

# VIVID meeting

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# Standardized Definition of Structural Valve Degeneration for Surgical and Transcatheter Bioprosthetic Aortic Valves

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**ABSTRACT:** Bioprostheses are prone to structural valve degeneration, resulting in limited long-term durability. A significant challenge when comparing the durability of different types of bioprostheses is the lack of a standardized terminology for the definition of a degenerated valve. This issue becomes especially important when we try to compare the degeneration rate of surgically inserted and transcatheter bioprosthetic valves. This document, by the VIVID (Valve-in-Valve International Data), proposes practical and standardized definitions of valve degeneration and provides recommendations for the timing of clinical and imaging follow-up assessments accordingly. Its goal is to improve the quality of research and clinical care for patients with deteriorated bioprostheses by providing objective and strict criteria that can be utilized in future clinical trials. We hope that the adoption of these criteria by both the cardiological and surgical communities will lead to improved comparability and interpretation of durability analyses.

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et al

# VIVID consensus statement

	<b>Prosthetic Aortic Valve Stenosis</b>		
	Normal	Moderate stenosis	Severe stenosis
<b>Qualitative parameters</b>			
Valve structure and motion	Normal	Often abnormal	Abnormal
<u>Transvalvular flow envelope</u>	Triangular, early peaking	Triangular to intermediate	Rounded, symmetrical
<b>Semi-quantitative parameters</b>			
Acceleration time (ms)	<80	80-100	>100
Acceleration time/LV ejection time ratio	<0.32	0.32-0.37	>0.37
<b>Quantitative flow dependent parameters</b>			
Peak velocity (m/s)	<3	3–3.9	≥4
Mean gradient (mmHg)	<20	20–39	≥40
Increase in mean gradient during follow up associated with decrease in EOA and DVI	<10	10-19	≥20
<b>Quantitative flow independent parameters*</b>			
Doppler velocity index	>0.35	0.25–0.35	<0.25
EOA for BSA ≥1.6 cm <sup>2</sup> (cm <sup>2</sup> )	>1.2	1.0–1.2	<1.0
EOA for BSA <1.6 cm <sup>2</sup> (cm <sup>2</sup> )	>1.1	0.8–1.1	<0.8

# VIVID consensus statement

Three-class grading scheme	None/Trace			Mild		Moderate	Severe
Five-class grading scheme	None/Trace	Mild	Mild-moderate	Moderate	Moderate-severe	Severe	
<b>Doppler parameters (qualitative or semi-quantitative)</b>							
Jet features*							
Extensive/wide jet origin	Absent	Absent	Absent	Present	Present	Present	
Multiple jets	Possible	Possible	Often present	Often present	Usually present	Usually present	
Jet path visible along the stent	Absent	Absent	Possible	Often present	Usually present	Present	
Proximal flow convergence visible	Absent	Absent	Absent	Possible	Often present	Often present	
E/A ratio†	<1.0	<1.0	<1.0	≥1.5	≥1.5	≥1.5	
Vena contracta width (mm)* (color Doppler)	Not quantifiable	<2	2 to <4	4 to <5	5 to <6	≥6	
Vena contracta area (mm <sup>2</sup> )‡ (3D color Doppler)	Not quantifiable	<5	5 to <10	10 to <20	20 to <30	≥30	
Jet width at its origin (% LVOT diameter)* (color Doppler)	Narrow (<5)	Narrow (5 to <15)	Intermediate (15 to <30)	Intermediate (30 to <45)	Large (45 to <60)	Large (≥60)	
Jet density (CW Doppler)	Incomplete or faint	Incomplete or faint	Variable	Dense	Dense	Dense	
Jet deceleration rate (PHT <sub>ms</sub> )†§   (CW Doppler)	Slow (>500)	Slow (>500)	Variable (200 to <500)	Variable (200 to <500)	Variable (200 to <500)	Steep (<200)	
Diastolic flow reversal in proximal descending aorta§   (PW Doppler)	Absent	Absent or brief early diastolic	Intermediate	Intermediate	Holodiastolic (end-diastolic velocity <20 to <30 cm/s)	Holodiastolic (end-diastolic velocity ≥30 cm/s)	
Circumferential extent of PVR (%) (color Doppler)  * (color Doppler)  *	Not quantifiable	<5	5 to <10	10 to <20	20 to <30	≥30	
<b>Doppler parameters (Quantitative)</b>							
Regurgitant fraction (%)#	<15	<15	15 to <30	30 to <40	40 to <50	≥50	

# VIVID consensus statement

## SVD Stage 0

- No significant change from immediate post implantation<sup>1</sup>

## SVD Stage 1

- Morphological leaflet abnormality without significant hemodynamic changes<sup>2</sup>

## SVD Stage 2S

- Moderate stenosis<sup>3</sup>

## SVD Stage 2R

- Moderate regurgitation<sup>4</sup>

## SVD Stage 2RS

- Moderate stenosis and moderate regurgitation

## SVD Stage 3

- Severe stenosis and/or severe regurgitation

SVD ≠ valve failure ≠ symptoms

Gradual process

SVD ≠ PPM

SVD hemodynamic ≠ morphological

Strict echo criteria

# Definitions of Stages of SVD following AVR

Baseline echo at discharge and 30-days  
Follow-up echo every year

## Stage 0

Normal bioprosthetic valve morphology and function.

## Stage 1

*Presence of morphological abnormalities of valve leaflets: thickening, calcification, fibrosis, tear*

## Stage 2

*Increase in mean gradient  $\geq 10$  mmHg with decrease in EOA  $\geq 0.3$  cm<sup>2</sup> AND/OR  $\geq 1$  grade new onset or worsening of transvalvular AR with final grade of moderate AR*

## Stage 3

*Increase in mean gradient  $\geq 20$  mmHg with decrease in EOA  $\geq 0.6$  cm<sup>2</sup> AND/OR  $\geq 2$  grades new onset or worsening of transvalvular AR with final grade of severe AR*

# Mitral SVD paper

- Previous definitions of structural valve degeneration
- Durability of bioprosthetic valves
- Challenges in assessing durability of transcatheter devices
- SVD Definition
- Imaging diagnosis of SVD
  - Echocardiography
  - Computed tomography
- Clinical approach to patients
- Future perspective

# Prosthetic Mitral Valve Stenosis Echo Criteria

	Normal	Possible Stenosis	Significant Stenosis
<b>Valve structure and motion</b>			
Mechanical or bioprosthesis	Normal	Often abnormal <sup>β</sup>	Abnormal <sup>β</sup>
<b>Doppler quantitative parameters</b>			
Peak velocity (m/s) <sup>*†</sup>	<1.9	1.9-2.5	≥2.5
Mean gradient (mmHg) <sup>*†</sup>	≤5	6-10	≥10
Doppler velocity index <sup>*</sup>	<2.2	2.2-2.5	>2.5
Effective orifice area (cm <sup>2</sup> ) <sup>*</sup>	≥2	1-2	<1
Difference (measured EOA - reference EOA) (cm <sup>2</sup> ) <sup>*</sup>	<0.30	0.30-0.6	≥0.60
Pressure half time (ms) <sup>‡</sup>	<130	130-200	>200
<b>Changes in echo parameters during FU</b>			
Increase in mean gradient (mmHg)	<3	3-5	>5
<b>Stress echocardiography</b>			
Increase in mean gradient (mmHg)	<5	5-12	>12



# Prosthetic Mitral Valve Regurgitation Echo Criteria

<b>TABLE 3 Assessment of PVL Severity in Prosthetic Aortic Valves</b>						
<b>3-Class Grading Scheme</b>	<b>None/Trace</b>	<b>Mild</b>		<b>Moderate</b>		<b>Severe</b>
<b>4-Class Grading Scheme</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>Unifying 5-Class Grading Scheme</b>	<b>Trace</b>	<b>Mild</b>	<b>Mild to Moderate</b>	<b>Moderate</b>	<b>Moderate to Severe</b>	<b>Severe</b>
<b>Doppler echocardiography</b>						
<b>Structural parameters</b>						
Sewing ring motion*	Usually normal	Usually normal	Normal/abnormal†	Normal/abnormal†	Usually abnormal†	Usually abnormal†
LV size‡§	Normal	Normal	Normal	Normal/mildly dilated	Mildly/moderately dilated	Moderately/severely dilated
<b>Doppler parameters (qualitative or semiquantitative)</b>						
<b>Jet features*</b>						
Extensive/wide jet origin	Absent	Absent	Absent	Present	Present	Present
Multiple jets	Possible	Possible	Often present	Often present	Usually present	Usually present
Proximal flow convergence visible	Absent	Absent	Absent	Possible	Often present	Often present
Vena contracta width, mm (color Doppler)‡	Not quantifiable	<2	2 to <4	4 to <5	5 to <6	≥6
Jet width at its origin, % LVOT diameter (color Doppler)*	Narrow (<5)	Narrow (5 to <15)	Intermediate (15 to <30)	Intermediate (30 to <45)	Large (45 to <60)	Large (≥60)
Jet density (CW Doppler)††	Incomplete or faint	Incomplete or faint	Variable	Dense	Dense	Dense
Jet deceleration rate (PHT), ms (CW Doppler)‡§¶	Slow (>500)	Slow (>500)	Variable (200-500)	Variable (200-500)	Variable (200-500)	Steep (<200)
Diastolic flow reversal in the descending aorta (PW Doppler)‡§¶	Absent	Absent or brief early diastolic	Intermediate	Intermediate	Holodiastolic (end-diastolic velocity >20 to <30 cm/s)	Holodiastolic (end-diastolic velocity ≥30 cm/s)
Circumferential extent of PVL, % (color Doppler)*	Not quantifiable	<5	5 to <10	10 to <20	20 to <30	≥30
<b>Doppler parameters (quantitative)</b>						
Regurgitant volume, mL/beat‡#	<10	<15	15 to <30	30 to <45	45 to <60	≥60
Regurgitant fraction, %‡	<15	<15	15 to <30	30 to <40	40 to <50	≥50
Effective regurgitant orifice area, mm <sup>2</sup> ‡**	<5	<5	5 to <10	10 to <20	20 to <30	≥30
<b>CMR</b>						
Regurgitant fraction, %††	<15	<15	15 to <30	30 to <40	40 to <50	≥50

# SVD definition

**EXCLUDING:** infective endocarditis, isolated prosthetic-patient-mismatch without deterioration in valve function, isolated perivalvular regurgitation, frame distortion without abnormal leaflet function

<b>SVD Stage 0</b>	• No significant change from immediate post implantation <sup>1</sup>
<b>SVD Stage 1</b>	• Morphological leaflet abnormality without significant hemodynamic changes <sup>2</sup>
<b>SVD Stage 2S</b>	• Moderate stenosis <sup>3</sup>
<b>SVD Stage 2R</b>	• Moderate regurgitation <sup>4</sup>
<b>SVD Stage 2RS</b>	• Moderate stenosis and moderate regurgitation
<b>SVD Stage 3</b>	• Severe stenosis and/or severe regurgitation

No significant new hemodynamic abnormality (**mean gradient <5mmHg** AND intravalvular regurgitation <moderate) without morphological leaflet abnormality (e.g. leaflet thickening).

Leaflet calcification, sclerosis, thickening or new leaflet motion disorder.

**Must include >3mmHg increase from baseline status.** Need to clinically exclude thrombotic leaflet thickening. If reversible with anticoagulation should be considered as stage 1.

If the main component is paravalvular then should not be considered as SVD.

# Definitions of Stages of SVD following MVR

Baseline echo at discharge and 30-days  
Follow-up echo every year

## Stage 0

Normal bioprosthetic valve morphology and function.

## Stage 1

*Presence of morphological abnormalities of valve leaflets:  
thickening, calcification, fibrosis, tear*

## Stage 2

*Increase in mean gradient  $\geq 3$  mmHg with decrease in EOA  $\geq 0.3$  cm<sup>2</sup>  
AND/OR  $\geq 1$  grade new onset or transvalvular AR with final  
grade of moderate MR*

## Stage 3

*Increase in mean gradient  $\geq 5$  mmHg with decrease in EOA  $\geq 0.6$  cm<sup>2</sup>  
AND/OR  $\geq 2$  grades new onset or worsening of transvalvular MR with final  
grade of severe MR*

Discuss cut-point values  
for delta EOA and  
gradient

Importance of using EOA  
by continuity (not PHT)

Consider including delta  
peak E velocity and DVI