

## Blood clots may complicate aortic valve replacements

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Heart valve replacements made from tissue (bioprosthetic valves) have long been thought to be spared the complication of blood clot formation. Researchers have now found that about 15 percent of all bioprosthetic aortic heart valve patients develop blood clots on the leaflets affecting valve opening, regardless of whether the patient received the new valve via open-heart surgery or a minimally-invasive catheter procedure, a new study from the Cedars-Sinai Heart Institute shows.

The study, published online today by the *New England Journal of Medicine* and scheduled for the Nov. 26 print edition, also shows that anticoagulant medications such as Warfarin quickly resolve the clotting issue for all <u>patients</u>, regardless of the type of valve or procedure.

Valve replacement is a treatment for <u>aortic</u> <u>stenosis</u>, which is narrowing of the valve between the main pumping chamber of the <u>heart</u> and the aorta, the main artery that carries blood from the heart to the rest of the body. According to the National Institutes of Health, about two percent of people over 65 years of age develop aortic stenosis. Symptoms include chest pain, fatigue, heart palpitations and breathing problems.

"The clinical impact of blood clots on stroke will need to be studied further definitively despite some preliminary signals that clots may predispose to mini strokes," said Raj Makkar, MD, associate director of the Cedars-Sinai Heart Institute, and who is widely regarded as a world leader in performing the minimally invasive heart valve procedures. "Transcatheter and surgically implantable tissue valves are life saving devices in patients with aortic valve stenosis. These findings allow us a potentially valuable opportunity to further optimize the outcomes of these procedures. We are not recommending that all patients with these devices be on blood thinners but clearly further studies need to be done to define best

medication regimens."

Said Hasan Jilaihawi, MD, director of Interventional Cardiology Imaging at the Cedars Sinai Heart Institute, "Our study also shows that the novel technique of four-dimensional high resolution CT is superior to routinely used transthoracic cardiac echocardiography for the detection of these valve leaflet clots."

Makkar began the study when a high-resolution imaging study of one of the patients in a clinical trial who had stroke showed clot formation on the aortic valve leaflets that open and close to regulate the flow of blood. "We wanted to find out if patients undergoing a tissue valve procedure are susceptible to blood clots on the leaflets and study the clinical consequences of the same. We also wanted to understand whether our aortic valve patients were more susceptible to having blood clots and whether those clots could indicate that the patient might experience a neurological complication - a mini-stroke," Makkar said.

"This brilliant work highlights a common, previously unsuspected complication of heart valve placement. Such valve replacements are becoming increasingly common as they can now be done with minimally invasive procedures," said Eduardo Marbán, MD, PhD, director of Cedars-Sinai Heart Institute. "Early recognition of clot formation on the valves could save lives and prevent stroke, as those affected could be effectively treated using blood thinners."

The study is the first systematic scientific study using four-dimensional CT angiography to assess valve performance of TAVR and surgical tissue valves in patients with aortic stenosis.

Researchers followed 187 patients who received a new valve by undergoing a transcatheter procedure or open-heart surgery to receive a new valve. All patients in the study had high-resolution imaging so



researchers could detect valve problems such as clots and reduced leaflet motion. Findings include:

- About 15 percent of all valve patients will experience <u>blood clots</u> on the valve's leaflets:
- In the vast majority of patients, an anticoagulation medicine like Warfarin, will dissolve the clots;
- There was some suggestion that the incidence of mini-stroke - called transient ischemic attacks - but not full blown strokes, could be increased by untreated <u>valve</u> leaflet clots but this was inconclusive and requires further study.

Provided by Cedars-Sinai Medical Center

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