

## CLINICAL PRACTICE GUIDELINE FOR EVALUATION AND MANAGEMENT OF PATIENTS WITH SEVERE AORTIC STENOSIS

- **Title:** Clinical Practice Guideline for Evaluation and Management of patients with Severe Aortic Stenosis
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- **Abstract:**
- **Background:** This paper abstracts the Clinical Practice guideline (CPG) for Evaluation and Management of patients with Severe Aortic Stenosis in the Peruvian Social Security (EsSalud).

**Objective:** to provide evidence-based clinical recommendations for Evaluation and Management of patients with Severe Aortic Stenosis in EsSalud.

**Methods:** a guideline task force (GTF) was formed with cardiologists, cardiovascular and thoracic surgeons; and methodologists. The group proposed 7 clinical questions to be answered in this Clinical practice guideline (CPG). Systematic searches of preview reviews were performed and when it was necessary, primary studies from PubMed and CENTRAL during 2018 were reviewed. The evidence was selected aiming to answer each proposed question. Certainty of evidence was evaluated using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. In periodical work sessions, the group used GRADE methodology for reviewing the evidence and formulating recommendations, good clinical practice items and the flowchart of management. Finally, the CPG was approved by Resolution N° 007-IETSI-ESSALUD-2018.

**Results:** This CPG approached seven clinical questions, divided into two topics: initial evaluation and management. Based on these questions; one strong recommendation, eight weak recommendations, 16 good clinical practice items and one flowchart were formulated.
- **Conclusion:** This paper abstracts the methodology and evidence-based conclusions of the CPG for Evaluation and Management of patients with Severe Aortic Stenosis in EsSalud.

**Key words:** Practice Guideline, GRADE Approach, Severe Aortic Stenosis

- PICO questions for CPG:

<b>DIAGNOSIS</b>			
<b>Question 1: In patients with aortic stenosis, what severity classification system should be used?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>
- Patients with aortic stenosis	-	-	- Classification systems for aortic stenosis associated with mortality
- Patients with aortic stenosis	- Comparison of different classification systems for aortic stenosis	- Comparison of different classification systems for aortic stenosis	- Mortality

<b>MANAGEMENT</b>			
<b>Question 2: In patients with severe aortic stenosis, which surgical risk score should be used: STS or EuroSCORE II?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>
- Patients with severe aortic stenosis undergoing SAVR or TARV indistinctly	- STS	- EuroSCORE II	- Prediction of post-operative mortality
- Patients with severe aortic stenosis undergoing SAVR	- STS	- EuroSCORE II	- Prediction of post-operative mortality
- Patients with severe aortic stenosis undergoing ARV	- STS	- EuroSCORE II	- Prediction of post-operative mortality
<b>Question 3: In patients with severe asymptomatic aortic stenosis, should aortic valve replacement be performed early or wait for the patient to develop symptoms?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>
- Patients with severe asymptomatic aortic stenosis	- Early aortic valve replacement	- Conservative management	- Mortality - Cardiovascular mortality
<b>Question 4: In patients with severe symptomatic aortic stenosis, should surgical aortic valve replacement (SAVR) or transcatheter aortic-valve replacement (TAVR) be performed?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>

- Patients with severe symptomatic aortic stenosis and low surgical risk	- Transcatheter aortic-valve replacement (TAVR)	- Surgical aortic valve replacement (SAVR)	- 30-days mortality - Late mortality - Stroke - Myocardial infarction - Acute kidney injury - Major vascular complications - Major bleeding - Permanent pacemaker implantation.
- Patients with severe symptomatic aortic stenosis and intermediate surgical risk	- Transcatheter aortic-valve replacement (TAVR)	- Surgical aortic valve replacement (SAVR)	- 30-days mortality - 12-months mortality - Stroke - Myocardial infarction - Acute kidney injury - Major bleeding - Pacemaker implantation - Moderate or severe aortic regurgitation
- Patients with severe symptomatic aortic stenosis and high surgical risk	- Transcatheter aortic-valve replacement (TAVR)	- Surgical aortic valve replacement (SAVR)	- 30-days mortality - Late mortality (1 year, 3 years and 5 years) - Stroke y transient ischemic attack - Myocardial infarction - Acute kidney injury - Major vascular complications - Major bleeding
- Patients with severe asymptomatic and inoperable aortic stenosis	- Transcatheter aortic-valve replacement (TAVR)	- Standard treatment	- 12-months mortality - 2-years mortality - 3-years mortality - 5-years mortality

**Question 5: In patients with severe aortic stenosis in whom TAVR is decided, what should be the first-choice approach for TARV**

POPULATION	INTERVENTION	COMPARATOR	OUTCOME(S)
- Patients who are candidates for TARV	- TF-TAVR (transfemoral transcatheter aortic valve replacement)	- TSc- TAVR (trans-subclavian transcatheter aortic valve replacement)	- 30-days mortality - Mortality per year - Major complications after 30 days - Acute kidney injure after 30 days.
- Patients who are candidates for TARV	- TF-TAVR (transfemoral transcatheter aortic valve replacement)	- TA- TAVR (trans-apical transcatheter aortic valve replacement)	- 30-days mortality - Mortality per year - Vascular complications - Acute kidney injure

			<ul style="list-style-type: none"> <li>- New Pacemaker implantation</li> <li>- Bleeding after 30 days</li> </ul>
<b>Question 6: In patients with severe aortic stenosis in whom TAVR is decided, who also have severe coronary artery disease (CAD), should percutaneous coronary intervention be performed?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>
- Patients who are candidates for TAVR and have CAD	- TAVR and percutaneous coronary intervention	- TAVR without percutaneous coronary intervention	<ul style="list-style-type: none"> <li>- 30-days mortality</li> <li>- Cardiovascular mortality</li> <li>- 6-months to 1-year mortality</li> <li>- Main vascular complications at the access site.</li> <li>- Renal failure</li> </ul>
- Patients who are candidates for TAVR and have CAD	- Concomitant TAVR and percutaneous coronary intervention	- TAVR with prior percutaneous coronary intervention	<ul style="list-style-type: none"> <li>- 30-days mortality</li> <li>- Cardiovascular mortality</li> <li>- 6-months to 1-year mortality</li> <li>- Main vascular complications at the access site.</li> <li>- Renal failure</li> </ul>
<b>Question 7: Should a Heart Team be formed to decide the management of the patient with severe aortic stenosis?</b>			
<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARATOR</b>	<b>OUTCOME(S)</b>
- Patients with severe aortic stenosis	- Evaluation by the Heart team to decide the intervention (TAVR or SAVR)	- No evaluation by the Heart Team	<ul style="list-style-type: none"> <li>- Mortality</li> <li>- Quality of life</li> <li>- Complications</li> </ul>