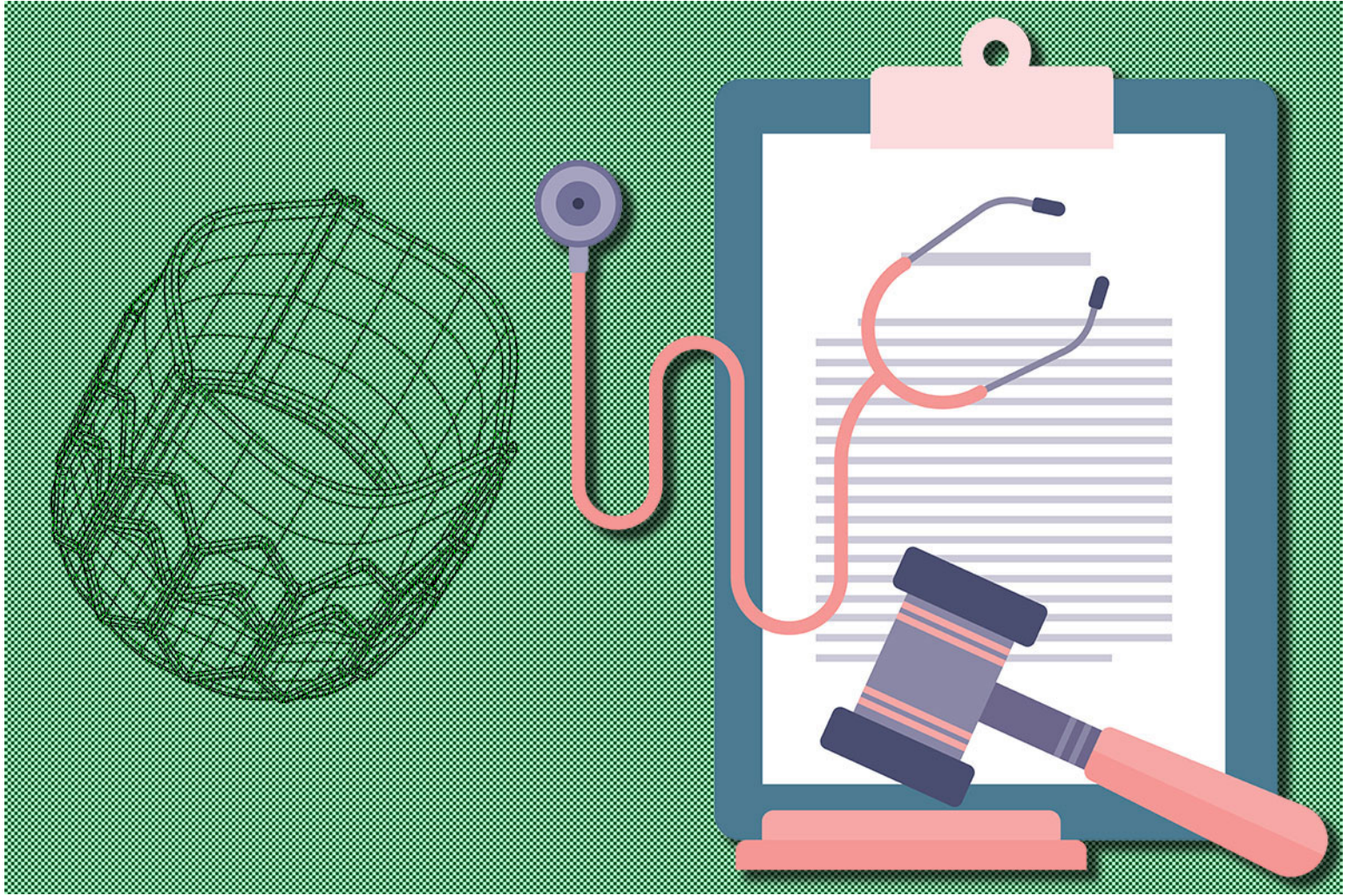




Business of Medicine | Lessons Learned From a Medical Malpractice Lawsuit

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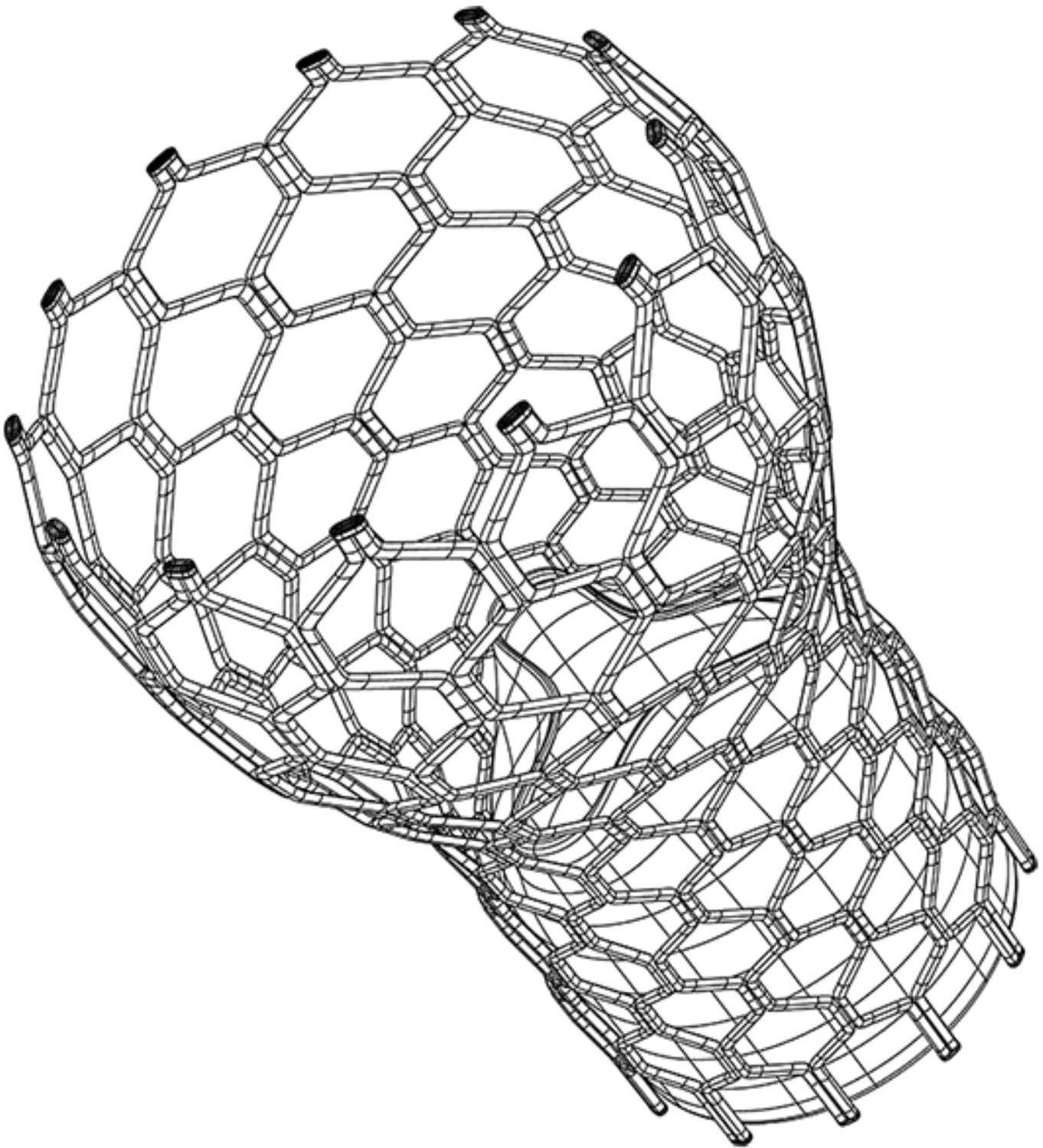
Cardiology Magazine



A mid-70-year-old male patient experienced a left ventricle perforation and cardiac arrest during a TAVR procedure. He did not recover and died six days later. His medical history was notable for a body mass index of 26.3, being a former smoker, past nephrectomy, chronic obstructive pulmonary disease, and a horizontal heart.

Six months prior to his TAVR, a transthoracic echo revealed he had severe aortic valve stenosis. He also had a large incisional hernia that required repair, but needed the aortic stenosis treated before hernia surgery.

Two months before the TAVR procedure, the patient had an office visit with the cardiac surgeon, who documented that he was mostly asymptomatic except for exertional shortness of breath. The plan was for a full work-up to determine the valve replacement approach.



The cardiac surgeon subsequently recommended TAVR believing it to be safer due to the patient having only one kidney and a low creatinine clearance. A multidisciplinary committee approved this, but this was not documented by the cardiac surgeon. The patient consented to TAVR.

On the day of the procedure, the patient went to hospital. The anesthesiologist incorrectly circled bicuspid aortic valve on the chart. Per the cardiac surgeon, the interventional cardiologist advanced the wire across the valve without releasing the built-up tension, which caused the wire to perforate the left ventricle. The patient began decompensating.

The anesthesiologist stated there was no tamponade on transesophageal echocardiography and decompensation was likely related to aortic regurgitation.

Cardiopulmonary bypass was planned but the machine brought in by the perfusionist did not have the proper size connectors resulting in a 10-minute delay during which the patient received CPR. The anesthesiologist then did see a tamponade and pericardial effusion. A pericardiocentesis was performed while the patient was placed on bypass. The perforation was repaired and the valve replaced. The patient was transferred to the ICU where he remained unresponsive.

Additional Resources

- [ESC/EACTS vs. ACC/AHA Guidelines for Severe Aortic Stenosis: Key Points](#)
- [Transcatheter Aortic Valve Replacement](#)
- [Valvular Heart Disease Guideline Comparison: Key Points](#)

Three days later a brain MRI showed diffuse cortical injury. The neurologist advised the family that the patient had brain damage and the family decided to extubate. The cardiac surgeon then consulted with a neuroradiologist who recommended further monitoring resulting in the cardiac surgeon recommending reintubation. Two additional neurologists agreed to continue with supportive care while acknowledging a grave prognosis.

Three days later MRI findings were worse, and the patient was extubated and died. There was no autopsy.

The family sued alleging 1) TAVR on the bicuspid valve was not approved by the U.S. Food and Drug Administration (FDA) at the time in a low-risk patient; 2) there was no multidisciplinary discussion and proper evaluation of the risk of TAVR related to the patient's anatomy, and 3) a delay in him being placed on bypass.

The defense was successful in proving the patient needed valve replacement; TAVR was an appropriate choice and often done on patients with horizontal hearts and bicuspid valves. Further, the FDA was a month away from approving TAVR for low-risk patients and it was more related to health insurance coverage rather than a surgical risk. Finally, perforation is a known risk.

However, it was determined there was delay getting the patient on bypass and a settlement was made to the family.



"Three P" Analysis

The "Three P's" refer to the three key elements to reduce practitioner risk related to malpractice litigation.¹



Prevent Adverse Events

An analysis of the closed lawsuit, including a review of medical records and the deposition testimony of both plaintiff and defense experts, found several contributing factors to this cardiac event.

1. Misinterpretation initially by the anesthesiologist of the echocardiogram whether there was tamponade affecting the cardiac surgeon's decision.

2. Poor technique in advancing the guidewire causing perforation.
3. The wrong size equipment brought for bypass machine causing a 10-minute delay.



Preclude a Malpractice Case Despite an Adverse Event

1. Patient selection: document the reasons the patient is a candidate for a TAVR procedure vs. other options. If FDA approval is an issue, address that in record documentation.

2. Understand possible challenges and anticipate possible complications to be prepared accordingly.
3. Help assist family members understand why there may be conflicting medical opinions and recommendations for treatment and document those family discussions.



Prevail in Lawsuits When a Claim is Made

Correct and comprehensive documentation of patient's symptoms, valvular anatomy and pathology is helpful to show

that the surgeon was aware of increased risk factors. Documentation should include the thought process for the treatment plan including discussions, and approval, with hospital committees.

Reference

1. Feldman DL. Prevent, Communicate, Document: Medical Malpractice Data Help Us Manage Risk. The Doctor's Advocate. Available [here](#).

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The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each health care provider considering the circumstances of the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.



Clinical Topics: **Noninvasive Imaging, Magnetic Resonance Imaging**

Keywords: *ACC Publications, Cardiology Magazine, Cardiologists, Magnetic Resonance Imaging, Hospitals, Office Visits, Insurance Coverage*

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