



**The Society of Thoracic Surgeons**  
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# News

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## **STS Press Release**

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## **Response to NEJM Article on Role of Bioprosthetic Aortic Valves**

***From the American College of Cardiology and The Society of Thoracic Surgeons***

Bioprosthetic aortic valves play a central role in the treatment of patients with severe aortic valve disease. They increasingly are used in patients undergoing surgical aortic valve replacement (SAVR), as well as more recently in patients undergoing transcatheter aortic valve replacement (TAVR). In both groups, there are abundant data regarding safety and effectiveness. In SAVR there has been an extensive long-term experience with these tissue prostheses, while TAVR has been studied in randomized clinical trials and registries more closely than any other therapeutic valvular procedure. In both sets of data, patients have been found to receive overall benefit from the bioprosthetic valve, and adverse events related specifically to the valves have been infrequent. The U.S. Food and Drug Administration (FDA) has reviewed the available data and has clearly stated that "the benefits of using these devices for the currently approved indications continue to outweigh the risks."

Recently however, there has been concern raised in both patient groups about impaired leaflet mobility assessed by 4D computed tomography (CT) and transesophageal echocardiography (TEE) early post-procedure that is presumably related to thrombus of the valve leaflets. This issue has been highlighted in a [New England Journal of Medicine article](#) with two accompanying editorials by [the FDA](#) and [members of the STS/ACC Transcatheter Valve Therapies Registry Steering Committee](#).

The issues related to this imaging abnormality are complex, including the incidence of the abnormality and its clinical significance, if any, as well as any possible need for treatment of the thrombus. Rigorous scientific efforts are being made to design appropriate trials to study these issues. In the interim, remember that:

1. Both TAVR and SAVR are very effective in appropriately selected patients;
2. The role of this imaging abnormality in predicting clinical events in large numbers of patients is unknown;
3. Use of anticoagulation in the absence of other indications should be weighed in carefully with the increased risk for bleeding; and
4. Any change in therapeutic regimens to address this imaging abnormality needs to be considered carefully.

In the absence of any rigorously controlled scientific data, clinicians and patients alike should be reassured that there is an abundance of data dealing with the clinical safety and efficacy of TAVR and SAVR. Concerns exist that identification of such an abnormality might lead to a change in protocols in which patients are uniformly dismissed on anticoagulants whether they be warfarin or new anticoagulants from what is often standard of care in individual institutions. This potentially could lead to an increase in bleeding complications, which may be frequent in these high-risk individuals and may be more of a problem than any adverse clinical problems related to this imaging abnormality.

Accordingly, ACC and STS believe that physicians should continue treating patients according to their own institutional and individual protocols with both SAVR and TAVR. These physicians should be encouraged to participate in the upcoming scientific trials that will study the incidence of this imaging modality in both TAVR and SAVR and the relationship (if any) to adverse clinical events. In patients who develop a clinical event, whether that be changes in the hemodynamic performance of the valve, late stroke, myocardial infarction, or unexplained heart failure, there should be consideration of further tests, including 4D CT and TEE to assess valve performance, and then treatment options should be individualized.

To access the CHSD outcomes directly visit [www.sts.org/congenital-public-reporting-module-search](http://www.sts.org/congenital-public-reporting-module-search).

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Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 6,900 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society's mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.