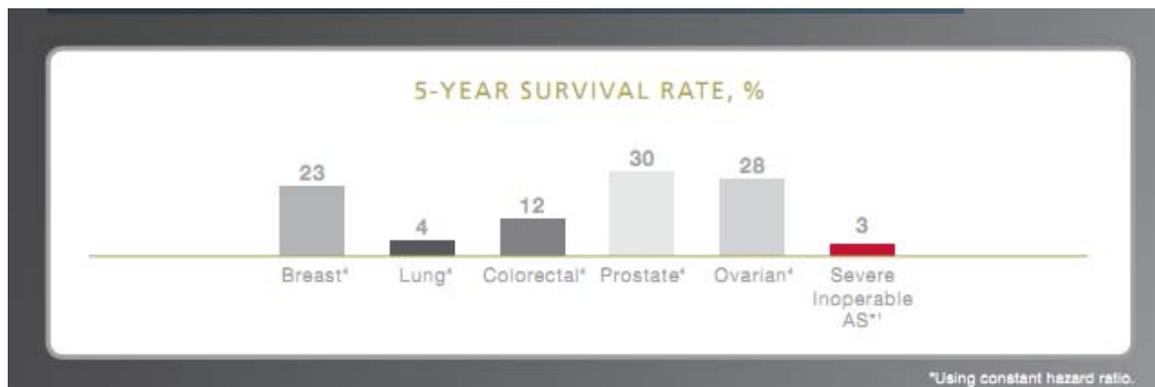


Facts & Figures

U.S. Aortic Stenosis Disease Prevalence & Treatment Statistics

- Cardiovascular disease is the number one cause of death, killing more than 600,000 Americans each year.
- According to the American Heart Association, more than five million Americans are diagnosed with heart valve disease each year.
- Heart valve disease can occur in any single valve or a combination of the four valves, but diseases of the aortic and mitral valves are the most common, affecting more than five percent of the population.
- While up to 1.5 million people in the U.S. suffer from AS, approximately 500,000 within this group of patients suffer from severe AS. An estimated 250,000 patients with severe AS are symptomatic.
- An echocardiogram (echo) is the primary imaging test used to diagnose severe AS.
- Without an aortic valve replacement (AVR), 50 percent of patients will not survive more than an average of two years after the onset of symptoms.
- The predicted survival of inoperable patients with severe AS who are treated with standard non-surgical therapy is lower than with certain metastatic cancers.



- Studies show that severe AS is undertreated. At many hospitals, more than 50 percent of patients that receive an echo and show the presence of the disease are not referred to a surgeon to be evaluated for an AVR. The absence of chest pain symptoms and overestimating risks associated with the AVR procedure have been identified as some of the reasons lack of patient referrals occur.
- An estimated 85,000 AVR procedures are performed every year in the U.S.

Facts & Figures

Transcatheter Aortic Valve Replacement (TAVR)

- The first successful TAVR procedure was performed in France on April 16, 2002, by Alain Cribier, M.D., University Hospital Charles Nicolle in Rouen, France.
- The Edwards SAPIEN transcatheter valve received CE Mark for commercial sale in Europe in 2007.
- To date, more than 30,000 patients have been implanted with Edwards' transcatheter valves by multi-disciplinary heart teams worldwide.
- Data from the inoperable patient group in The PARTNER Trial were published in *The New England Journal of Medicine* in the fall of 2010.
- The Edwards SAPIEN valve was approved in November of 2011 by the U.S. Food and Drug Administration (FDA) for the treatment of patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.
- Certain inoperable patients with severe, symptomatic native valve aortic stenosis are not candidates for TAVR due to the presence of other co-existing medical conditions or disease processes that would preclude the expected benefit from correction of the aortic stenosis.
- The Edwards SAPIEN valve is the first and only FDA-approved transcatheter aortic heart valve in the U.S.
- The PARTNER Trial was the world's first randomized controlled trial of TAVR, and importantly, cardiac surgeons and interventional cardiologists were brought together in a clinical trial to collaborate to evaluate and treat patients.

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