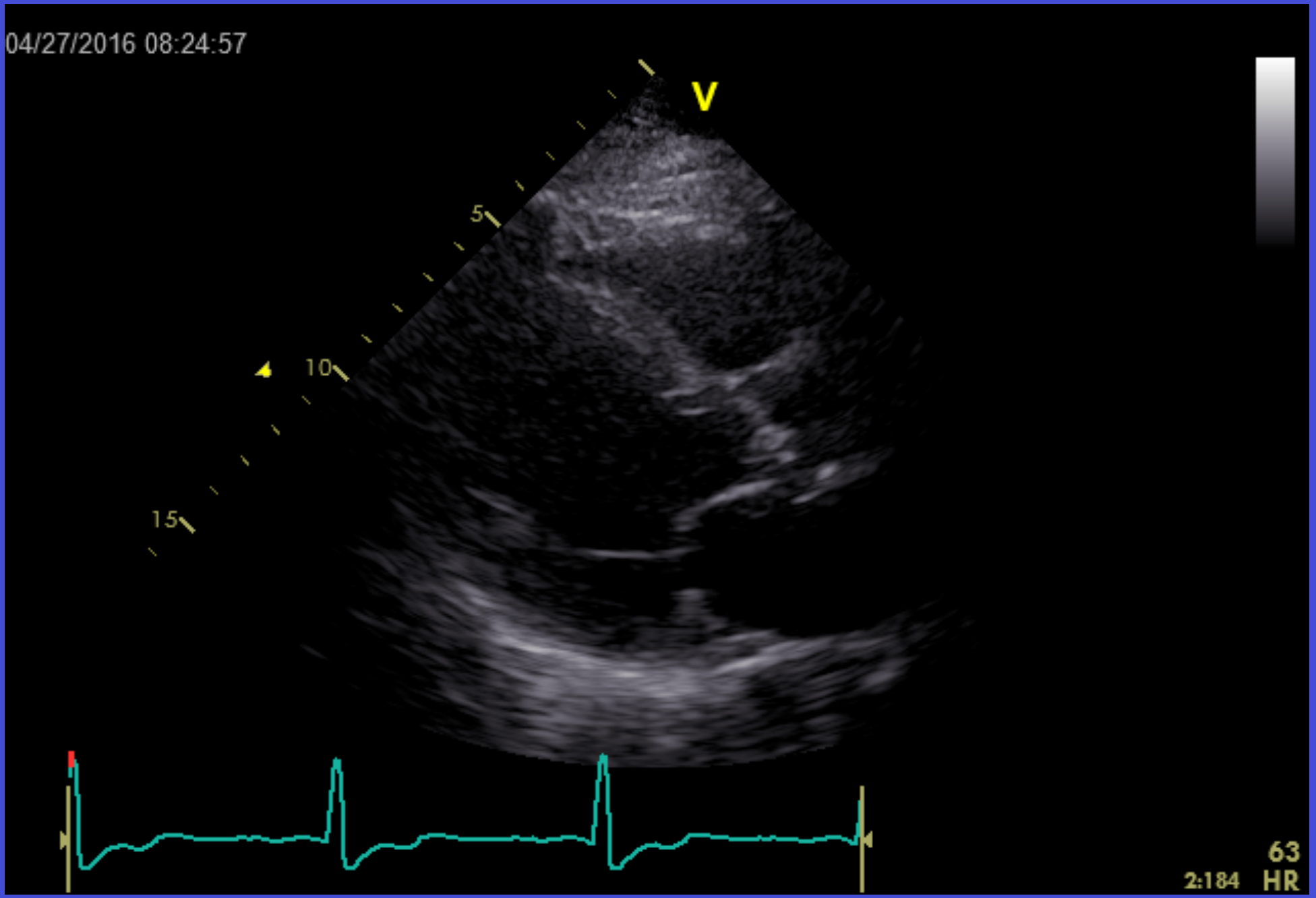
Case Presentation

-75-year old woman with HTN, HLD, DM, overweight, breast cancer (surgery and XRT) and aortic valve stenosis

-Worsening exertional dyspnea on most recent clinic visit. No CP or syncope

- Murmur late peaking with soft S2 and parvus et tardus on physical exam

-Serial echoes 1/2010 AVA 1.3cm2
4/2014 AVA 1.1cm2
4/2016 AVA 0.5cm2, mean grad 55mmHg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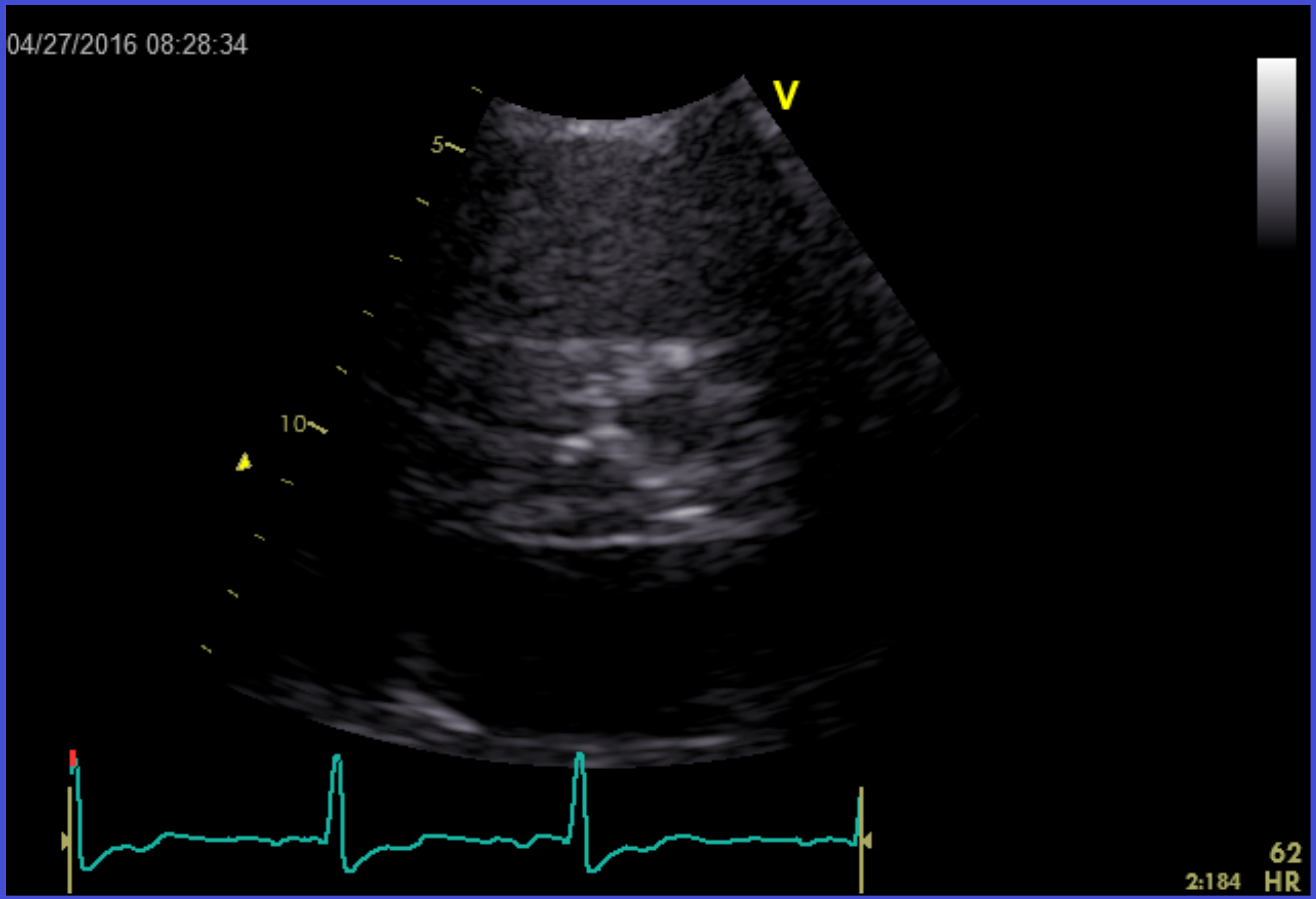
V
5
10
15
63
2:184
HR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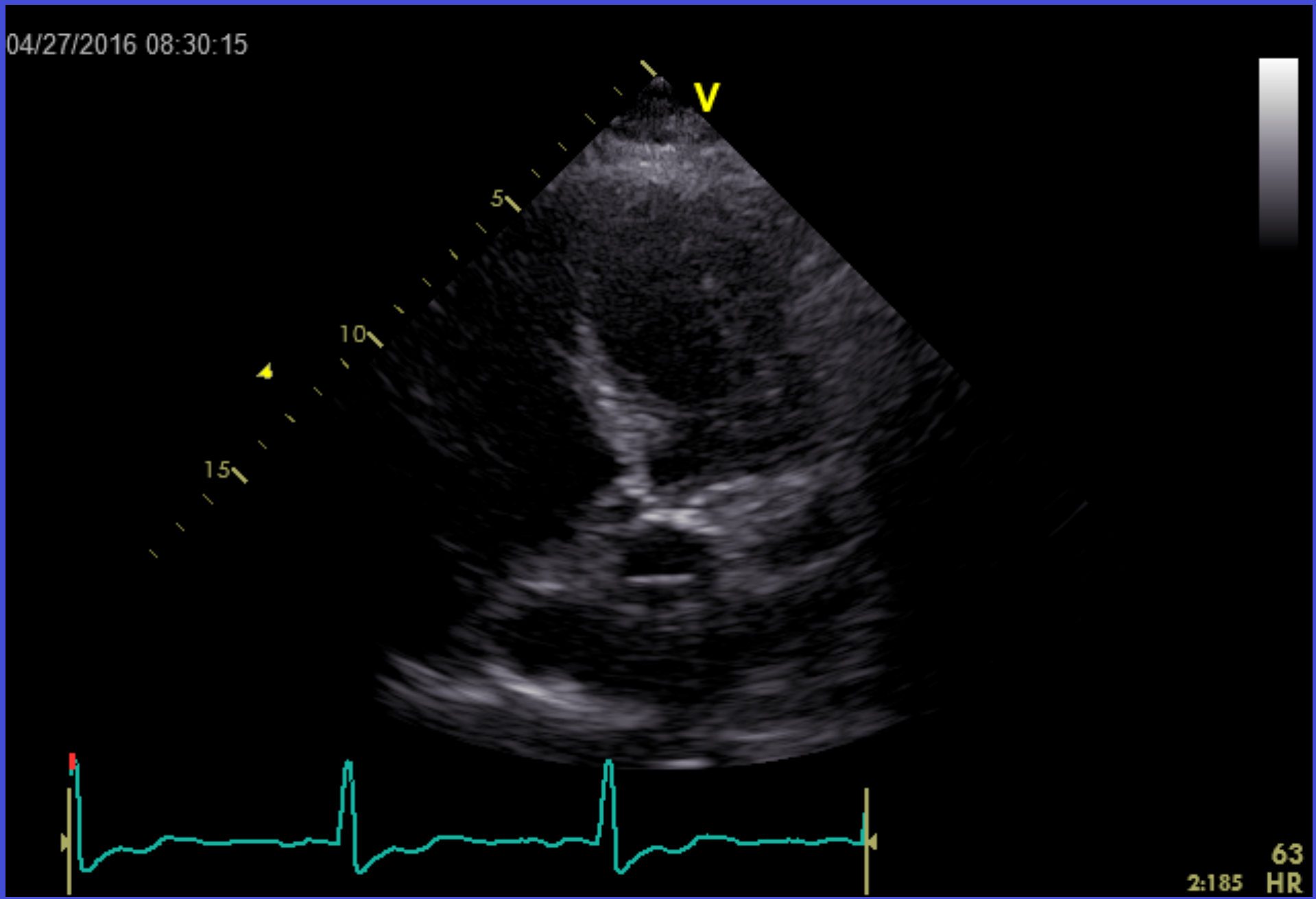
V
5
10
62
2:184 HR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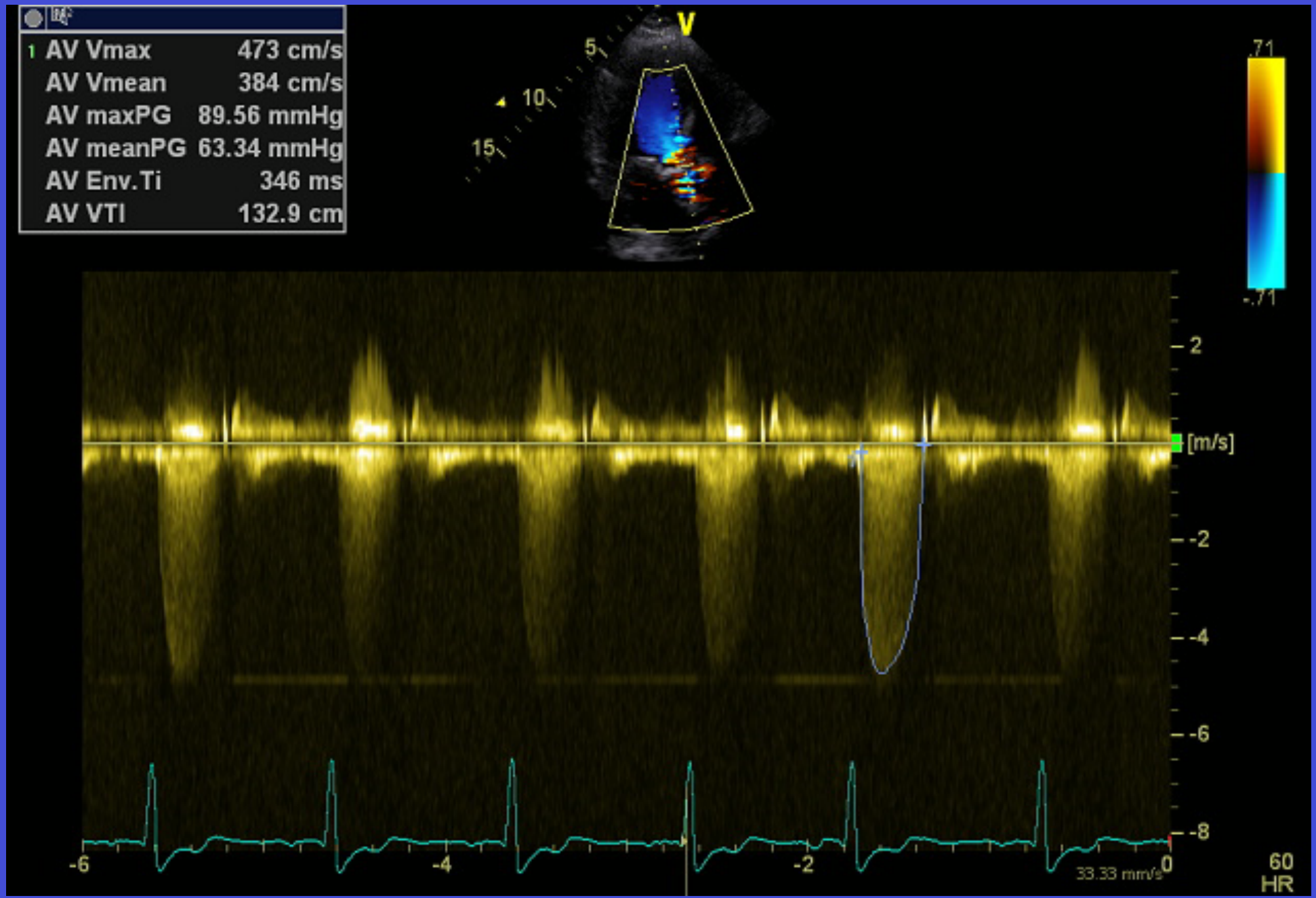
V
5
10
15
63
2:185 HR


1 AV Vmax 473 cm/s
AV Vmean 384 cm/s
AV maxPG 89.56 mmHg
AV meanPG 63.34 mmHg
AV Env.Ti 346 ms
AV VTI 132.9 cm
V
5
10
15
.71
-.71
2
[m/s]
-2
-4
-6
-8
-6
-4
-2
0
33.33 mm/s
60
HR

Case Presentation Continued

Patient reluctantly agreeable to proceeding with surgery

Heard that aortic valves can be replaced through the groin

Has a strong desire to pursue that option.

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D. et. al. PARTNER 2 Investigators

N Engl J Med
Volume 374(17):1609-1620
April 28, 2016

Overview and Study Design

- In high risk patients survival is similar between TAVR and surgical aortic valve replacement.
- What about intermediate risk patients?
- Randomly assigned 2032 patients with severe AS and intermediate risk to undergo either TAVR or surgical aortic valve replacement
  - 76% transfemoral access
  - 24% transthoracic access

Characteristics of the Patients at Baseline.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	TAVR (N=1011)	Surgery (N=1021)
Age — yr	81.5±6.7	81.7±6.7
Male sex — no. (%)	548 (54.2)	560 (54.8)
Body-mass index†	28.6±6.2	28.3±6.2
STS risk score‡	5.8±2.1	5.8±1.9
NYHA class III or IV — no./total no. (%)	782/1011 (77.3)	776/1020 (76.1)
Coronary artery disease — no. (%)	700 (69.2)	679 (66.5)
Previous myocardial infarction — no. (%)	185 (18.3)	179 (17.5)
Previous CABG — no. (%)	239 (23.6)	261 (25.6)
Previous PCI — no. (%)	274 (27.1)	282 (27.6)
Previous balloon aortic valvuloplasty — no. (%)	51 (5.0)	50 (4.9)
Cerebral vascular disease — no. (%)	325 (32.1)	317 (31.0)
Peripheral vascular disease — no. (%)	282 (27.9)	336 (32.9)
Diabetes mellitus — no. (%)	381 (37.7)	349 (34.2)
COPD — no. (%)		
Any	321 (31.8)	306 (30.0)
Oxygen-dependent	34 (3.4)	32 (3.1)
Creatinine >2 mg/dl — no. (%)§	51 (5.0)	53 (5.2)
Atrial fibrillation — no. (%)	313 (31.0)	359 (35.2)
Permanent pacemaker — no. (%)	118 (11.7)	123 (12.0)
Frail condition — no./total no. (%)		
5-Meter walk-test time >7 sec	416/936 (44.4)	418/901 (46.4)
Serum albumin <3.5 g/dl	150/988 (15.2)	140/951 (14.7)
Liver disease — no. (%)	19 (1.9)	26 (2.5)
Aortic-valve area — cm^2	0.7±0.2	0.7±0.2
Mean gradient — mm Hg	44.9±13.4	44.6±12.5
Left ventricular ejection fraction — %	56.2±10.8	55.3±11.9
Left ventricular mass index — g/m^2	119.8±31.5	120.6±32.6
Moderate or severe mitral regurgitation — no./total no. (%)	151/899 (16.8)	171/894 (19.1)

* Plus–minus values are means ±SD. There were no significant between-group differences in the characteristics at baseline, except for peripheral vascular disease (P=0.02) and atrial fibrillation (P=0.05). Data on left ventricular ejection fraction were missing for 348 patients in the TAVR group and 347 in the surgery group. CABG denotes coronary-artery bypass grafting, COPD chronic obstructive pulmonary disease, NYHA New York Heart Association, PCI percutaneous coronary intervention, and TAVR transcatheter aortic-valve replacement.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ Scoring on the risk model of the Society of Thoracic Surgeons (STS) uses an algorithm that is based on the presence of coexisting illnesses in order to predict 30-day operative mortality. The STS score equals the predicted mortality expressed as a percentage. Less than 5% of patients in the population on which the STS algorithm is based had a predicted operative mortality (risk score) of more than 10%. Data on this score were missing for one patient.

§ To convert values for creatinine to micromoles per liter, multiply by 88.4.

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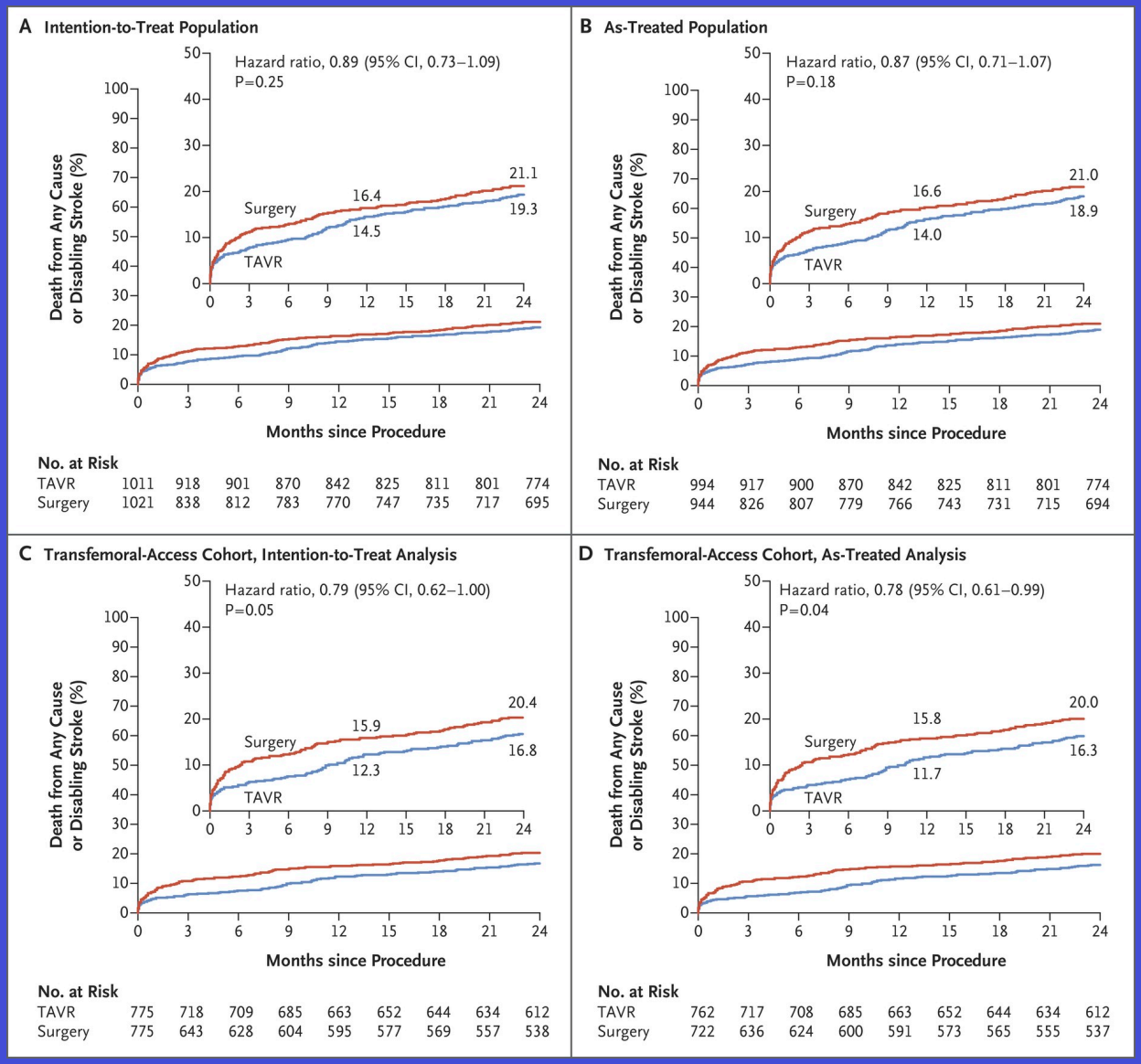
Time-to-Event Curves for the Primary Composite End Point.



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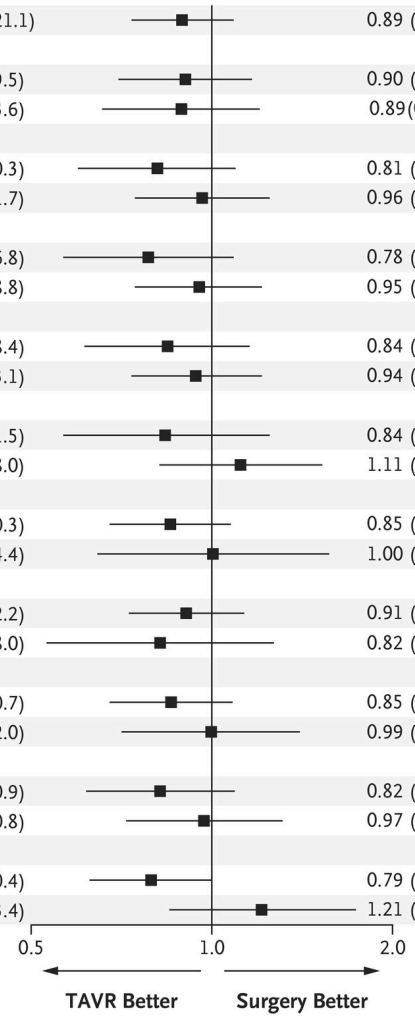
Subgroup Analyses of Death from Any Cause or Disabling Stroke.

Subgroup	No. of Patients	TAVR	Surgery	Hazard Ratio (95% CI)	P Value
		no. of patients with event/total no. of patients (%)			
Overall	2032	192/1011 (19.3)	202/1021 (21.1)	0.89 (0.73–1.09)	0.25
Age					0.96
<85 yr	1245	111/626 (18.0)	114/619 (19.5)	0.90 (0.69–1.17)	
≥85 yr	787	81/385 (21.5)	88/402 (23.6)	0.89(0.65–1.20)	
Sex					0.37
Female	924	77/463 (16.9)	88/461 (20.3)	0.81 (0.59–1.10)	
Male	1108	115/548 (21.4)	114/560 (21.7)	0.96 (0.74–1.25)	
Body-mass index					0.37
≤25	611	66/303 (22.1)	75/308 (26.8)	0.78 (0.56–1.09)	
>25	1421	126/708 (18.1)	127/713 (18.8)	0.95 (0.74–1.22)	
STS score					0.60
≤5	897	73/469 (15.8)	75/428 (18.4)	0.84 (0.61–1.16)	
>5	1134	119/542 (22.4)	127/592 (23.1)	0.94 (0.73–1.21)	
Left ventricular ejection fraction					0.27
≤55	496	44/237 (19.1)	53/259 (21.5)	0.84 (0.56–1.25)	
>55	841	85/426 (20.1)	71/415 (18.0)	1.11 (0.81–1.53)	
Moderate or severe mitral regurgitation					0.53
No	1471	132/748 (17.8)	141/723 (20.3)	0.85 (0.67–1.08)	
Yes	322	38/151 (25.9)	39/171 (24.4)	1.00 (0.64–1.57)	
Previous CABG					0.69
No	1532	156/772 (20.6)	158/760 (22.2)	0.91 (0.73–1.13)	
Yes	500	36/239 (15.3)	44/261 (18.0)	0.82 (0.53–1.27)	
Peripheral vascular disease					0.47
No	1414	130/729 (18.2)	134/685 (20.7)	0.85 (0.67–1.09)	
Yes	618	62/282 (22.3)	68/336 (22.0)	0.99 (0.71–1.40)	
5-Meter walk test					0.43
≤7 sec	1003	91/520 (17.7)	97/483 (20.9)	0.82 (0.62–1.09)	
>7 sec	834	85/416 (20.7)	82/418 (20.8)	0.97 (0.71–1.31)	
Access route					0.06
Transfemoral	1550	128/775 (16.8)	149/775 (20.4)	0.79 (0.62–1.00)	
Transthoracic	482	64/236 (27.7)	53/246 (23.4)	1.21 (0.84–1.74)	



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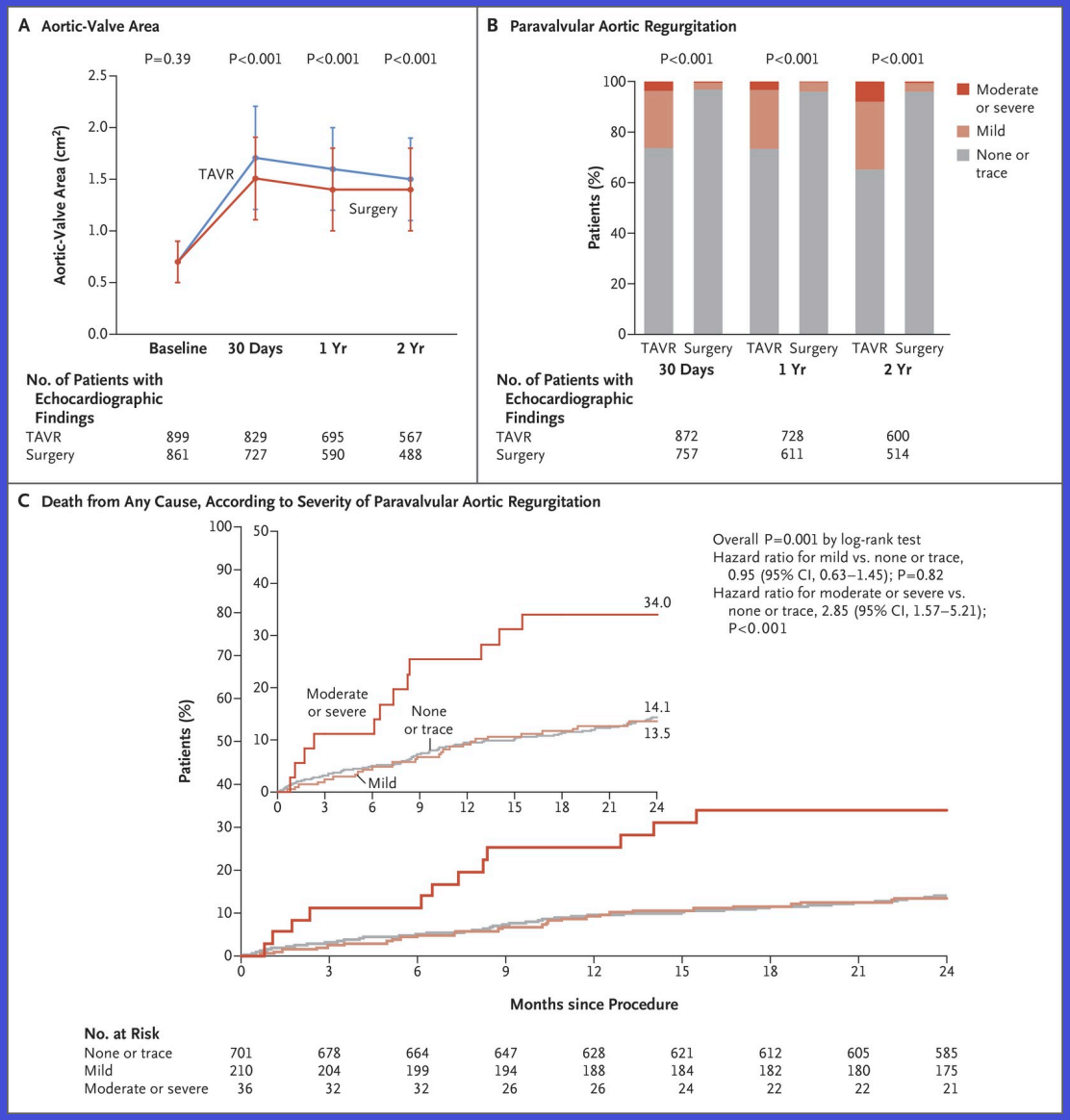
Echocardiographic Findings.



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Clinical End Points at 30 Days, 1 Year, and 2 Years.

Table 2. Clinical End Points at 30 Days, 1 Year, and 2 Years.*

End Point	At 30 Days			At 1 Year			At 2 Years		
	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value
	no. of patients (%)			*no. of patients (%)*			*no. of patients (%)*		
Death from any cause or disabling stroke	62 (6.1)	80 (8.0)	0.11	145 (14.5)	160 (16.4)	0.24	192 (19.3)	202 (21.1)	0.33
Death									
From any cause	39 (3.9)	41 (4.1)	0.78	123 (12.3)	124 (12.9)	0.69	166 (16.7)	170 (18.0)	0.45
From cardiac causes	33 (3.3)	32 (3.2)	0.92	70 (7.1)	77 (8.1)	0.40	97 (10.1)	104 (11.3)	0.38
Not from cardiac causes	6 (0.6)	9 (0.9)	0.41	53 (5.6)	47 (5.2)	0.71	69 (7.4)	65 (7.4)	0.98
Neurologic event									
Any event	64 (6.4)	65 (6.5)	0.94	99 (10.1)	93 (9.7)	0.76	121 (12.7)	103 (11.0)	0.25
Transient ischemic attack	9 (0.9)	4 (0.4)	0.17	23 (2.4)	16 (1.8)	0.38	34 (3.7)	20 (2.3)	0.09
Any stroke	55 (5.5)	61 (6.1)	0.57	78 (8.0)	79 (8.1)	0.88	91 (9.5)	85 (8.9)	0.67
Disabling stroke	32 (3.2)	43 (4.3)	0.20	49 (5.0)	56 (5.8)	0.46	59 (6.2)	61 (6.4)	0.83
Nondisabling stroke	23 (2.3)	18 (1.8)	0.43	30 (3.0)	24 (2.5)	0.44	33 (3.4)	27 (2.9)	0.51
Rehospitalization	64 (6.5)	62 (6.5)	0.99	142 (14.8)	135 (14.7)	0.92	183 (19.6)	156 (17.3)	0.22
Death from any cause or rehospitalization	99 (9.8)	101 (10.2)	0.78	234 (23.4)	225 (23.3)	0.97	303 (30.5)	281 (29.6)	0.67
Death from any cause, any stroke, or rehospitalization	140 (13.9)	153 (15.3)	0.37	274 (27.4)	276 (28.3)	0.64	344 (34.6)	326 (33.9)	0.75
Myocardial infarction	12 (1.2)	19 (1.9)	0.22	24 (2.5)	29 (3.0)	0.47	33 (3.6)	37 (4.1)	0.56
Major vascular complication	80 (7.9)	51 (5.0)	0.008	84 (8.4)	54 (5.3)	0.007	86 (8.6)	55 (5.5)	0.006
Life-threatening or disabling bleeding	105 (10.4)	442 (43.4)	<0.001	151 (15.2)	460 (45.5)	<0.001	169 (17.3)	471 (47.0)	<0.001
Acute kidney injury	13 (1.3)	31 (3.1)	0.006	32 (3.4)	48 (5.0)	0.07	36 (3.8)	57 (6.2)	0.02
New atrial fibrillation	91 (9.1)	265 (26.4)	<0.001	100 (10.1)	272 (27.2)	<0.001	110 (11.3)	273 (27.3)	<0.001
New permanent pacemaker	85 (8.5)	68 (6.9)	0.17	98 (9.9)	85 (8.9)	0.43	114 (11.8)	96 (10.3)	0.29
Endocarditis	0	0	—	7 (0.8)	6 (0.7)	0.84	11 (1.2)	6 (0.7)	0.22
Aortic-valve reintervention	4 (0.4)	0	0.05	11 (1.2)	4 (0.5)	0.10	13 (1.4)	5 (0.6)	0.09
Coronary obstruction	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53

* All percentages are Kaplan–Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number of patients in the treatment group. P values are for point-in-time comparisons.

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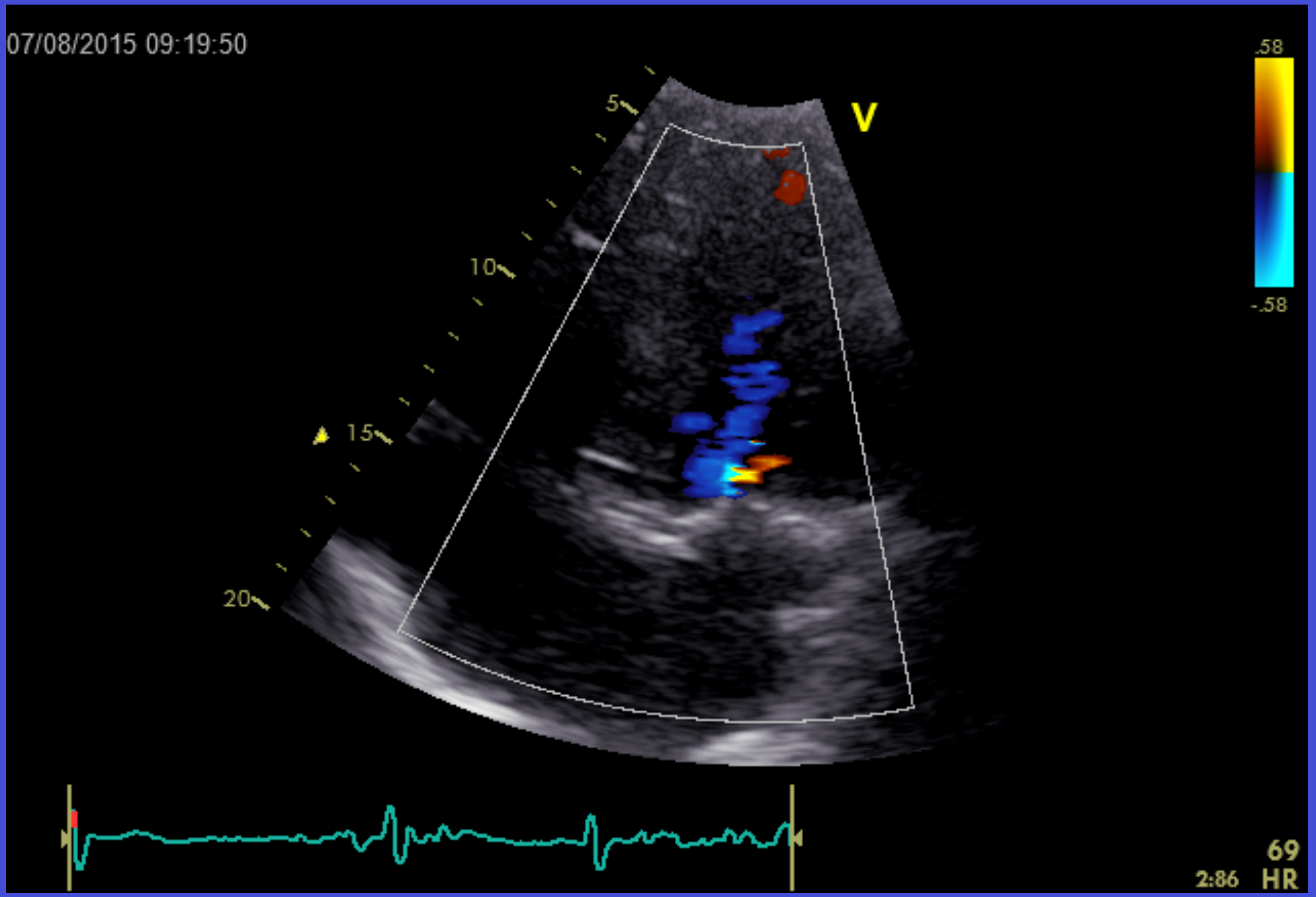
Conclusions

- In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke, but only 2 year f/u data available.

- Transfemoral approach favorable compared to transthoracic approach with respect to primary outcome

- Complications more likely in surgical arm include life-threatening bleeding, atrial fibrillation, acute kidney injury

- Complications more likely in the TAVR arm include:
  - frequency and severity of paravalvular regurgitation (mild 20%, mod/severe 4% at 30d)
  - Major vascular complications (9% vs. 5%)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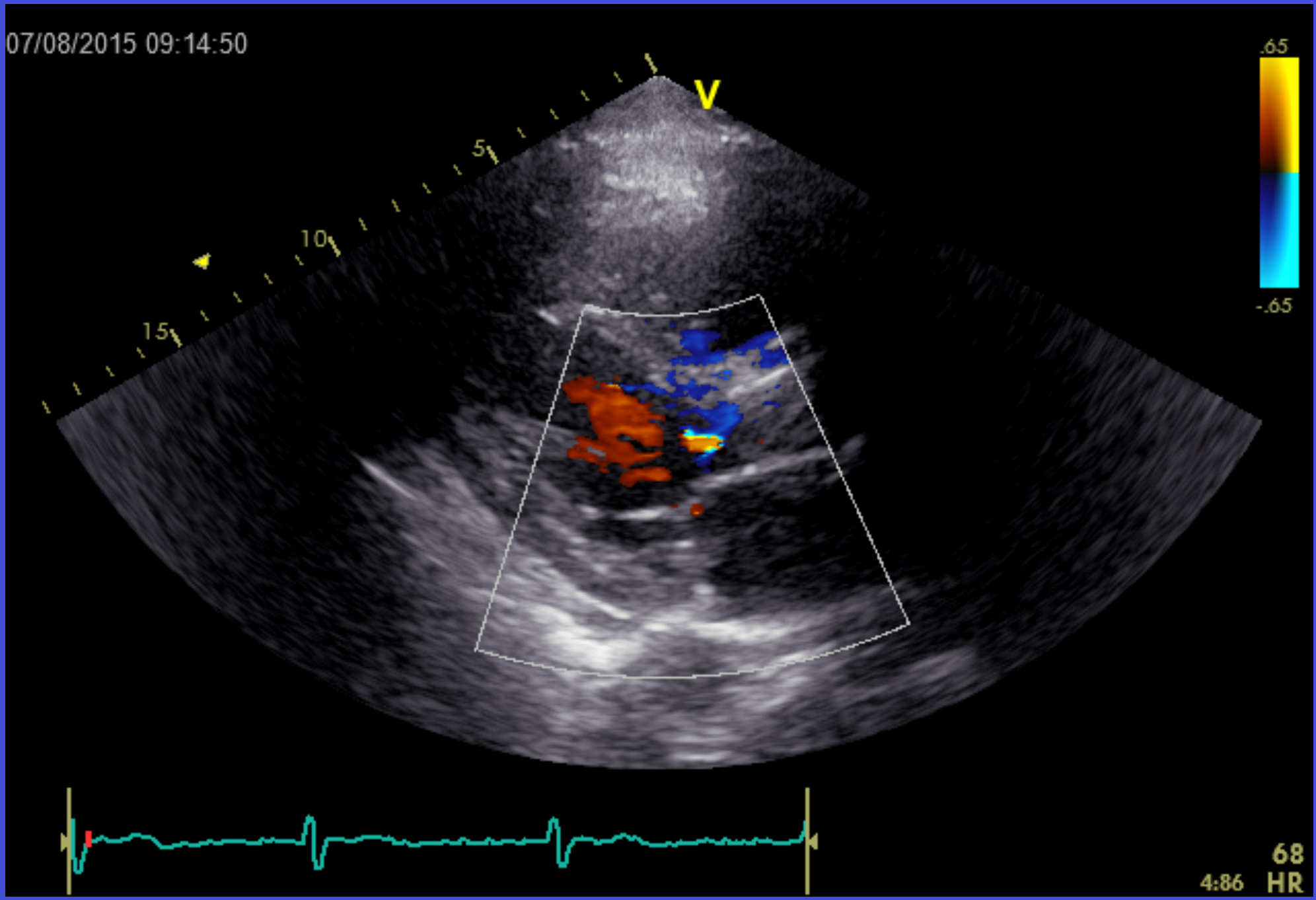
.58
-.58
5
10
15
20
V
69
HR
2:86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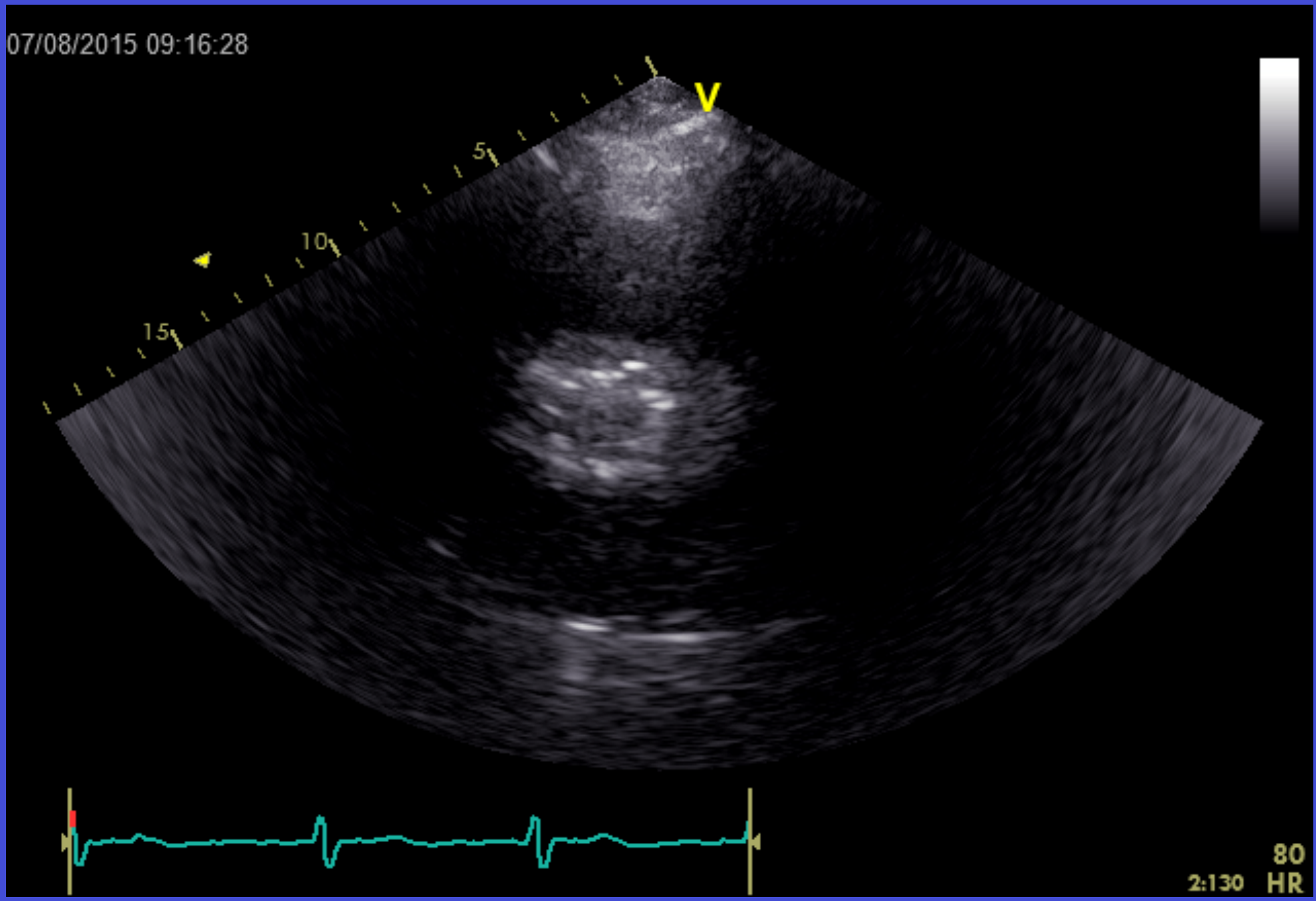
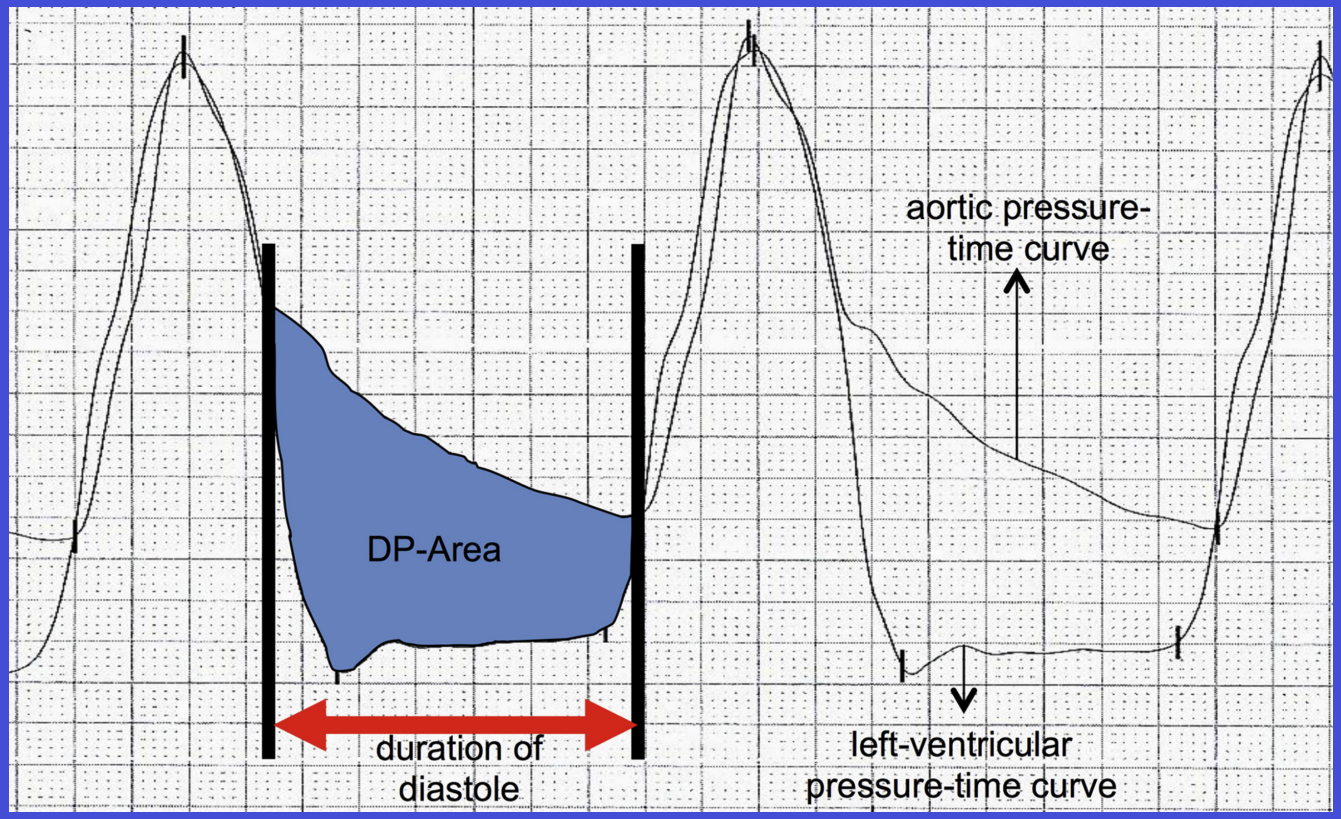
V
5
10
15
.65
-.65
68
4:86 HR


07/08/2015 09:16:28
5
10
15
80
2:130 HR

Hemodynamic Characterization Aortic Regurgitation For Predicting Survival After TAVR Diastolic Pressure-Time Index



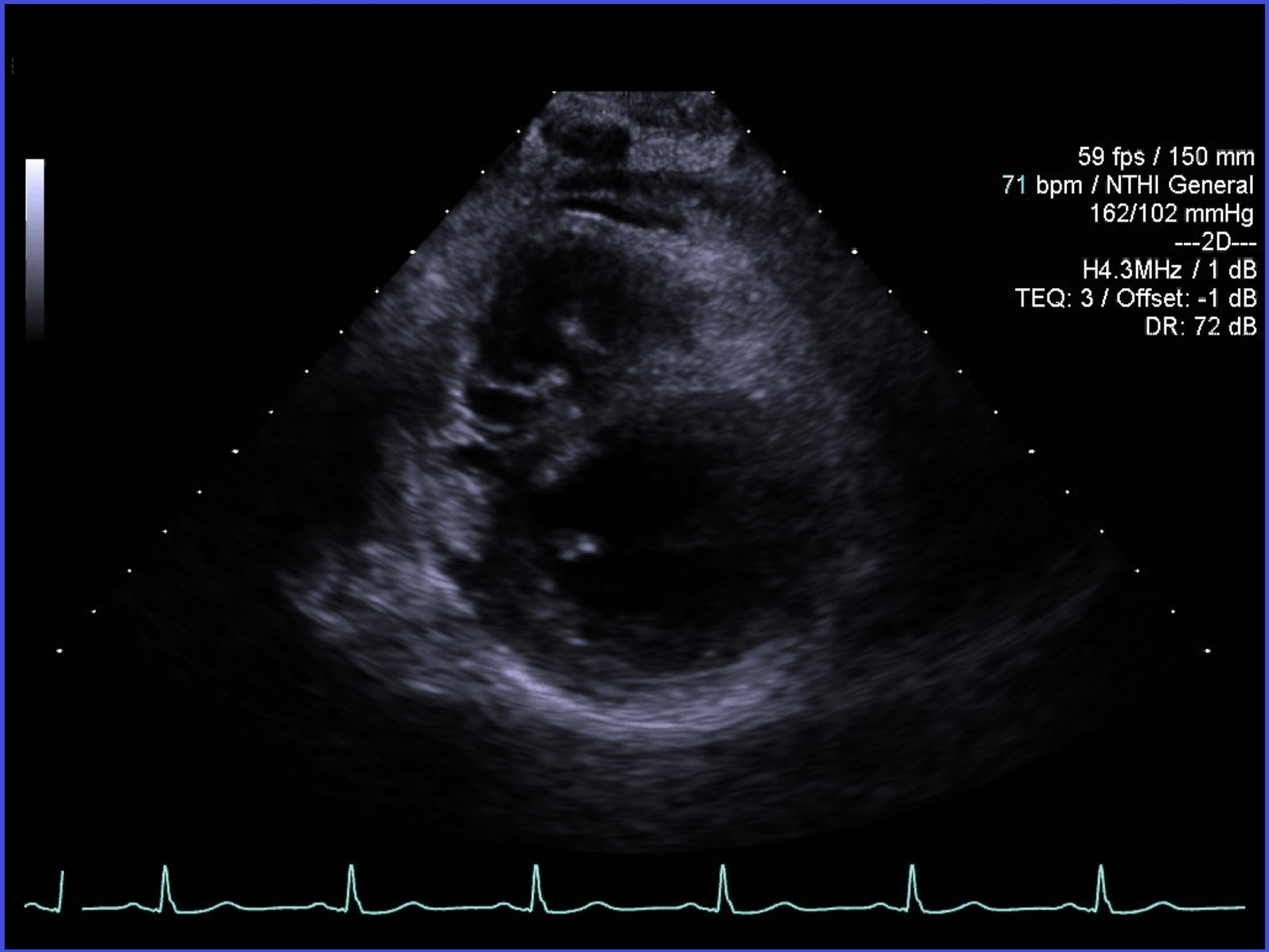
J Am Coll Cardiol Intv. Published online April 27, 2016. doi:10.1016/j.jcin.2016.02.012

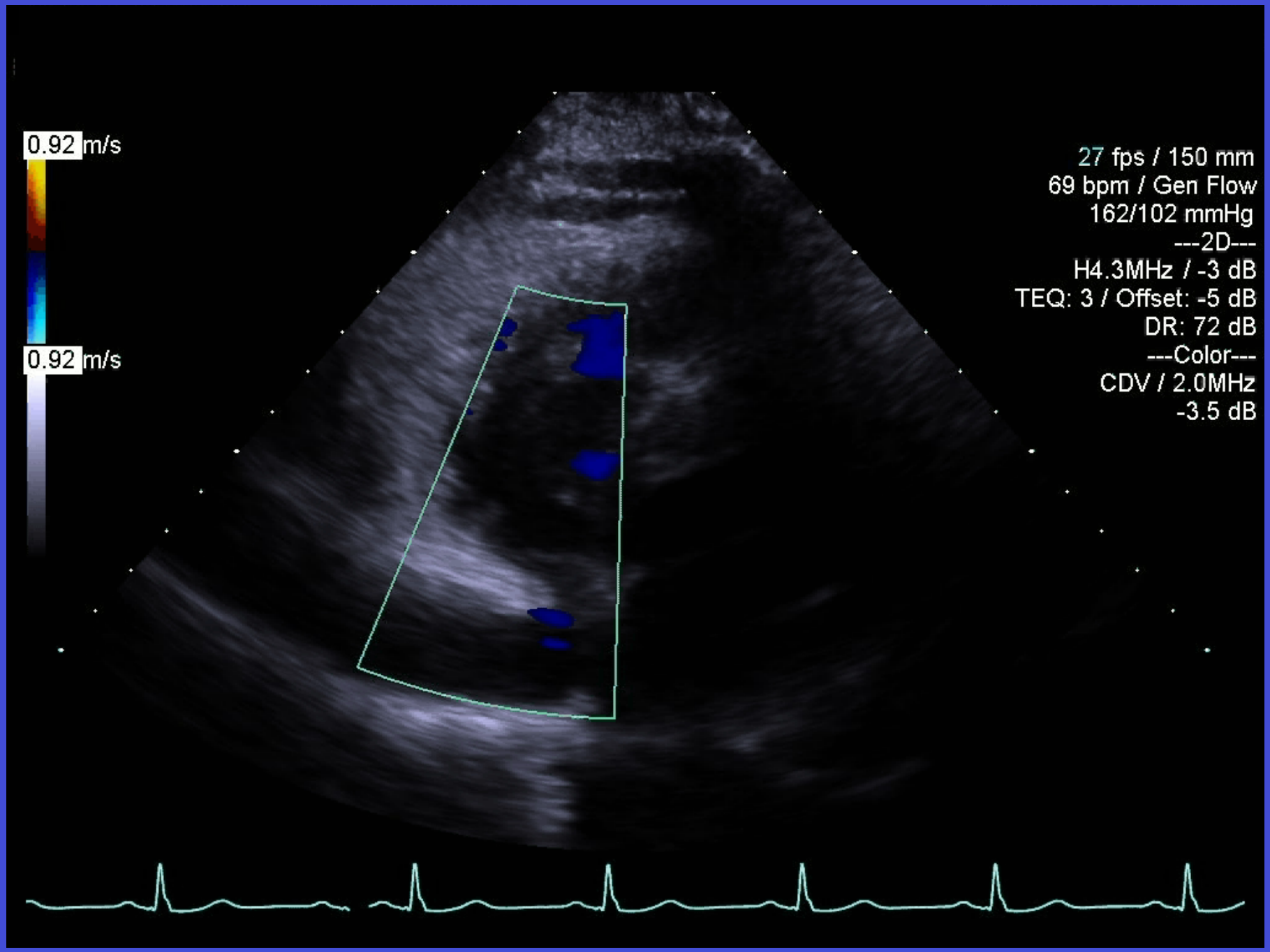
Case Presentation

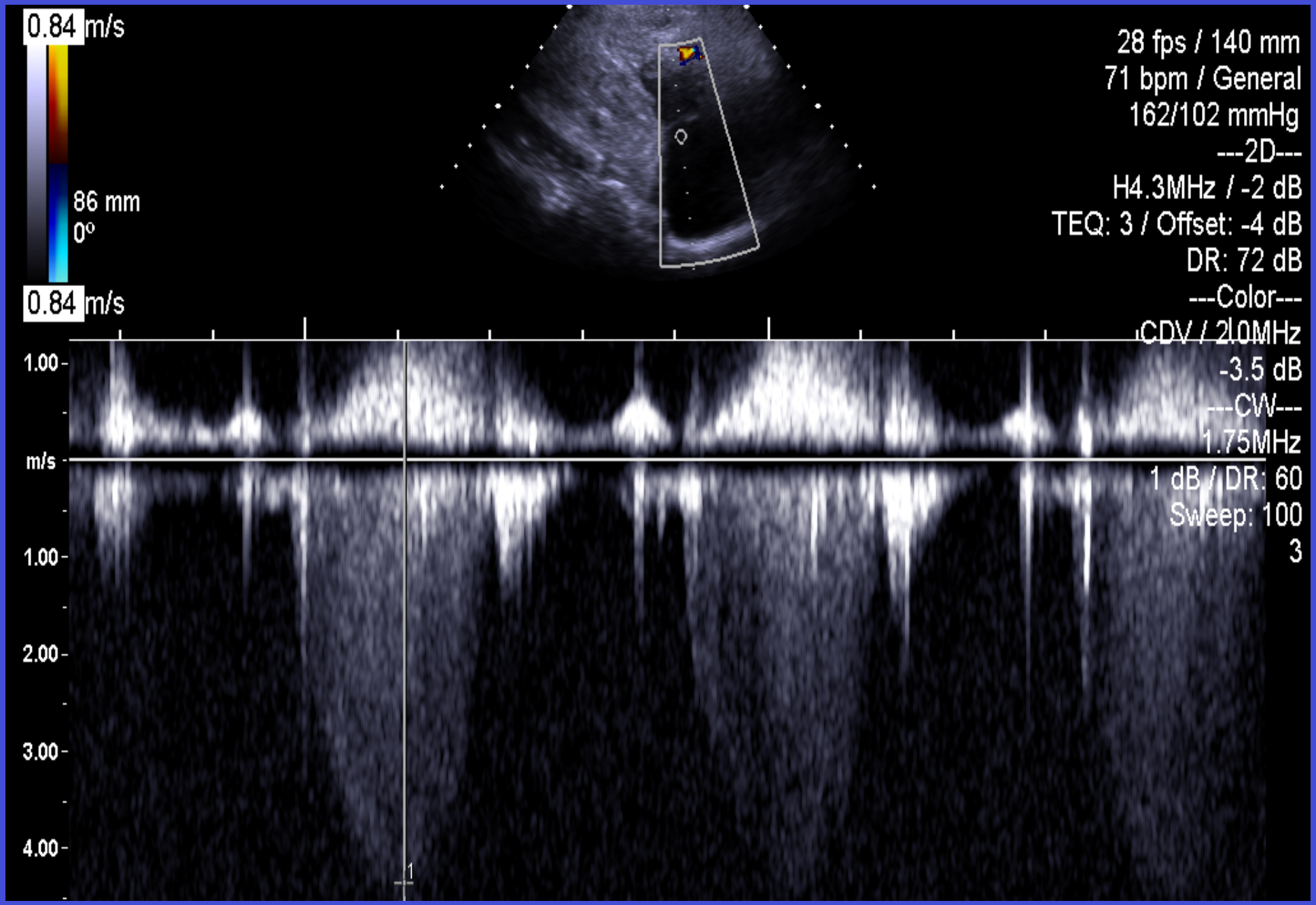
- 76-year old woman
- Murmur since childhood with echocardiogram reporting small restrictive ventricular septal defect
- No treatment
- HTN and smoking, ongoing
- Atypical CP with normal nuclear stress test 2009 except LV hypertrophy
- Now presents with mild exertional dyspnea and persistent cough after a URI

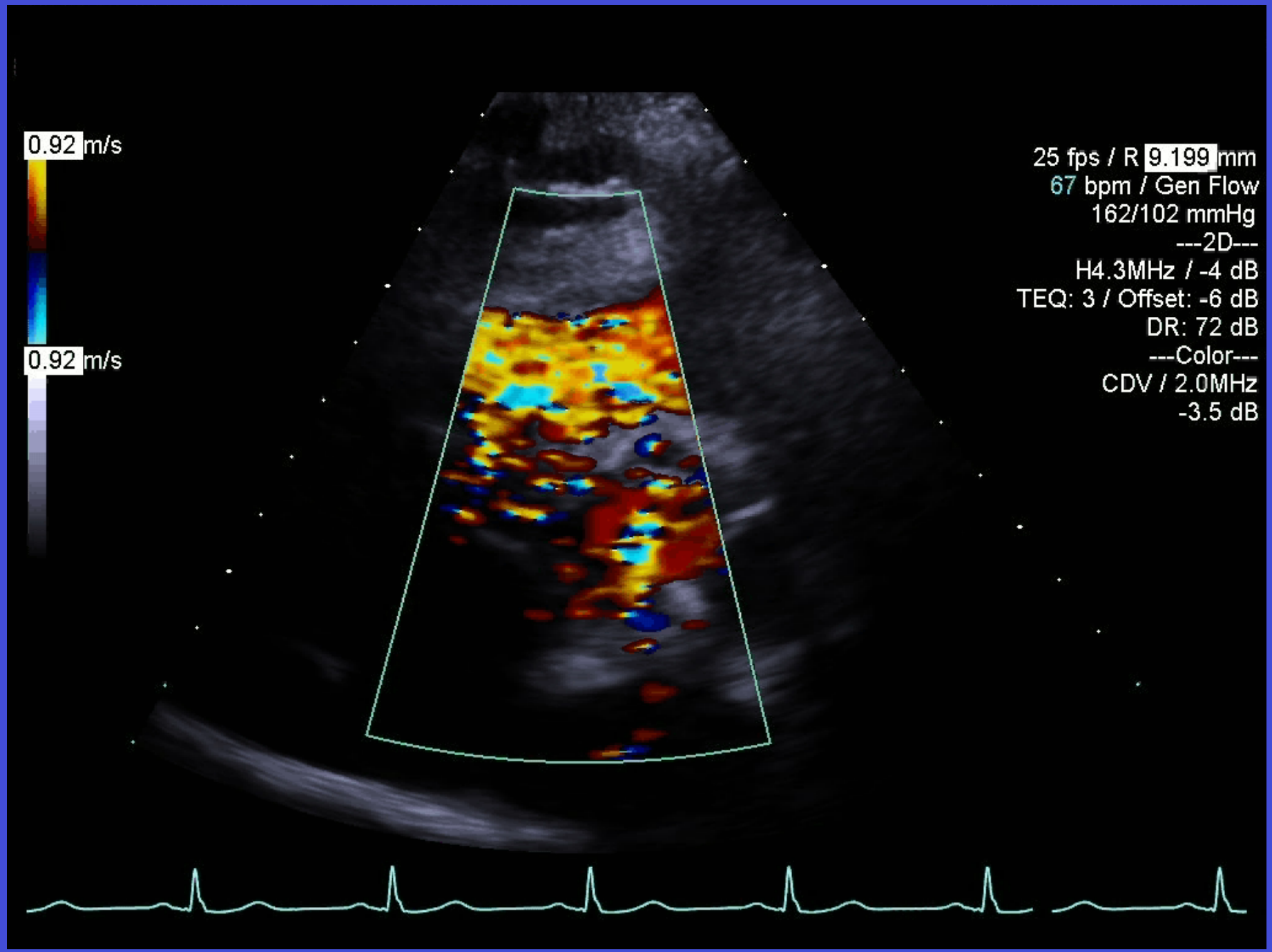
Case Presentation Continued

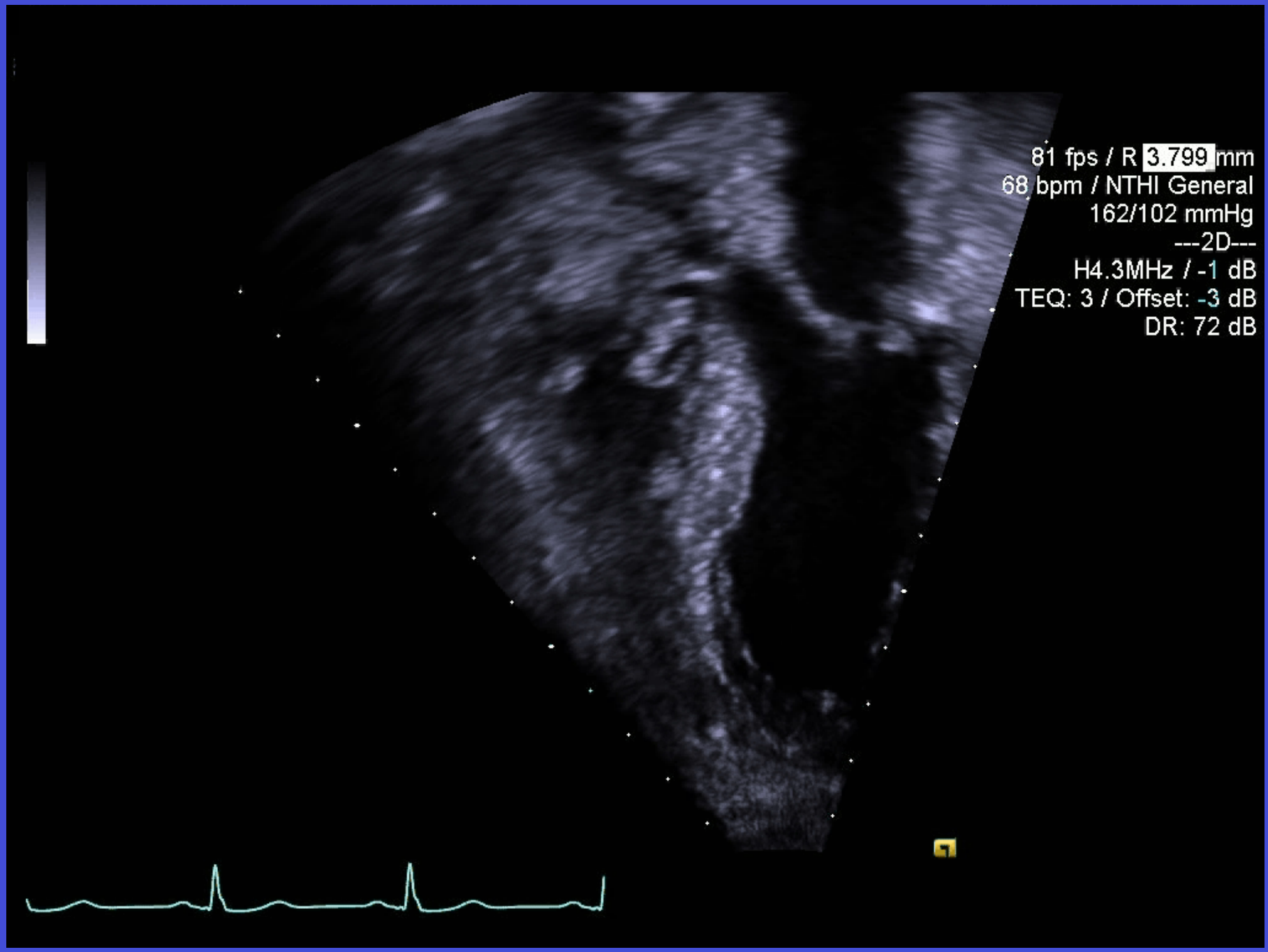
- Current meds: Benicar/HCT 40/12.5/d, Nexium 40mg/d, metoprolol 25mg/d
- PEx
  - BP 162/100
  - Clear lungs, normal JVP
  - 3/6 mildly < > systolic murmur best in LLSB but radiates all across the precordium
  - Increases with inspiration and decreases with Valsalva
- ECG with NSR, LVH by voltage and lateral Tw inversions

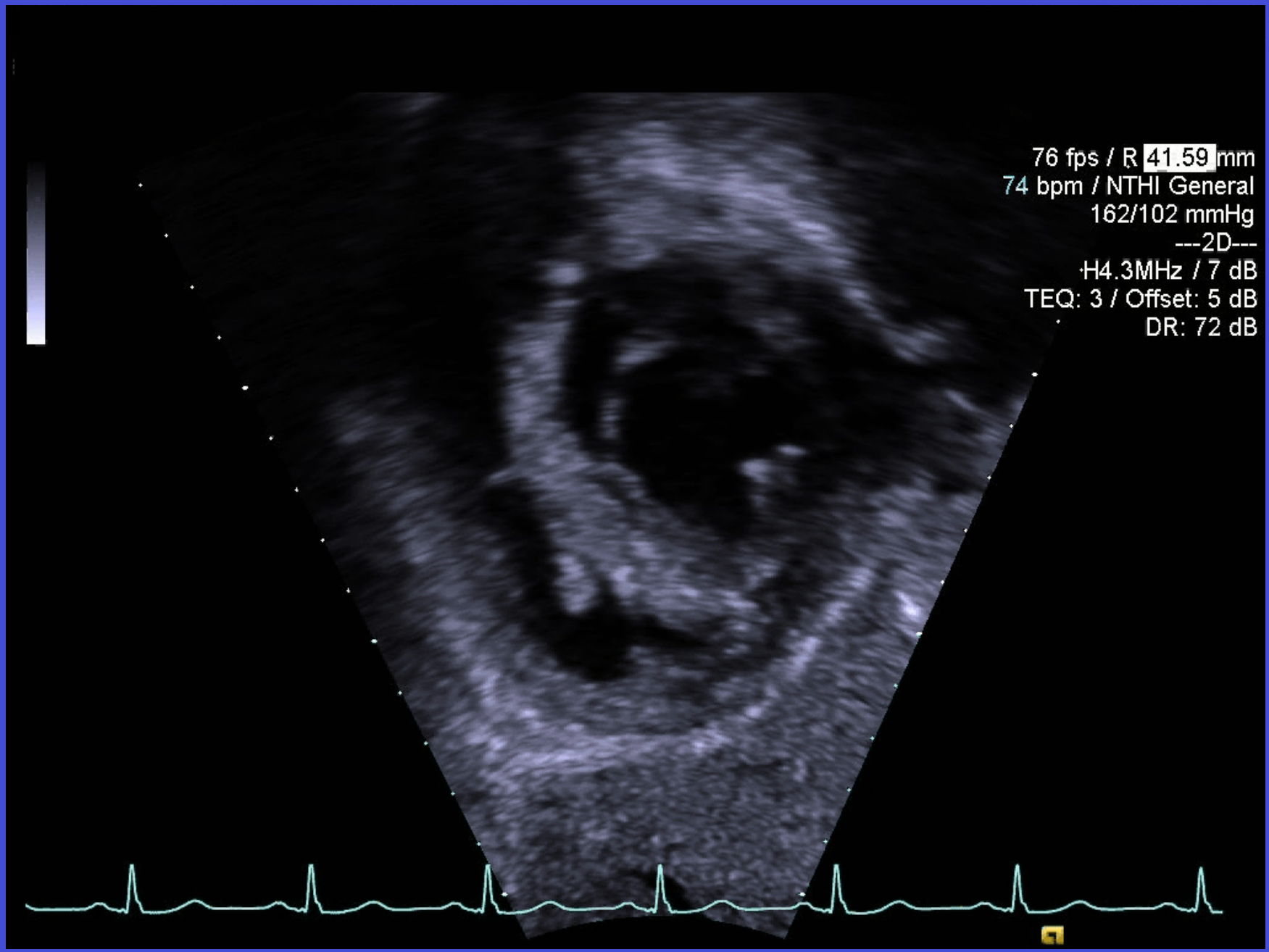

59 fps / 150 mm
71 bpm / NTHI General
162/102 mmHg
---2D---
H4.3MHz / 1 dB
TEQ: 3 / Offset: -1 dB
DR: 72 dB


0.92 m/s
0.92 m/s
27 fps / 150 mm
69 bpm / Gen Flow
162/102 mmHg
---2D---
H4.3MHz / -3 dB
TEQ: 3 / Offset: -5 dB
DR: 72 dB
---Color---
CDV / 2.0MHz
-3.5 dB


0.84 m/s
86 mm
0°
0.84 m/s
28 fps / 140 mm
71 bpm / General
162/102 mmHg
---2D---
H4.3MHz / -2 dB
TEQ: 3 / Offset: -4 dB
DR: 72 dB
---Color---
CDV / 2l.0MHz
-3.5 dB
---CW---
1.75MHz
1 dB / DR: 60
Sweep: 100
3
1.00
m/s
1.00
2.00
3.00
4.00


0.92 m/s
0.92 m/s
25 fps / R 9.199 mm
67 bpm / Gen Flow
162/102 mmHg
---2D---
H4.3MHz / -4 dB
TEQ: 3 / Offset: -6 dB
DR: 72 dB
---Color---
CDV / 2.0MHz
-3.5 dB


81 fps / R 3.799 mm
68 bpm / NTHI General
162/102 mmHg
---2D---
H4.3MHz / -1 dB
TEQ: 3 / Offset: -3 dB
DR: 72 dB


76 fps / R 41.59 mm
74 bpm / NTHI General
162/102 mmHg
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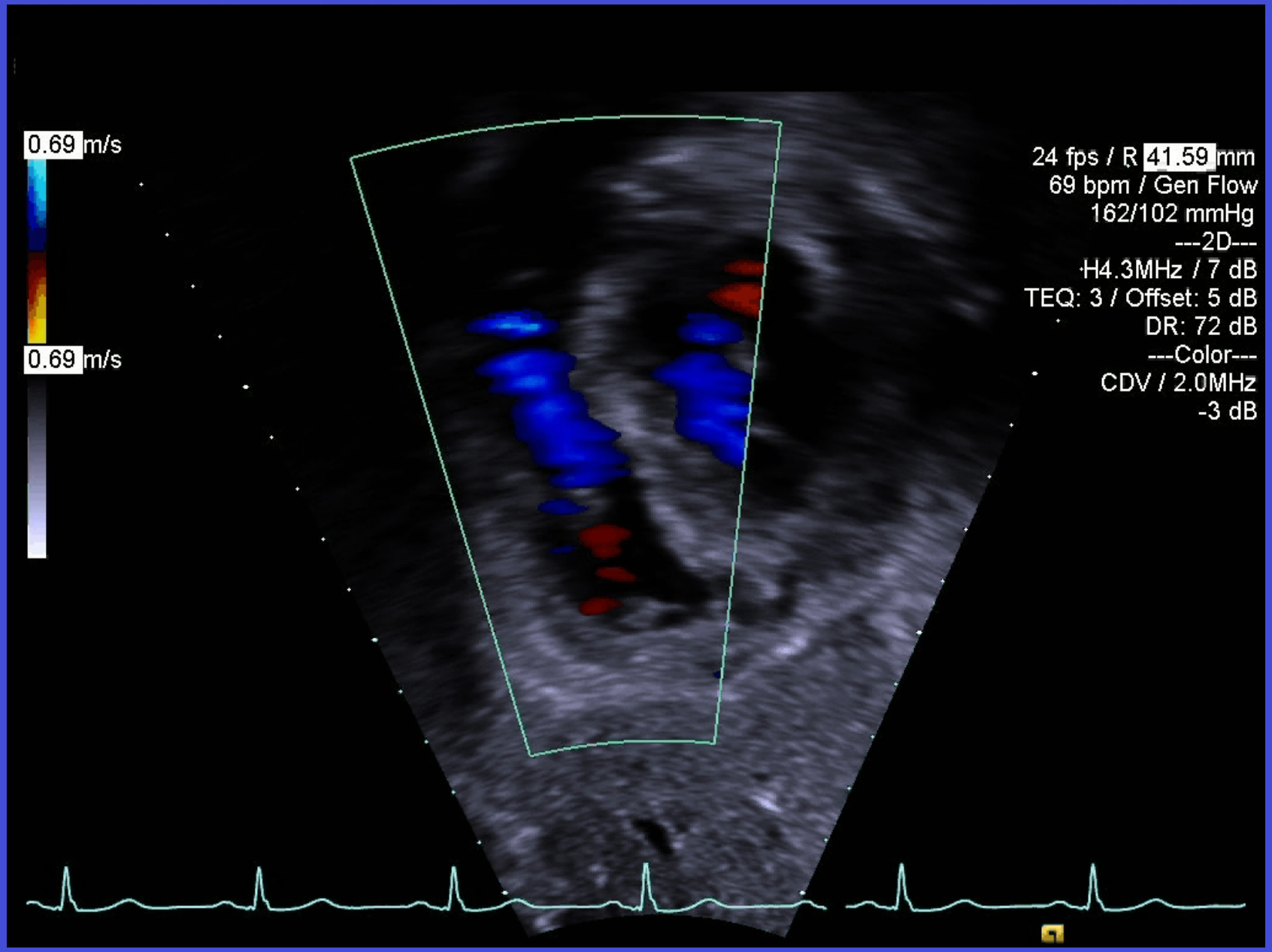
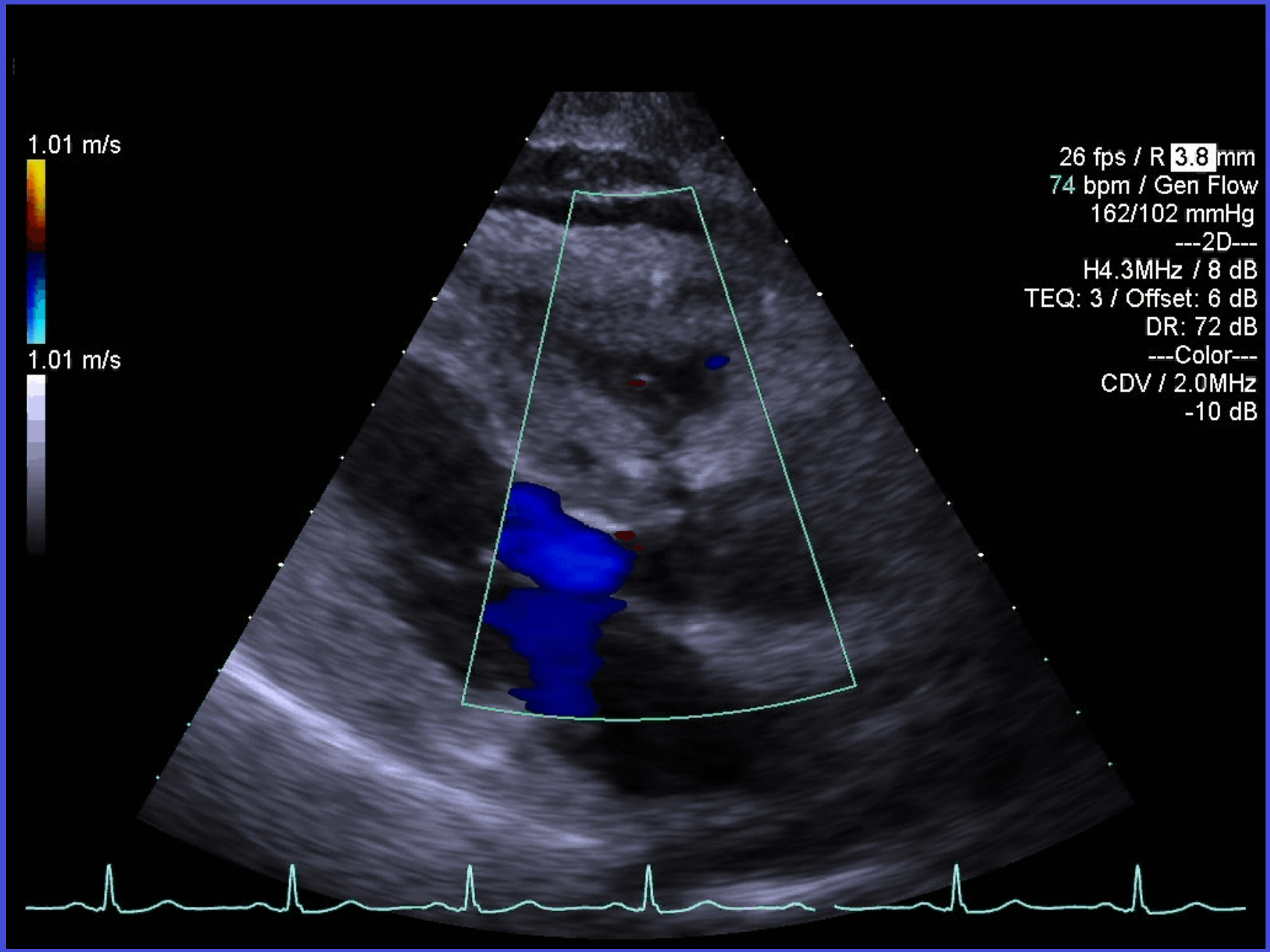
H4.3MHz / 7 dB
TEQ: 3 / Offset: 5 dB
DR: 72 dB


0.69 m/s
0.69 m/s
24 fps / R 41.59 mm
69 bpm / Gen Flow
162/102 mmHg
---2D---
H4.3MHz / 7 dB
TEQ: 3 / Offset: 5 dB
DR: 72 dB
---Color---
CDV / 2.0MHz
-3 dB

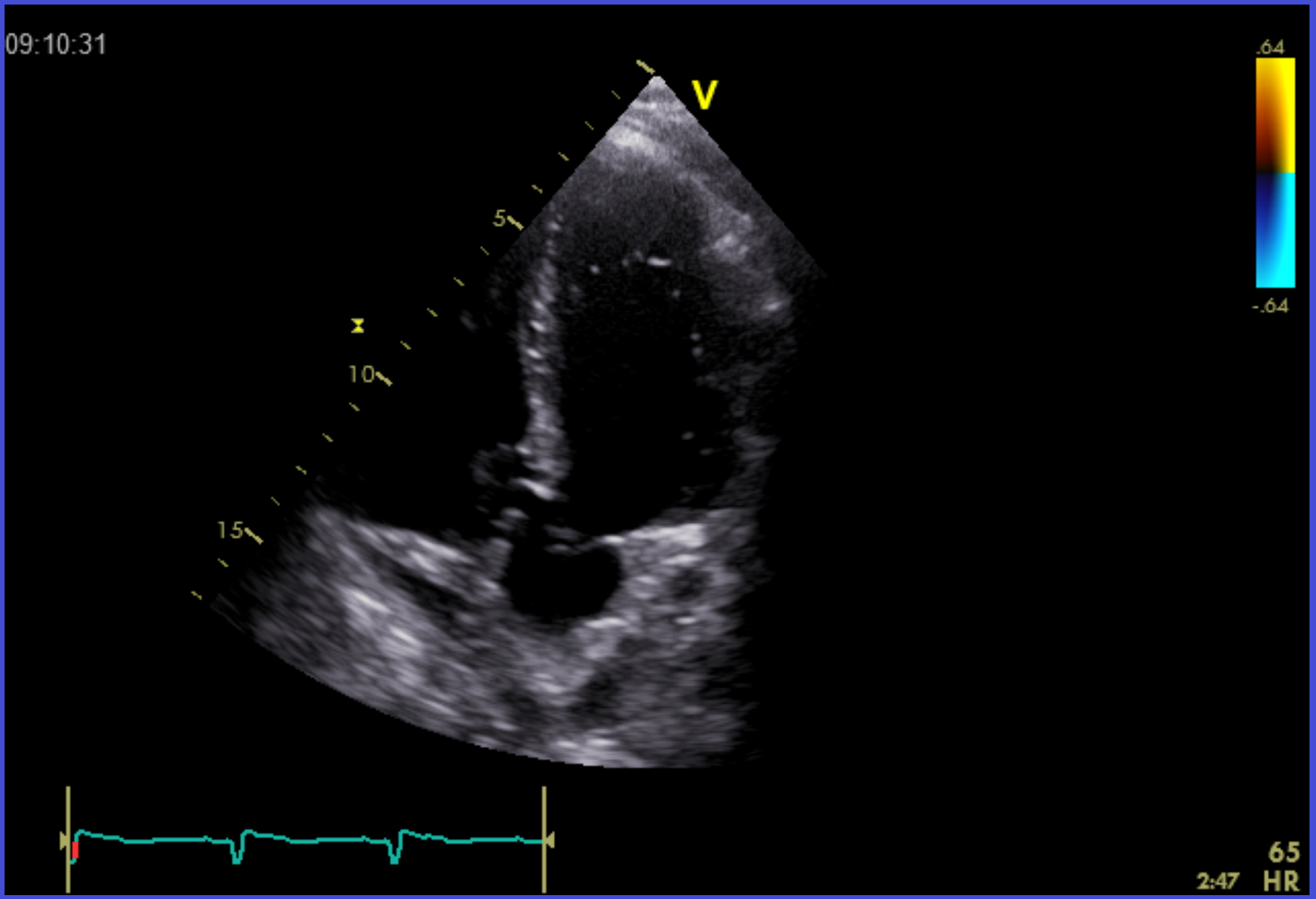

1.01 m/s
1.01 m/s
26 fps / R 3.8 mm
74 bpm / Gen Flow
162/102 mmHg
---2D---
H4.3MHz / 8 dB
TEQ: 3 / Offset: 6 dB
DR: 72 dB
---Color---
CDV / 2.0MHz
-10 dB

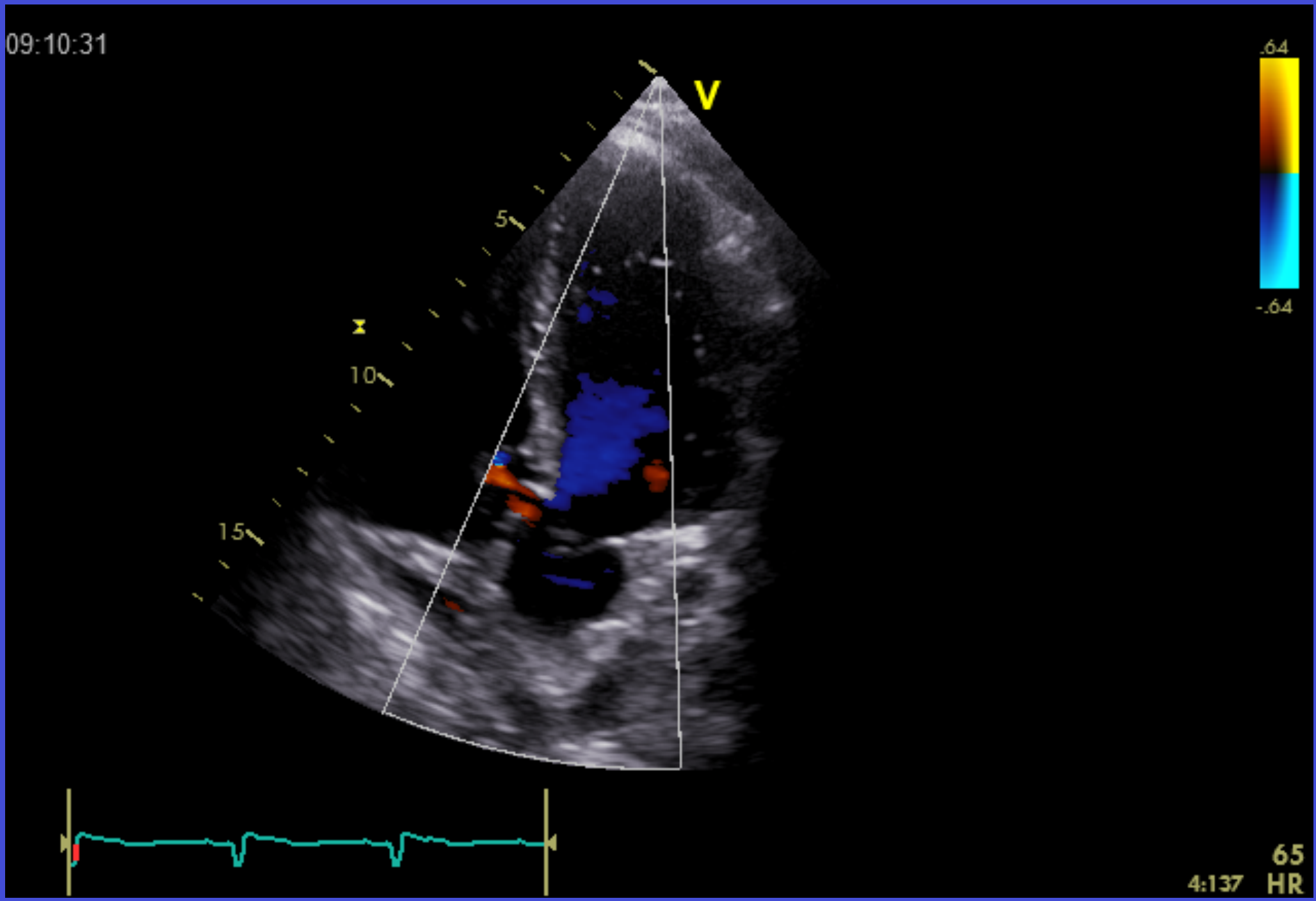
Double Chambered RV

- Form of subvalvular RVOT obstruction
- Anomalous muscle bands that divide the RV
- Often systolic dimple at anterior RV free wall, attachment point of RV band
- Acquired in most cases, but underlying substrate congenital
- Unlike TOF where outlet septum is anteriorly deviated (maligned)
- VSD present in > 75% of patients, mostly perimembranous
- VSD may have closed

Double Chamber RV (Continued)

- Natural history not well defined
- Obstruction can progress over time
- No association with genetic abnormality
- Most present before adulthood
- Surgery recommended in children with significant RVOT obstruction
- Not usually responsive to balloon dilation
- Low risk of recurrence after surgery
- Variable medical treatment recommended (Digoxin vs. b-blocker)
- Verntricular conduction usually normal
- Ventricular arrhythmias uncommon in unrepaired patients.


09:10:31
V
5
10
15
.64
-.64
65
HR
2:47


09:10:31
.64
-.64
V
5
10
15
65
HR
4:137