MEMORANDUM

Introduction

This memo addresses an innovative technology that is an alternative to Open-Heart surgery for patients who suffer from severe aortic stenosis (AS). This disease is caused when the aortic valve in the heart becomes too narrow due to calcium build up, which effects the flow of blood in the body. Approximately 250,000 people in the United States suffer from AS and require Open-Heart surgery (John Muir Health). Instead of operating on a completely exposed heart, this Food and Drug Administration (FDA) approved technology is utilized by creating a small incision near the groin, and then inserting the Sapien Transcatheter Aortic Valve through it. Not all patients who need Open-Heart surgery qualify for it due to certain health risks, in fact there are a high number of non-operative patients who fit under this category. Therefore, this method provides the high-risk patients who suffer from severe AS with a safer option. This memo discusses, background and difficulty of Open-Heart surgery, living with Aortic Stenosis, the difference between TAVR and Open-Heart surgery, long term outcomes of TAVR vs Open-Heart surgery, and finishes with a conclusion.

Background and Difficulty of Open-Heart Surgery

Open-Heart surgery is commonly done to accomplish the following: to either replace or repair heart valves to improve the efficiency of blood flow to and from the heart, to insert medical devices to regulate the beating of the heart or to perform a Coronary Artery Bypass Graft (CABG) where the arteries of the heart become narrow and hard thus this bypass is necessary to regulate the blood flow. This surgery is done by temporarily stopping the heart and then hooking it up to a heart-lung machine while the remainder of the procedure is completed. One of the main difficulties of traditional heart surgery is that not all patients are "healthy" enough to be operated on. Those who are over 70 years old, are 50 pounds overweight, smoke or suffer from diseases such as Diabetes, Hypertension or Lung Disease are not considered good candidates for this procedure. One risk of Open-Heart surgery that is most commonly found among patients with diabetes, are obese or have already undergone a CABG, is a chest wound infection. Other risks include blood clots, ruptured blood vessels, Pneumonia, Kidney Failure and Heart Attack.

Discussion

Life with Aortic Stenosis (AS)

Aortic Stenosis is a disease one can be born with, can be developed from rheumatic heart disease caused from strep throat or it can be developed over time due to high cholesterol for those who are older. According to the American Heart Association people do not experience AS symptoms until there is a significant decrease in the amount of blood flow in their body. However, some symptoms include heart murmurs, chest pain and irregular heartbeats. According to a Chief Medical Officer of the American Cancer Society, those who experience such symptoms, suffer from severe AS and do not receive a valve replacement, only live about two to three years. Those patients who are diagnosed with mild and moderate AS do not require surgery but are recommended to avoid certain physical activities.

Differences Between TAVR and Open-Heart Surgery

As stated before, the TAVR procedure is done by making a small incision near the groin and then the Edward's Sapien Transcatheter Aortic Valve is inserted through it and into the largest and main blood in the leg, called the femoral artery and that is used as a guide to the heart. Attached to the tube, is the new valve which consists of three cusps made from bovine pericardial tissue (cow tissue) and that is compressed on an expandable balloon stent (Figure 1). Once this new valve makes its way to the aortic valve, the balloon stent is expanded which is when the new valve is put into its designated position (Figure 2). Once this new valve is being replaced, it simply gets rid of what is left of the current valve. After this, the balloon is removed, and the new valve immediately begins taking on the role of the old one. Patients who undergo this procedure typically are able to walk a few hours post operation due to the minimal invasiveness of this surgery.

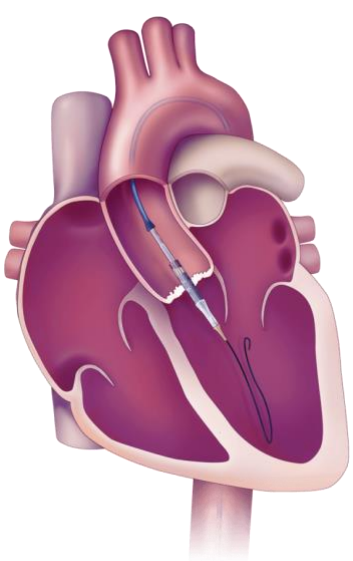

Figure 1: The insertion of the new valve is shown (Edwards LifeSciences, 2018)

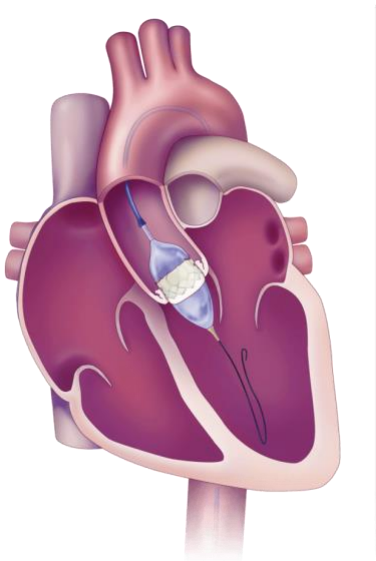

Figure 2: The inflation of the balloon stent and replacement of the new valve is shown. (Edwards LifeSciences, 2018)

Valve replacements completed through Open-Heart surgery are done differently and in a more invasive manner compared to TAVR. To begin with, the chest is completely opened, and the breastbone is separated in order to get to the membrane that covers the heart. Once the membrane is cut through and the heart is exposed, the heart is stopped once connected to a heart-lung machine. After this the valve is opened, gets cut out and the new valve is replaced. The risks that could take place during this operation are higher than the TAVR.

Future Implications

Long Term Outcomes of TAVR vs Open-Heart Surgery

According to the American College of Cardiology, a long-term outcome the TAVR provides that Open-Heart surgery does not, is that the aortic valve's quality of performance is better after a TAVR compared to its performance after Open-Heart surgery. This is significant because it shows the impact surgeries can make with technological advancements that traditional practices cannot. Not only are the functions of the valve better with TAVR, but the death and stroke rates that have been recorded are lower as well compared to those who undergo Open-Heart surgery. For TAVR, the rate is 19.3% while for surgery it is 21.1% (American College of Cardiology, 2016). This new procedure finally provides non-operative high-risk patients with the opportunity of a better quality of life. The implementation and accessibility of TAVR in more hospitals in the U.S and also around the globe, would be a step into the right direction for advancing medical practices.

Conclusion

The Edward's Sapien Transcatheter Aortic Valve is an innovate way to provide non-operative patients a procedure that is safe for them. There has been research to prove that patients who have completed a TAVR operation, show an improvement in their health 30 days after surgery. Patient's experience a less harsh recovery, are relieved of their symptoms at a fast rate, show an improvement in their overall heart function and are able to participate in physical activities soon after. These factors provide patients with the confidence they need to continue to live their life to the fullest, without having to worry about issues with their heart. Not only does this procedure give patients a better recovery compared to the traditional valve replacements, but it is more cost-effective as well. The FDA's approval for this TAVR is a perfect example of putting the patient's needs above all and creating technology that puts their health first.

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