leaflet Adverse Events*	1.1% (6)	2.0% (20)	1.5% (17)	4.8% (28)
SLDA	1.1% (6)	1.7% (18)	1.5% (4)	4.8% (28)

*Single leaflet device attachment (SLDA), leaflet injury events in the EXPAND G4 study were adjudicated by the echo core lab based on procedural and follow up images.







Komplexnost postižení a zkušenost centra u TEER

Repair!		Centre experience	
Anatomical suitability for M-TEER		Replacement?	
Non-complex Ideal for M-TEER	Complex Suitable for M-TEER	Very complex Challenging for M-TEER	Criteria favouring replacement M-TEER hard or impossible
<ul style="list-style-type: none"> - Central pathology - No calcification - MVA >4.0 cm² - Posterior leaflet >10 mm - Tenting height <10 mm - Flail gap <10 mm - Flail width <15 mm 	<ul style="list-style-type: none"> - Isolated commissural lesion (A1/P1 or A3/P3) - Annular calcification without leaflet involvement - MVA 3.5-4.0 cm² - Posterior leaflet length 7-10 mm - Tenting height >10 mm - Asymmetric tethering²⁶ - Coaptation reserve <3 mm²⁴ - Leaflet-to-anulus index <1.2²⁵ - Flail width >15 mm - Flail gap >10 mm - Two jets from leaflet indentations 	<ul style="list-style-type: none"> - Commissural lesion with multiple jets - Annular calcification with leaflet involvement - Fibrotic leaflets - Wide jet involving the whole coaptation - MVA 3.0-3.5 cm² - Posterior leaflet length 5-7 mm - Barlow's disease - Cleft - Failed surgical annuloplasty 	<ul style="list-style-type: none"> - Concentric MAC with stenosis - MVA <3.0 cm² - Relevant mitral valve stenosis (mean gradient >5 mmHg) - Posterior leaflet <5 mm - Calcification in the grasping zone - Deep regurgitant cleft - Leaflet perforation - Multiple/wide jets - Rheumatic mitral stenosis



TEER mitrální chlopně

	MitraClip (4 th -generation)	PASCAL Precision (2 nd -generation)
Delivery catheter		
Available implants	 NT NTW XT XTW	 P10 ACE
Device material	Rigid arms of cobalt-chromium alloy	Flexible arms of nitinol
Central spacer	No	Yes
Optional independent grasping	Yes	Yes
Closure mechanism	Active (locking element)	Passive (nitinol shape memory)
Number of working catheters	2	3
Orientation of hooks/friction elements	Longitudinal	Horizontal
Continuous LA pressure	Yes	Yes
Overall system stability	High	Improved with PASCAL Precision

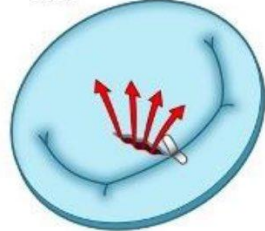
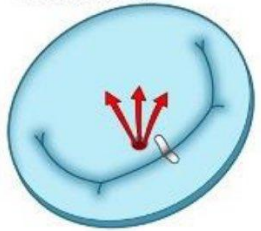
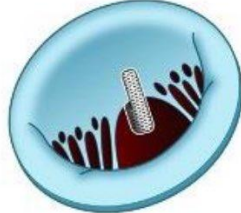
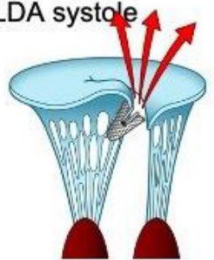
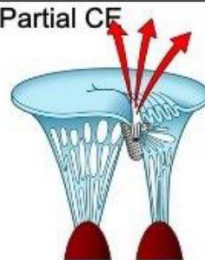
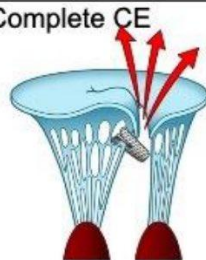
Komplikace chytání cípů

Embolizace klipu a SLDA

- se projeví nejčastěji ihned na sále nebo během 24h od výkonu
- pozdní případy jsou vzácné

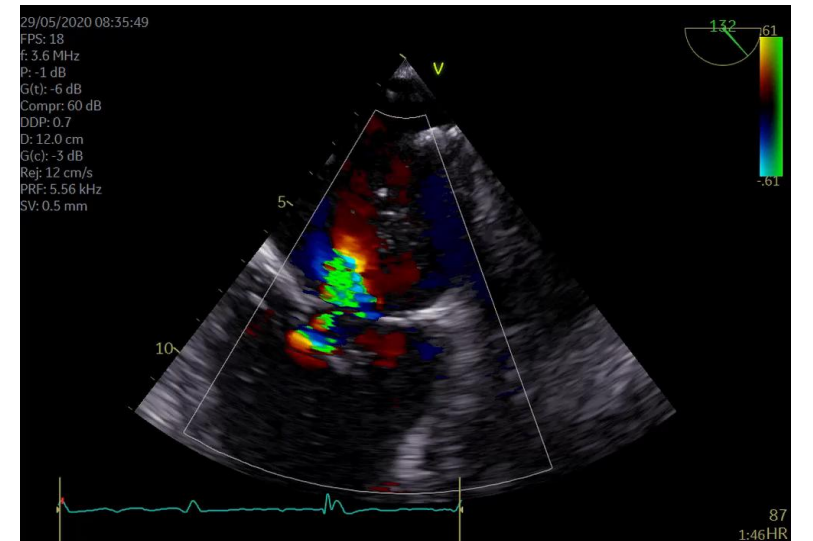
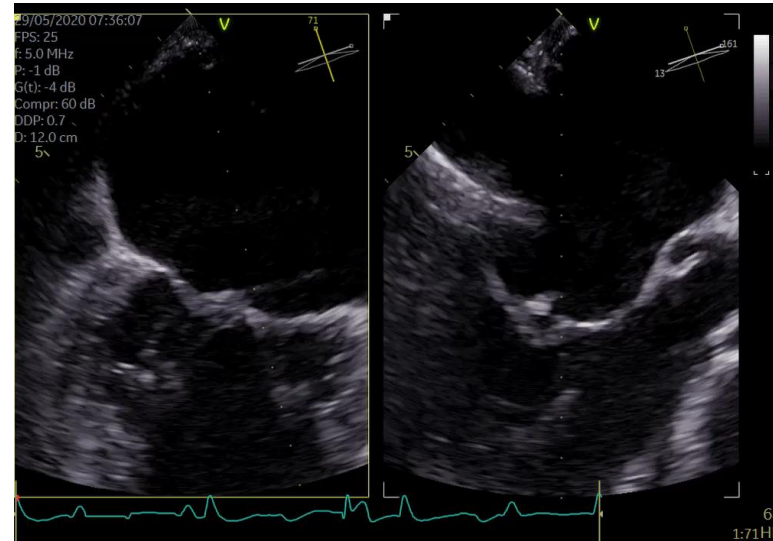
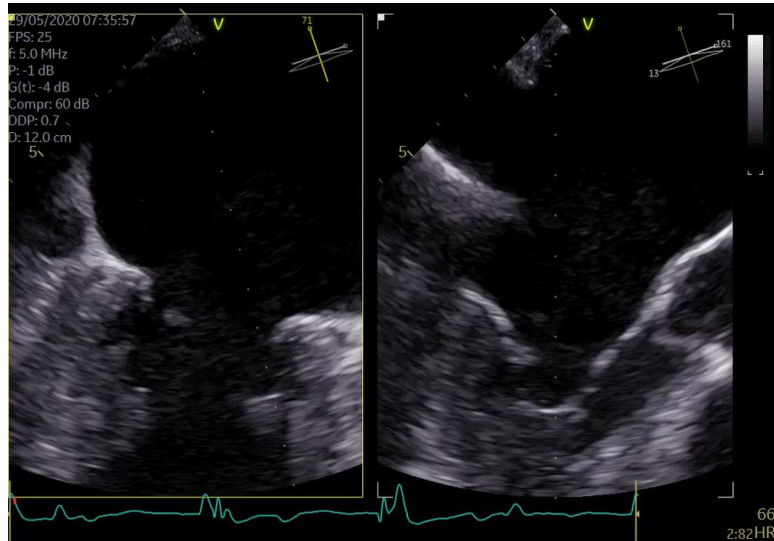
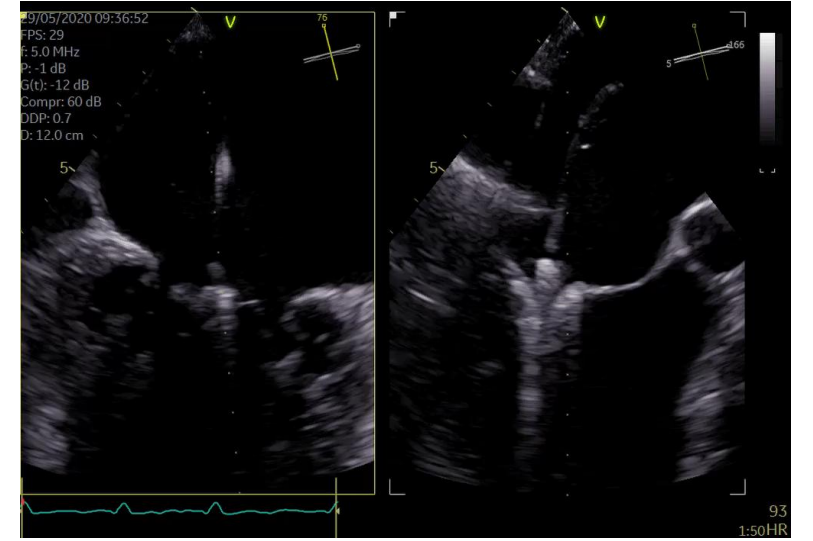
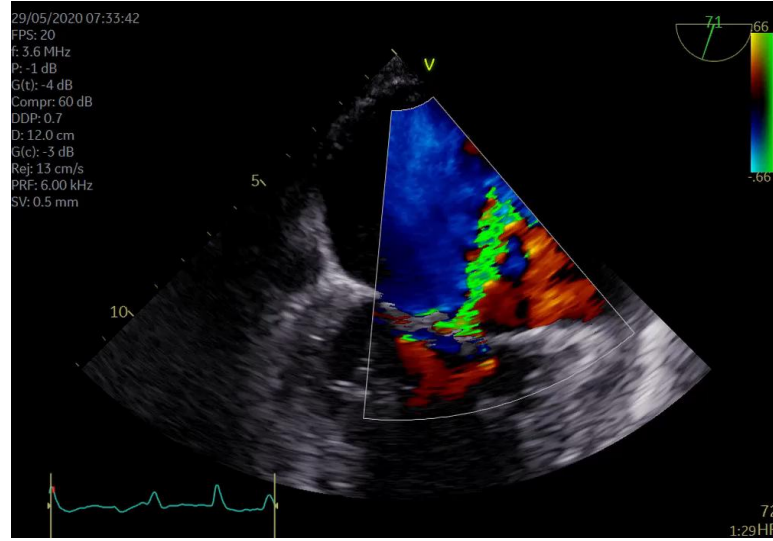
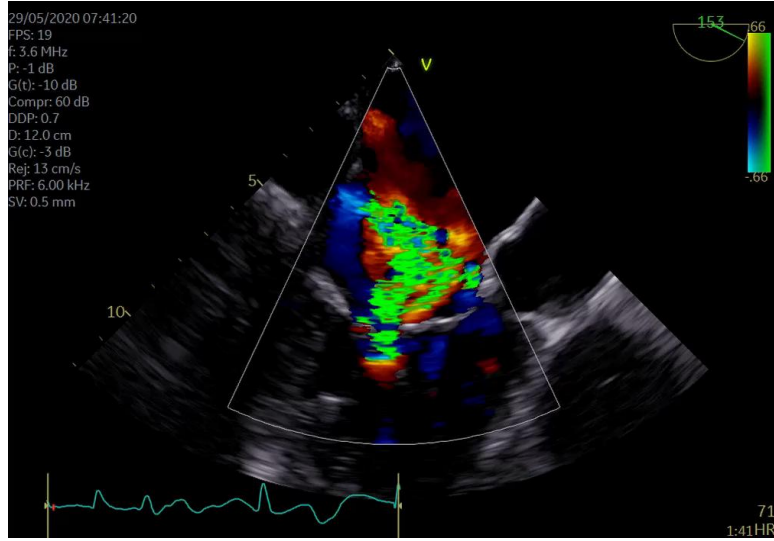
Poškození cípů chlopně

- natrhnutí a perforace cípů nebo chordal entrapment se projeví ihned na sále
- pozdější výskyt je extrémně vzácný

Leaflet Injury	Tear	Disruption of leaflet integrity reaching the leaflet edge		
	Perforation	Disruption of leaflet integrity NOT reaching the leaflet edge.		
	Shape distortion	Shape distortion affecting leaflet coaptation, without disruption of the leaflet integrity. Examples include, but are not limited to, leaflet folding, tension/pin-wheeling, etc.		
Single Leaflet Device Attachment (SLDA)*	Criteria 1	Confirmation of complete SLDA at surgery or autopsy.		
	Criteria 2	Echocardiographic or fluoroscopic demonstration of complete separation of device and a single leaflet tissue.		
	Criteria 3	3.1 - Failure to demonstrate diastolic tissue bridge. 3.2 - Color Doppler demonstration of significant MR through the device/leaflet interface. 3.3 - New excessive leaflet mobility following device deployment		
Chordal Entrapment (CE)	Partial leaflet insertion and/or chordal rupture	Only one clip arm gripping chordae.		
	Complete Entrapment	Both clip arms tangled/gripping chordae		

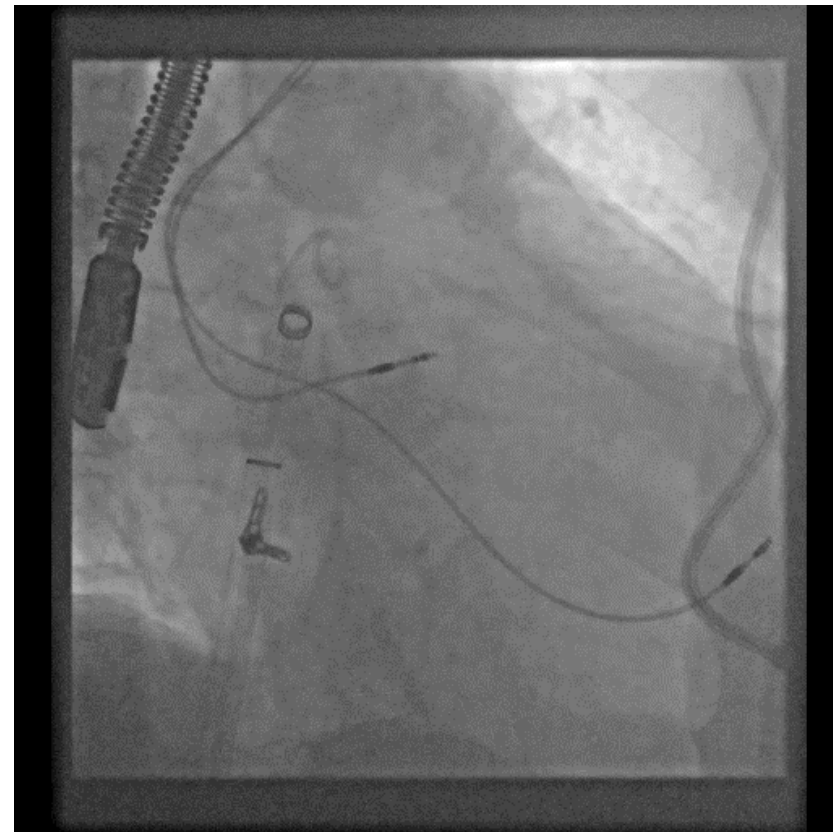
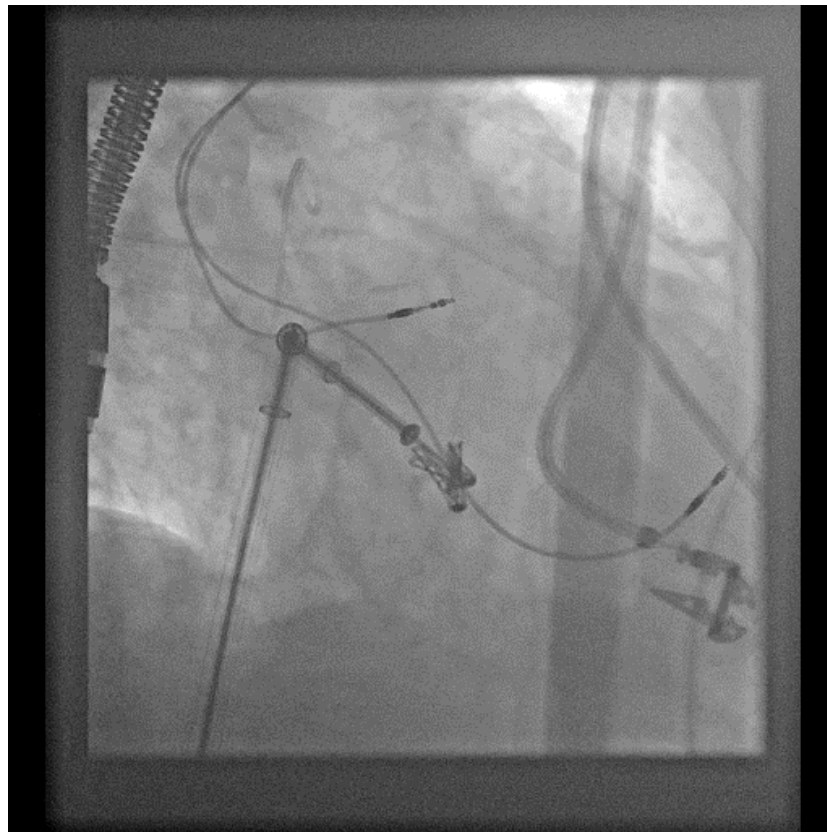
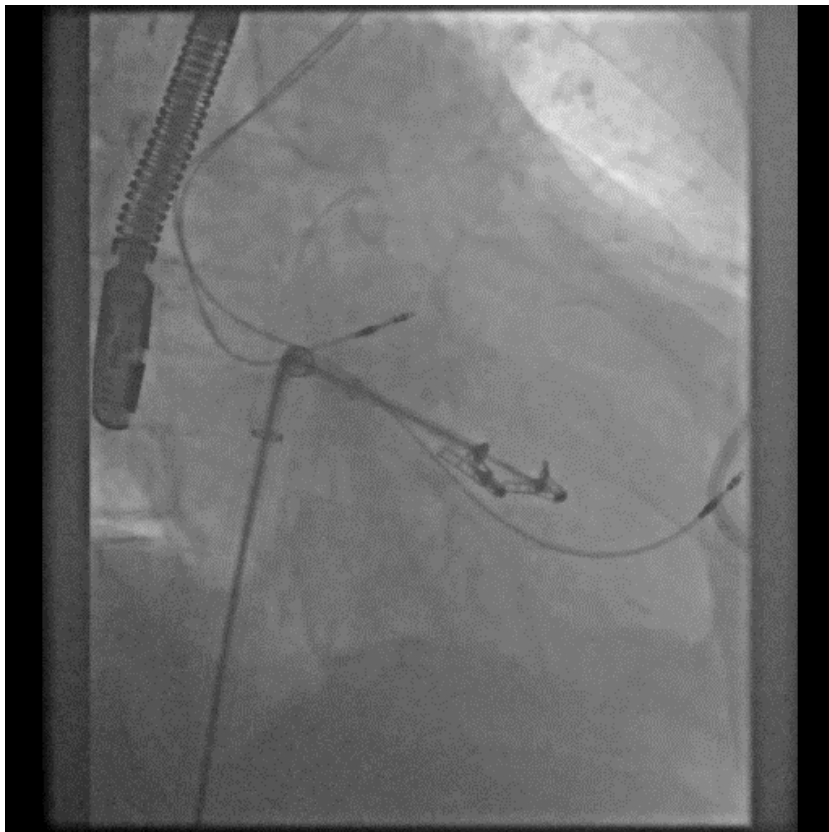
*
 - Definite SLDA: Fulfillment of criteria 1 or 2 or 3 (all 3.1, 3.2 and 3.3)
 - Likely SLDA: Partial fulfillment of criteria 3. Criteria 3.1 must be met, with either 3.2 or 3.3 (not both).
 - Unconfirmed SLDA: Failure to meet criteria for Definite or Likely SLDA.

Embolizace klipu



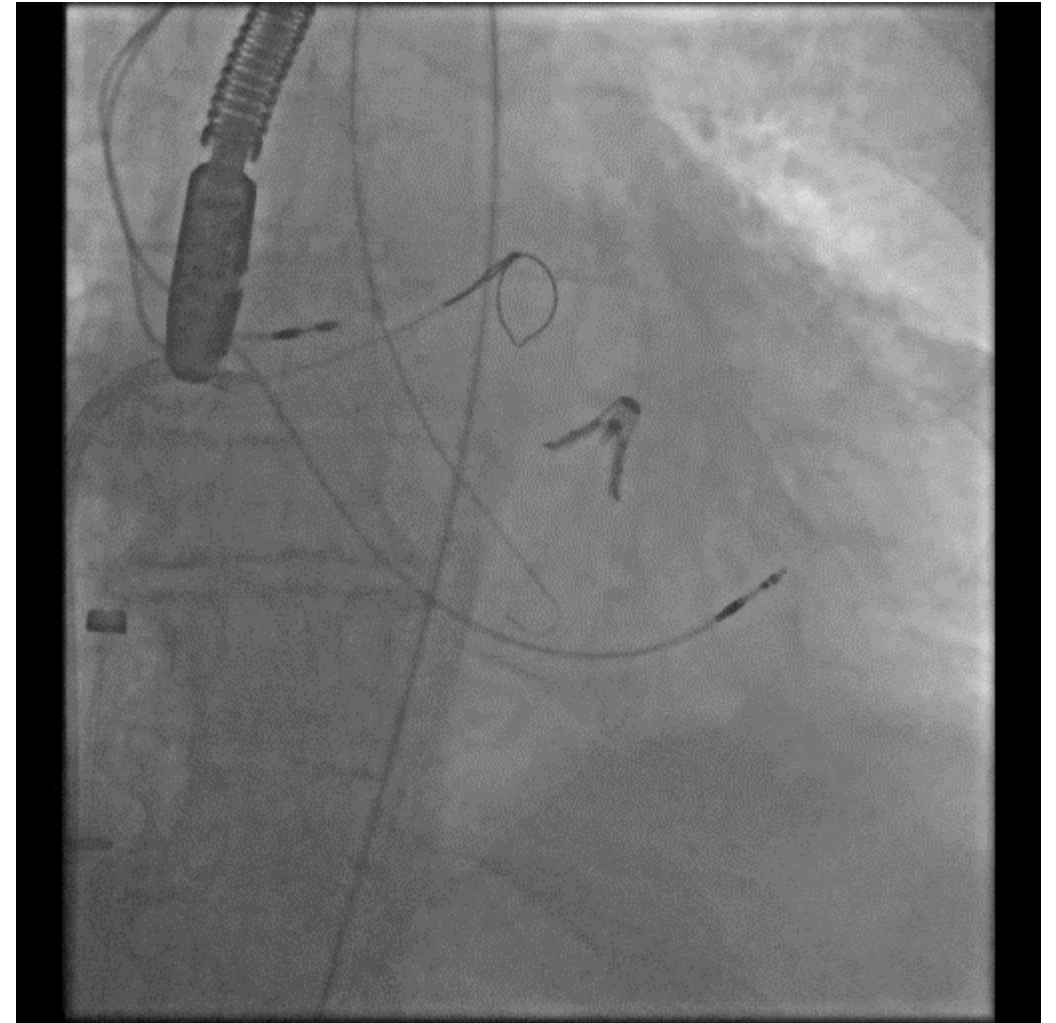
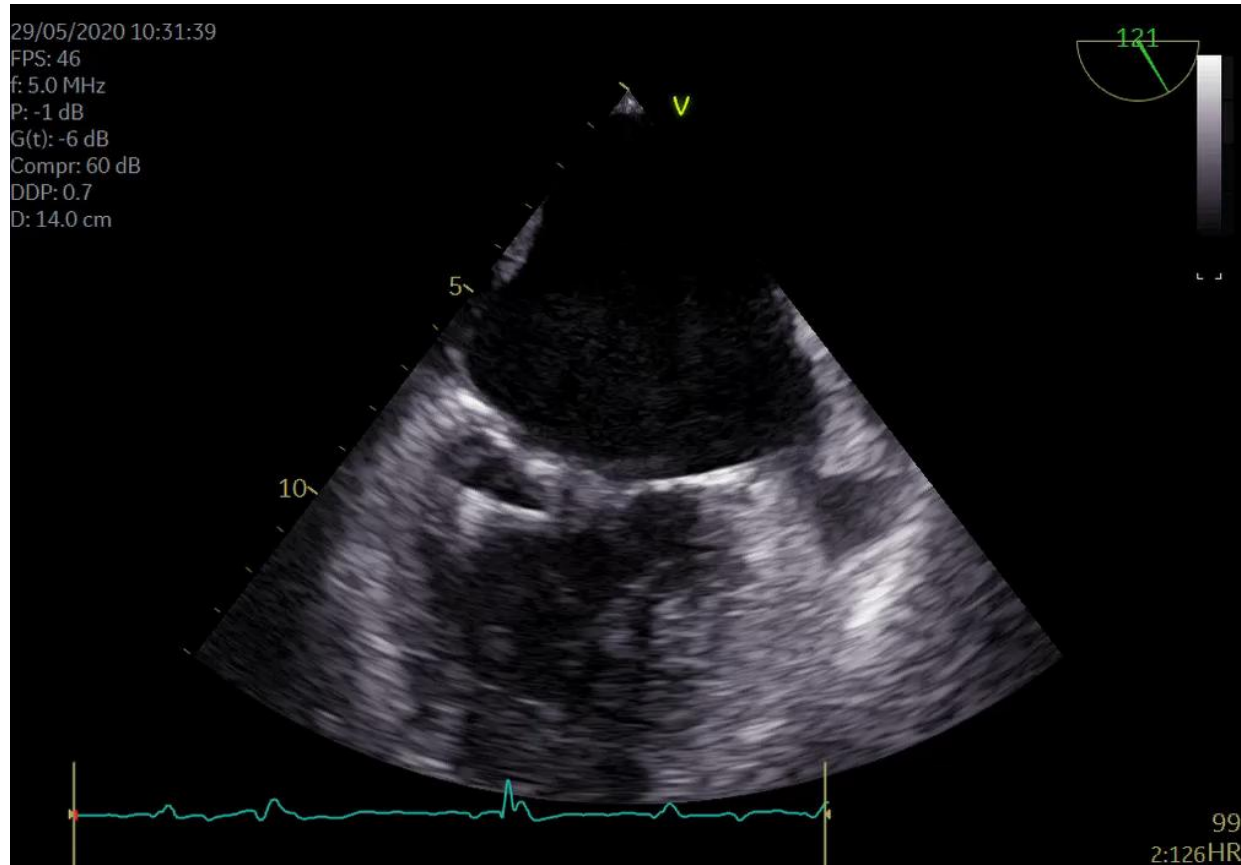
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Embolizace klipu



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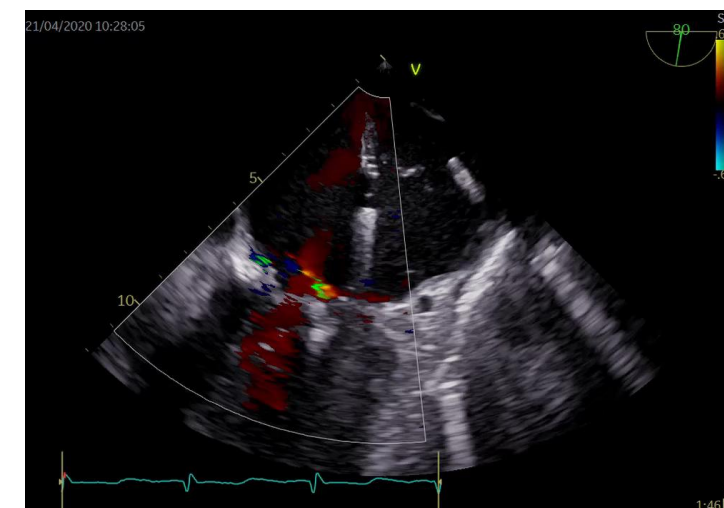
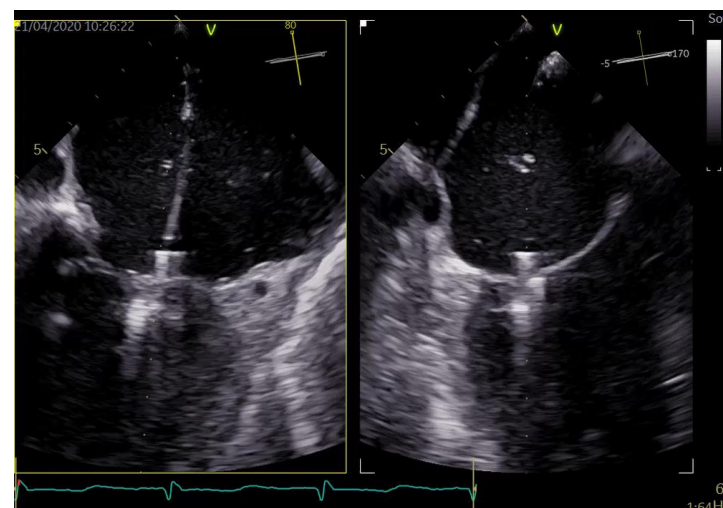
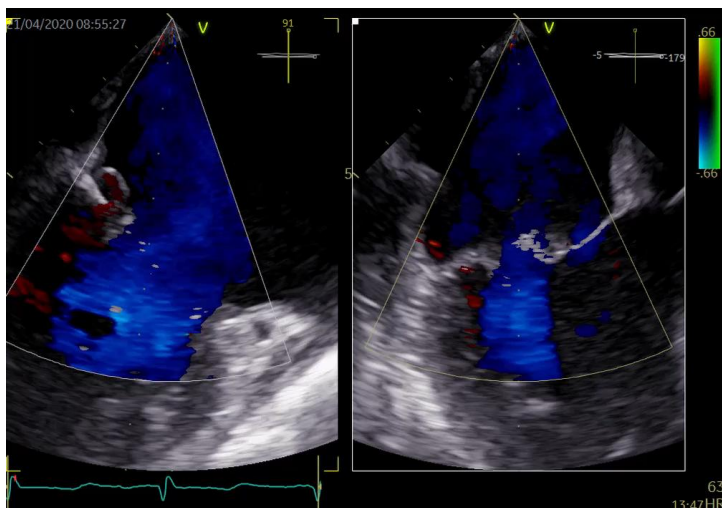
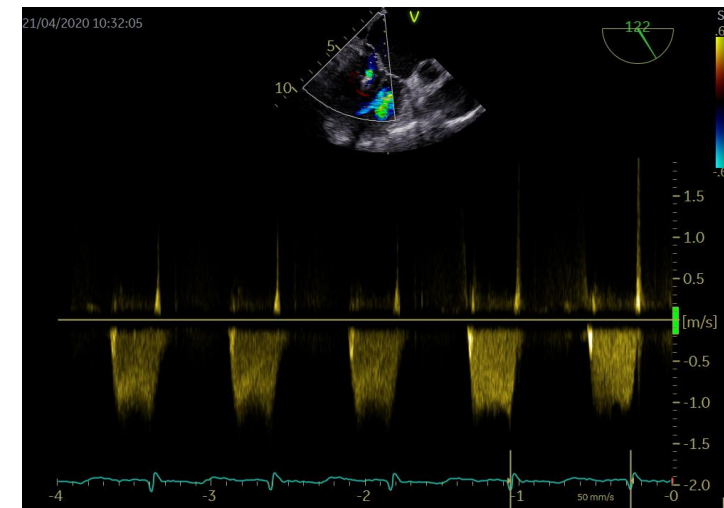
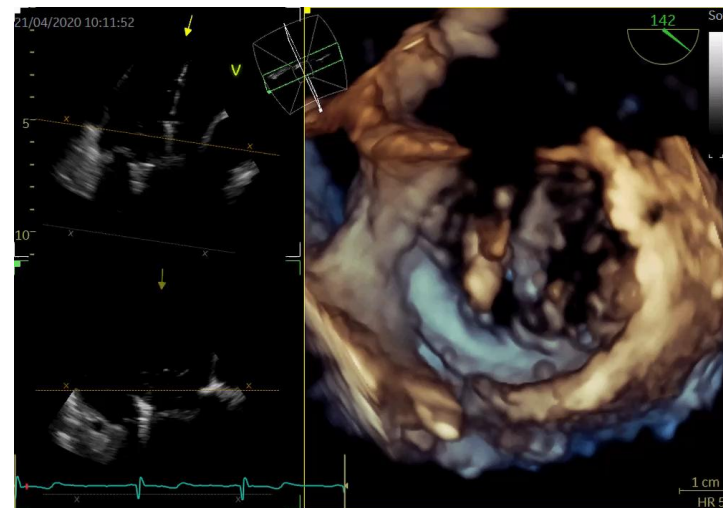
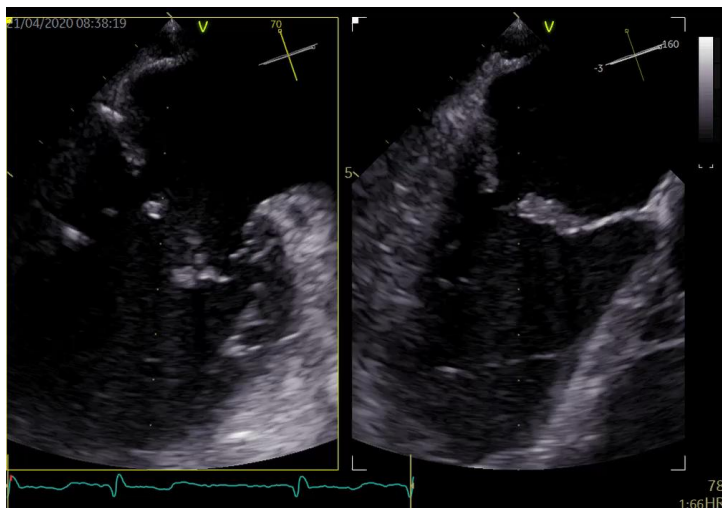
Embolizace klipu



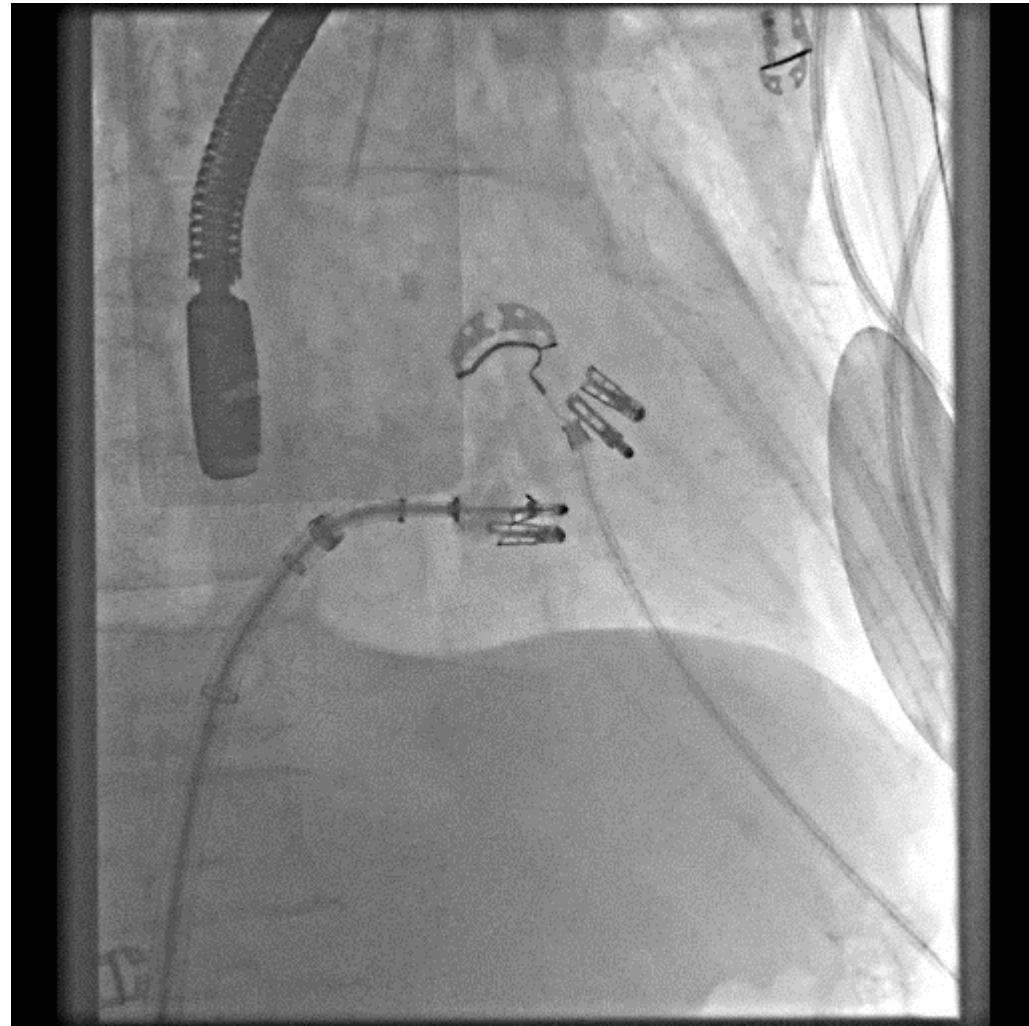
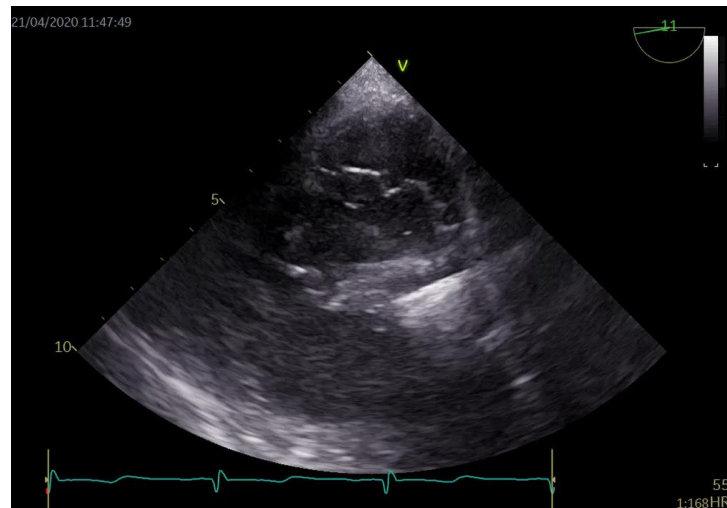
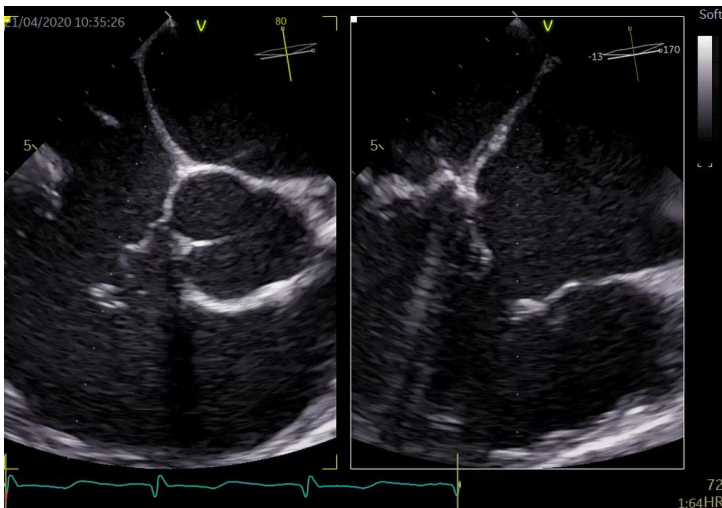
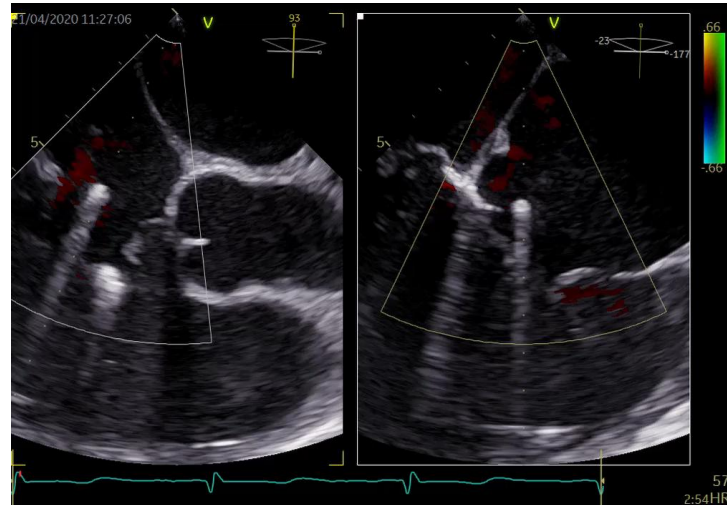
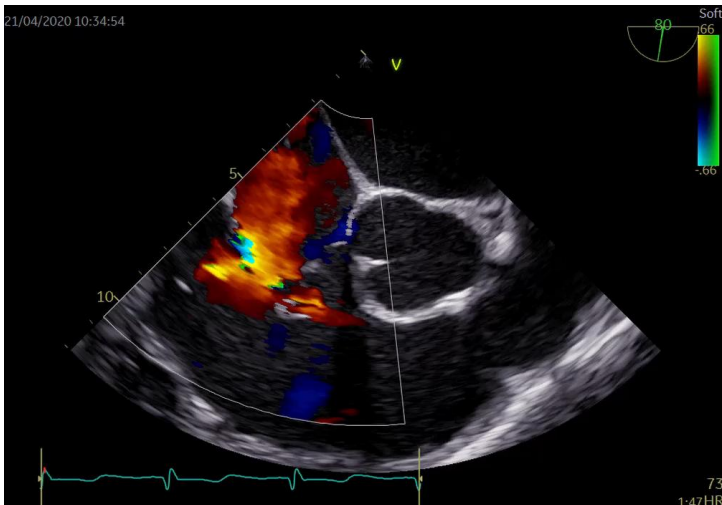
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SLDA – TEER mitrální a trikuspidální chlopně

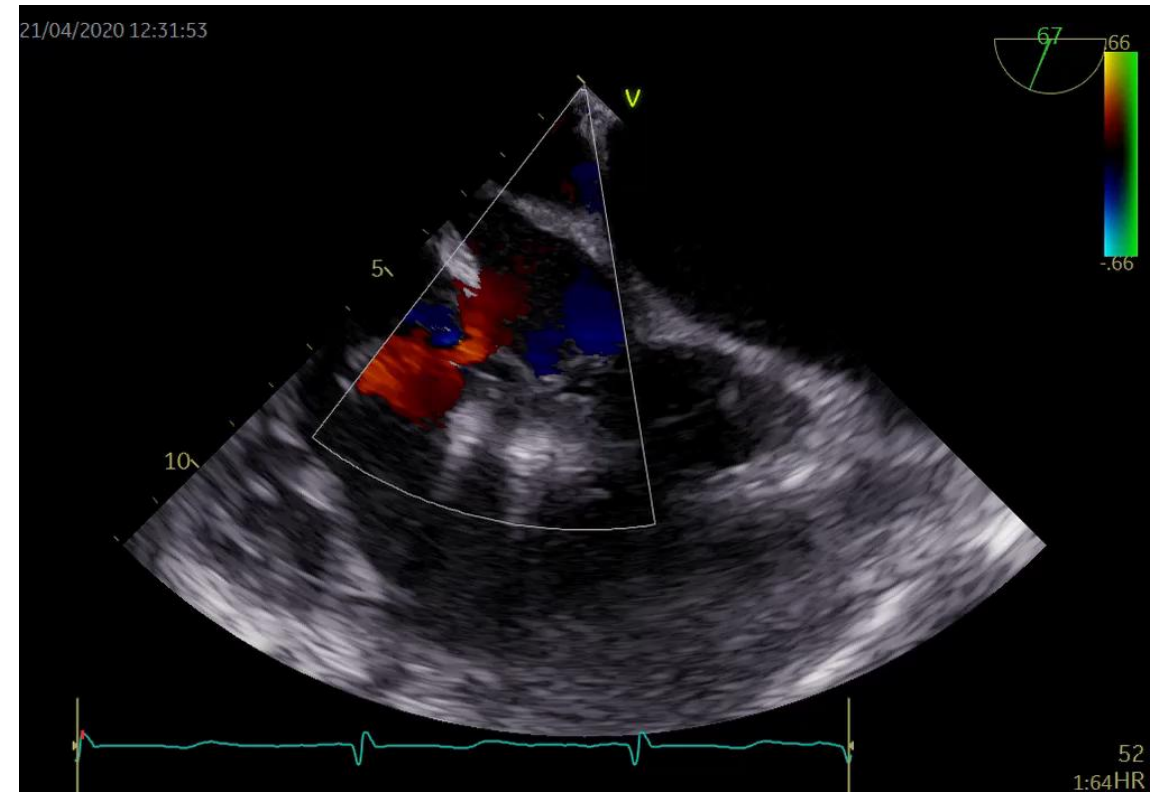
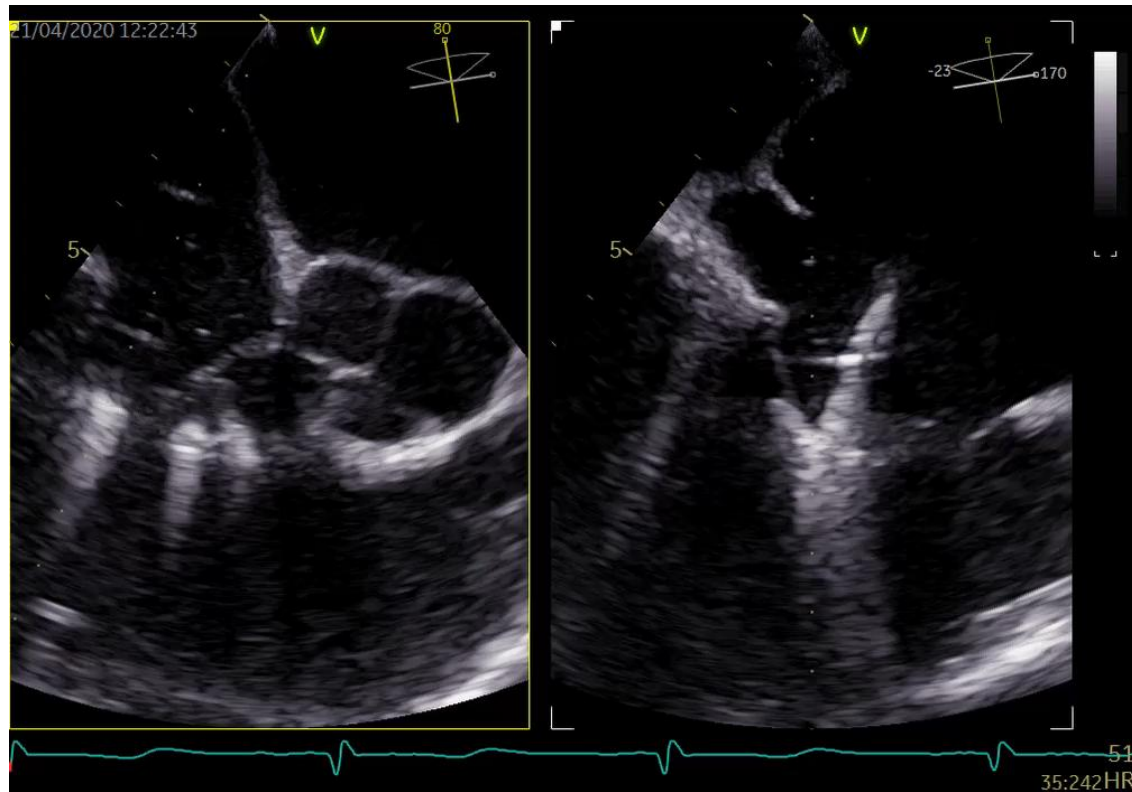


SLDA trikuspidální TEER



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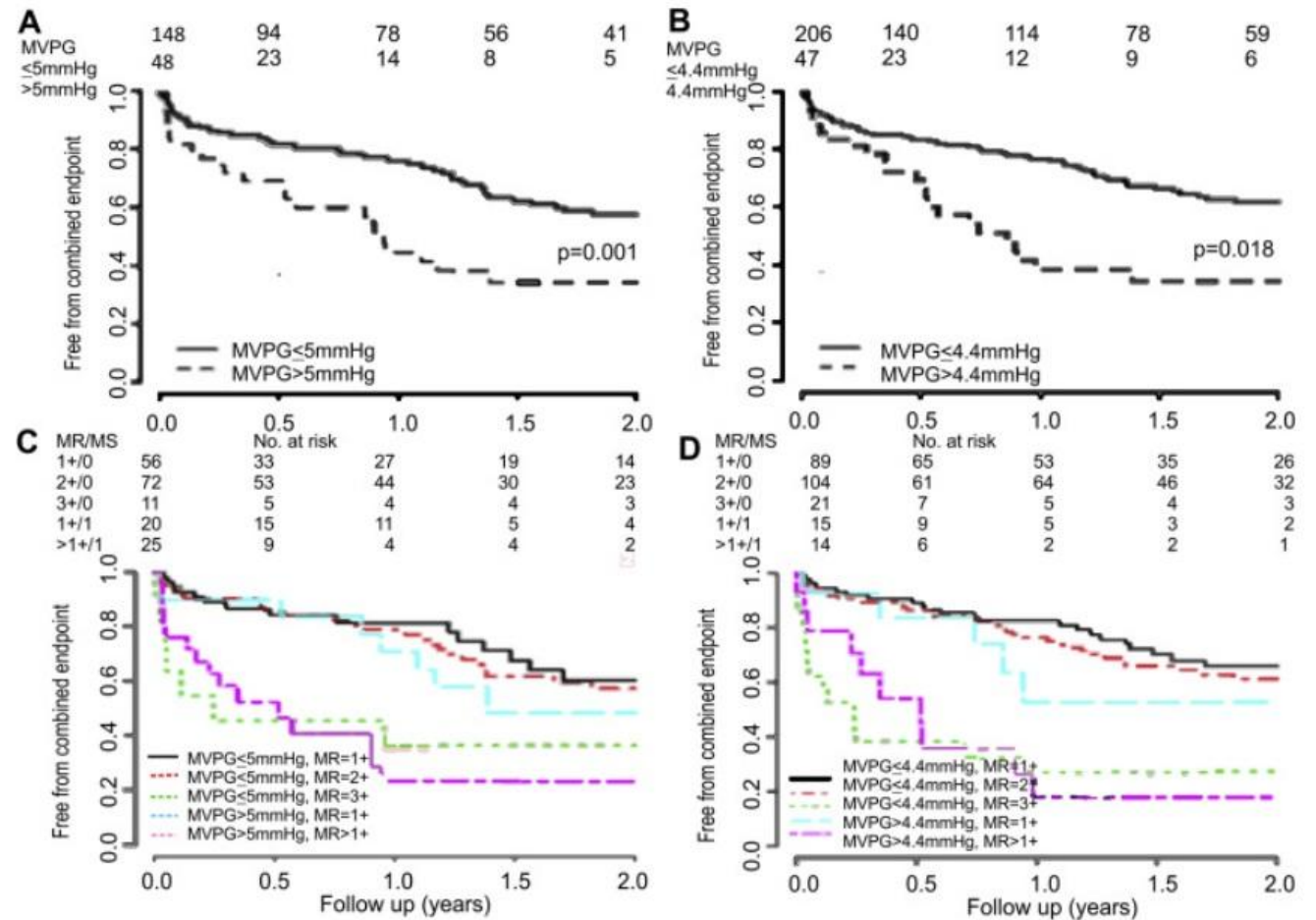
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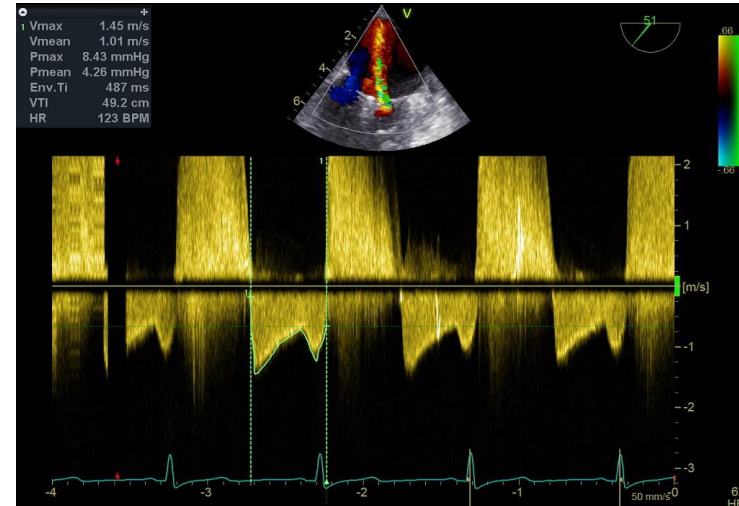
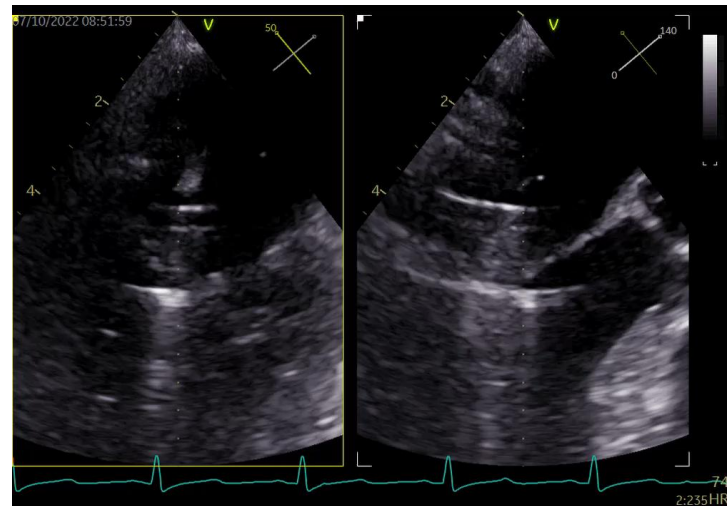
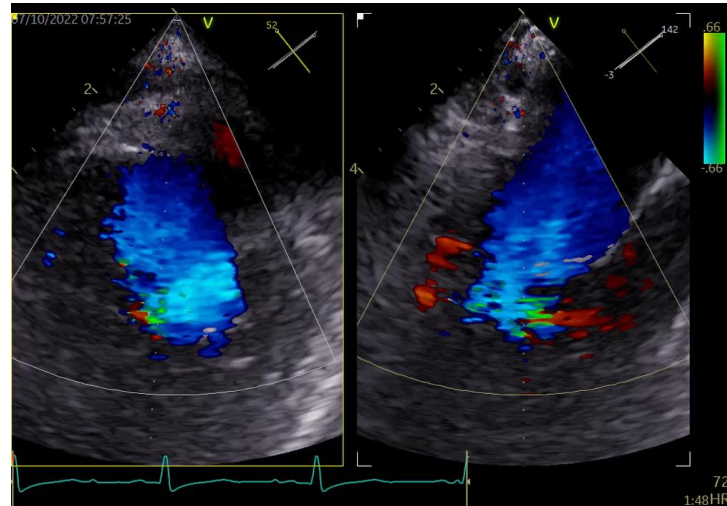
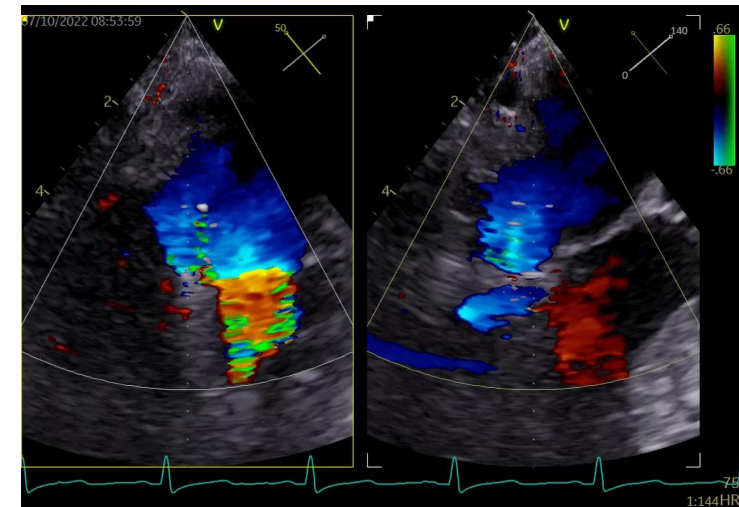
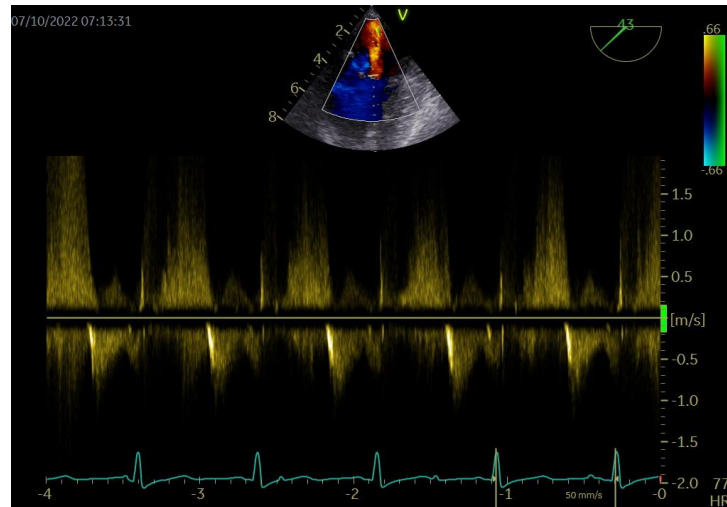
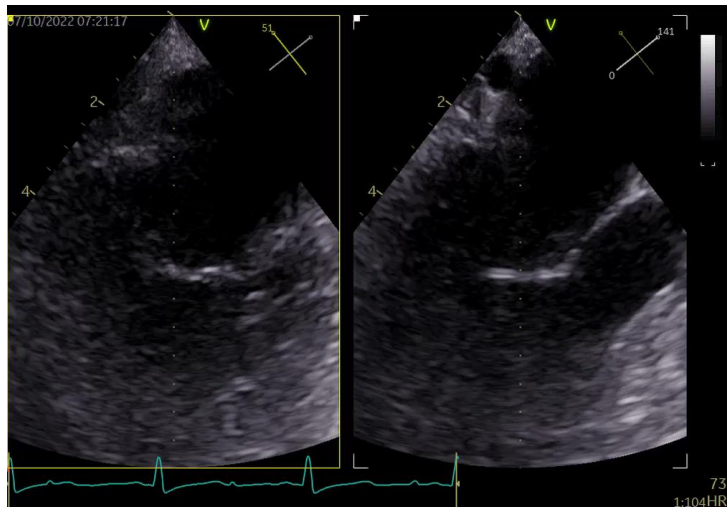
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Mitrální stenóza nebo regurgitace?

- Existuje jednoznačná klinická evidence, že reziduální regurgitace má dopad na prognózu
- Použití více klipů může vést ke ↓ výsledné regurgitace
- Mezi počtem klipů a reziduální plochou mitrálního ústí existuje přímá úměra



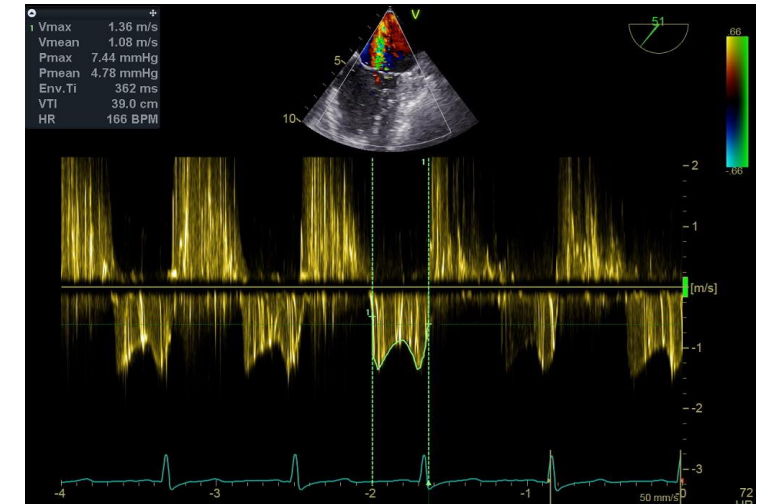
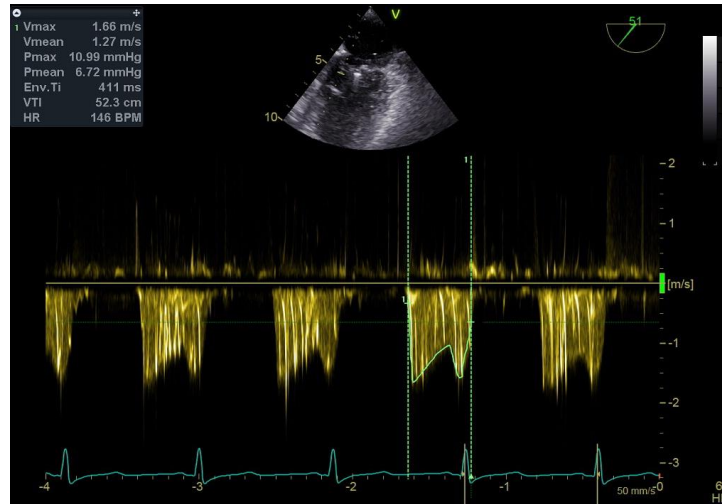
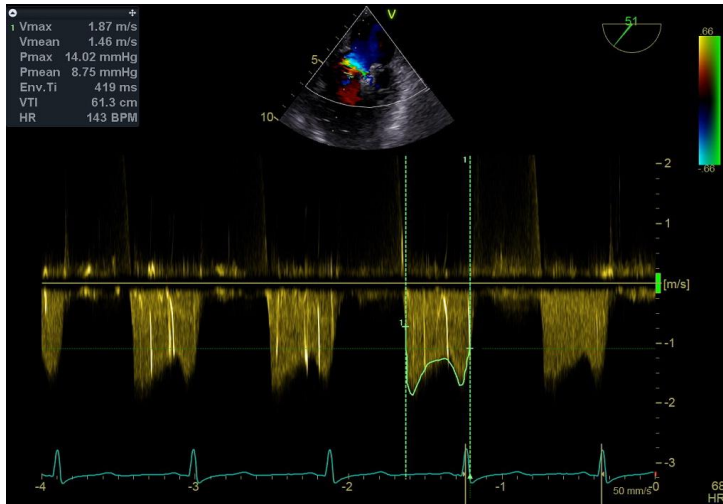
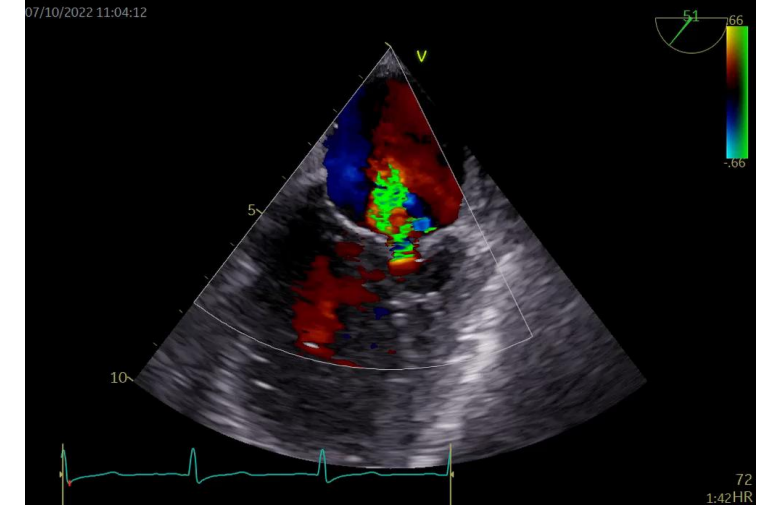
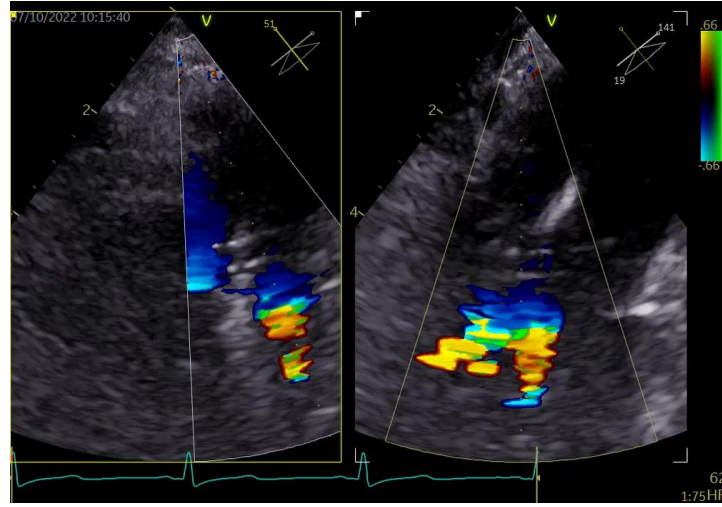
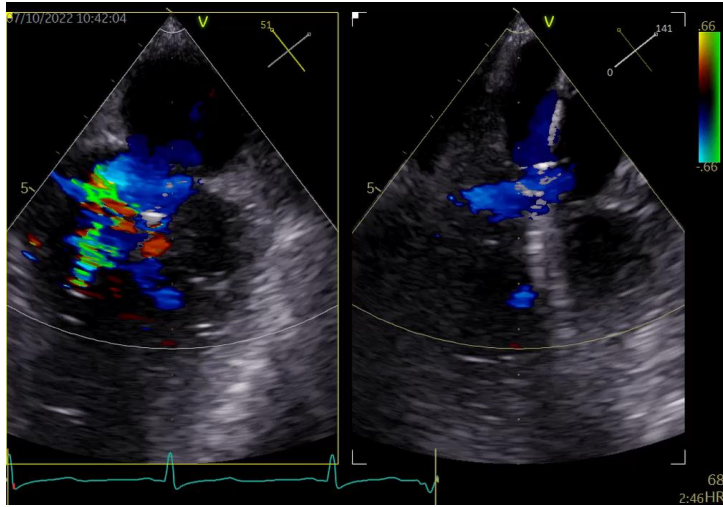
Mitrální stenóza nebo regurgitace?



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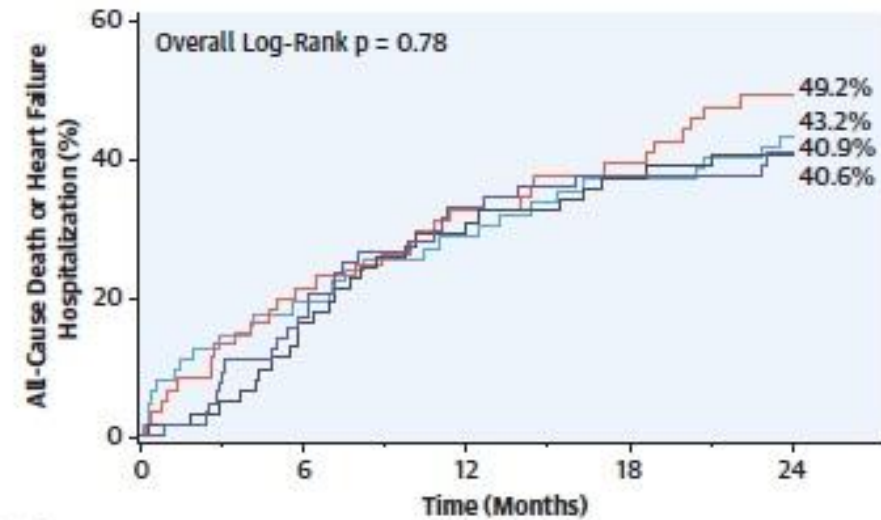
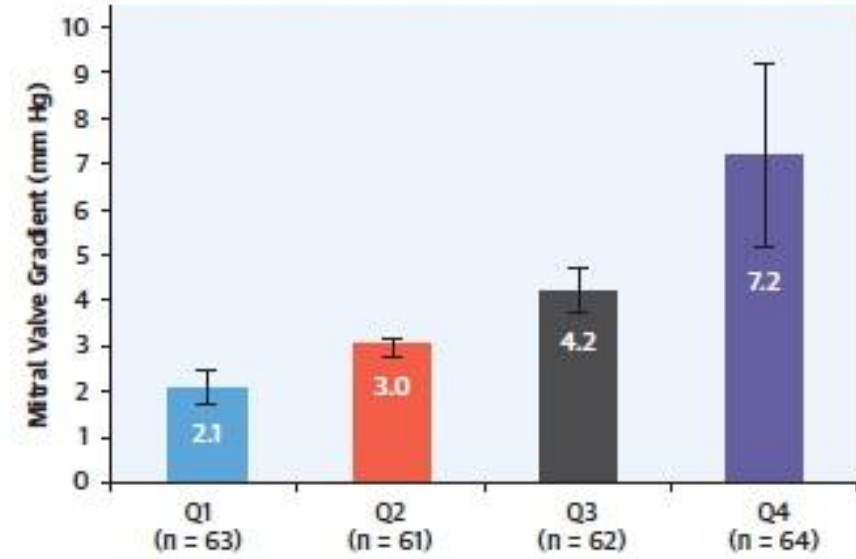
Mitrální stenóza nebo regurgitace?



Nebo to neplatí?

	Quartile 1 (n = 63)	Quartile 2 (n = 61)	Quartile 3 (n = 62)	Quartile 4 (n = 64)	Overall p Value
Procedural characteristics					
Average number of MitraClips implanted	1.7 ± 0.6	1.5 ± 0.6	1.8 ± 0.7	1.8 ± 0.7	0.04
None	1.6 (1/63)	0.0 (0/61)	0.0 (0/62)	1.6 (1/64)	0.58
1 clip	34.9 (22/63)	52.5 (32/61)	33.9 (21/62)	29.7 (19/64)	0.05
2 clips	57.1 (36/63)	44.3 (27/61)	51.6 (32/62)	57.8 (37/64)	0.40
3 clips	6.3 (4/63)	3.3 (2/61)	14.5 (9/62)	10.9 (7/64)	0.13
Echocardiographic measures on discharge					
Mitral regurgitation					
None, 0	3.4 (2/59)	0.0 (0/61)	1.6 (1/62)	0.0 (0/62)	0.28
Mild, 1+	83.1 (49/59)	83.6 (51/61)	79.0 (49/62)	83.9 (52/62)	0.88
Moderate, 2+	10.2 (6/59)	13.1 (8/61)	14.5 (9/62)	12.9 (8/62)	0.91
Moderate to severe, 3+	1.7 (1/59)	1.6 (1/61)	4.8 (3/62)	1.6 (1/62)	0.58
Severe, 4+	1.7 (1/59)	1.6 (1/61)	0.0 (0/62)	1.6 (1/62)	0.79
Moderate or less, ≤2+	96.6 (57/59)	96.7 (59/61)	95.2 (59/62)	96.8 (60/62)	0.96
Left ventricular ejection fraction	25.9 ± 9.4	27.6 ± 9.6	26.2 ± 7.8	30.0 ± 7.8	0.08

Mean Mitral Valve Gradient by Quartiles



No. at risk:

Time (Months)	0	6	12	18	24
Quartile 1	63	51	44	39	34
Quartile 2	61	48	41	37	30
Quartile 3	62	52	43	38	34
Quartile 4	64	53	43	40	32

Halaby R et al. JACC Cardiovasc Interv 2021



Take home message

- TEER mitrální chlopně je klinicky ověřený a zavedený postup léčby mitrální regurgitace s nízkým výskytem závažných komplikací (úmrtí, CMP ~ 1%)
- Technické selhání (embolizace klipu, SLDA, MR 3+ a více) je přítomná u přibližně 5 %
- Výskyt technických komplikací závisí na selekci pacientů, zkušenosti centra a typu zvoleného klipu pro určitou situaci

