TAVI: A Safe Alternative for Aortic Stenosis?

Christie Linh

University of California, Merced

Keywords: Heart, Aortic Stenosis, TAVI, SAVR

Abstract

Aortic valve stenosis is a heart condition where the aortic valve narrows leading to a decrease in blood flow which can make the heart work harder to pump blood. As of today, there are two methods to treating this condition, TAVI and SAVR. Transcatheter Aortic Valve Implantation (TAVI) is a method used to replace the aortic valve located in the heart through the blood vessels. This method is a less invasive method as opposed to Surgical Aortic Valve Replacement (SAVR) which is the traditional method that requires open heart surgery. There is still doubts as to whether TAVI is considered to be a more successful technique as compared to the traditional technique. Based on a large amount of evidence, the debate of TAVI versus SAVR will be further explored to establish which method is more beneficial. This review will analyze the numerous studies conducted on the different risks and complication that can occur with TAVI as well as its health benefits in contrast to SAVR.

Introduction

TAVI along with SAVR are the two most common methods to replace the aortic valve due to severe aortic valve stenosis. Aortic valve stenosis is a condition where the aortic valve narrows which leads to a decrease in blood flow which can make the heart work harder in order to pump enough blood to reach the entire body (Malaisrie 2016). SAVR is considered to be the more traditional method for dealing with patients suffering from heart conditions seeing as how SAVR deals with open heart surgery.

Those that are typically selected to have a TAVI are patients who for example, have severe aortic stenosis, and are determined to be at high risk for open heart surgery. There are two different approaches that can be used during TAVI, the transfemoral approach and the transapical approach. The transfemoral approach is where a catheter is fed through the femoral artery, a large artery located on the leg, all the way to the aorta in the heart (Malaisrie 2016). The transapical approach is where a small incision is made in the chest and a catheter is fed either through an artery or through the left ventricle in order to reach the aorta (Malaisrie 2016). Both approaches either require little to no surgical incision through the chest leaving this technique to be a safe, minimally invasive method.

TAVI appears to favor patients in the age range of 60 and above due to the fact that these patients tend to pose a higher risk for the surgical approach because of their fragility (Lawrie 2012). These patients that are deemed to not be suitable for heart surgery, are more than likely suitable for the TAVI method. This approach shows a lot of promise because it is more technologically advanced than the more traditional method. It has been seen that although TAVI has its benefits, there are risks and complications that have been associated with it. In this review, the effect of TAVI and SAVR has on mortality will be examined based on the different complications each

procedure has as well as the cost-effectiveness of the surgeries. It is important to review the different types of complications that can occur to a patient who ops to undergo TAVI or SAVR in order to ultimately decide which approach proves to be the safest**.**

Discussion

The Effect of TAVI and SAVR on Mortality Rate

TAVI has become an amazing alternative for many patients whose circumstances make them unfit for the traditional SAVR. And although this may be the case, data has shown that the mortality rate of TAVI is substantially higher than that of SAVR. A mortality rate, also known as a death rate, is a measure of the amount of deaths in a population and in this case, the population of people who suffer aortic stenosis. A mortality rate can be divided into two, early and late. Both of which are determined based on the stage at which a patient has died. Early, or short term, mortality rates are the amount of deaths that have occurred in the early stages of treatment or immediately after treatment. Late mortality rates are the amount of deaths that occurred in the late stages of treatment or after a period of time following a treatment.

In a study done in the International Journal of Cardiology by Hisato and Takagi, they were able to determine that TAVI did not improve the short term mortality rate for patients who were at moderate to high risk for SAVR, but not inoperable (Takagi et al., 2016). In their analysis of 19 observational studies, it was discovered that the average 1-year and 3-year survival rates after TAVI were 82.7% and 71.3% while SAVR had survival rates of 84.8% and 77.9% (Takagi et al., 2016). This meant that 82.7% of patients who underwent TAVI survived for a year while 84.8% of SAVR patients survived for a year. Now looking at the 3-year survival rates, 71.3% of TAVI patients survived while 77.9% of SAVR patients survived. This data shows that although TAVI gives patients an alternative course of treatment, it also decreases their chances of survival

compared to the traditional SAVR method. Patients with severe aortic stenosis pose to have greater mortality with TAVI over SAVR. It has also been suggested that patients with more cardiac related dysfunctions pose a greater operating risk which can in turn affect TAVI's survival rate.

Based on research done by Hayashida et al., postprocedural aortic regurgitation after TAVI has been recently identified as an indicator of late mortality. Aortic regurgitation is a condition in the heart where the aortic valve is unable to close properly leading to the leakage of blood flow back into the heart ventricle instead of to the rest of the body. Post procedural aortic valve regurgitation can occur because TAVI requires a stent-like bioprosthesis, a heart valve containing tissue of an animal, to be placed and compressed against the original aortic valve without having it resected (Hayashida et al., 2012). The calcification of the original valve can create a space between the bioprosthesis and the original aortic valve thus leading to a leakage of blood (Hayashida et al., 2012). It is also thought that mild aortic regurgitation can be associated with a 1-year mortality increase. The irony in this is that TAVI is a method that is to be used to help with cardiac functions, but it is in turn creating a new cardiac related condition. Since TAVI is a technique that is still being researched on, there are numerous risks and complications that can occur.

The Risks and Complications of TAVI

According to the data collected from many experimental studies, there are approximately five different complications that can occur due to TAVI. As mentioned earlier, aortic regurgitation is a very common risk that can occur ultimately leading to a smaller chance of survival. Many patients ended up requiring a permanent pacemaker implantation after a TAVI procedure. In one study, patients who received a permanent pacemaker implantation displayed over time an insufficiency in development of their left ventricular ejection fraction. An ejection fraction

measures how well the right or left ventricle pumps blood within each heart beat (Takagi et al., 2016). Based on the data collected, it can be assumed that a permanent pacemaker implantation is an independent indicator of a decrease in the left ventricular ejection fraction. The dysfunction of blood circulation throughout the body can ultimately affect a patient's long term survival rate after TAVI.

Not only can the left ventricle be affected by TAVI, but the right ventricle can also be affected as well. Another study that was conducted by Crouch et al. in 2015, examined patients with a significant increase in right ventricle dysfunction amongst those post TAVI procedure. Their study discusses how the right ventricular ejection fraction was lower in TAVI patients compared to SAVR patients. The right ventricle is made up of a thin compliant wall, therefore the researchers suggest that the increase in left ventricular and atrial pressure can lead to straining of the right ventricle ultimately lowering the right ventricular ejection fraction. In their study they discovered that as the right ventricle ejection fraction decreased, the aortic regurgitation fraction increased. The data confirms that TAVI patients with moderate or greater aortic regurgitation had worse right ventricle ejection fraction whereas TAVI patients with mild or less aortic regurgitation did not (Crouch et al., 2015). The study shows that the patients with dysfunction to the right ventricle end up suffering from aortic regurgitation which can ultimately lead to heart failure. Although TAVI has proven to have many complications, SAVR is still a method that involves severe consequences as well.

The Risks of SAVR

Although TAVI has become the new alternative method in treating severe aortic stenosis, SAVR is still considered to be the standard form of care for this heart condition. Despite SAVR being the traditional technique, there is still a risk for all kinds of complications. Major

hemorrhaging, which is the the loss of blood due to a ruptured blood vessel, has been reported to be significantly more likely to occur following SAVR over TAVI (Indraratna et al., 2016). Generuex et al. recently discussed in his study the correlation between SAVR with severe bleeding than TAVI. The amount of major bleeding that occurs from TAVI did not display to have much long term impact on patients unlike SAVR patients. Patients that underwent SAVR had a 21.2% 30-day mortality rate compared to 14.8% 30-day mortality rate for patients that underwent TAVI (Généreux et al., 2014). Within bleeding complications are several predictors. Some of these predictors are vascular complications, procedural complications and baseline anemia (Généreux et al., 2014). Any of these complications of SAVR can lead to the decrease of a patient's survival.

Vascular and procedural complications leading to hemorrhaging is quite common and often difficult to define when it comes to SAVR therefore this review will focus mainly on baseline anemia of SAVR. Baseline anemia is a heart condition where the blood does not have enough healthy red blood cells (Généreux et al., 2014). Combining anemia with the amount of blood that can be lost during surgery can result in major bleeding complications for SAVR. When there is loss of blood during an operation, blood transfusions are used to compensate for the loss. Reports show that the short and long term risks of infection that can occur, increase dramatically as the number of transfusions post surgery increase. Data recorded by Genereux et al. show that SAVR patients receive approximately 2.5 red blood cell units after surgery while TAVI patients receive 0.5 red blood cell units. The transfusion of red blood cell units occurs three almost four times more frequent in SAVR patients than in TAVI patients. After having done an extensive review on the danger of each method, this review will now examine how cost-effective and efficient each method is.

Cost-effectiveness: TAVI vs. SAVR

In a study that was conducted by Burrage et al. in 2017, the initial length of hospital stay lowered by three days for TAVI patients compared to SAVR patients. The average length of stay for those treated with TAVI is about 9.6 days while those treated with SAVR is about 12.2 days (Burrage et al., 2017). Based on those statistics alone, it is clear that patients have a decrease in hospital stay if operated on through TAVI. Along with an early hospital release, experimental trials show that the need for rehabilitation services has also decreased. This study shows that TAVI patients 65% more likely to be discharged straight to their home over a short term rehabilitation center while SAVR patients were only 38% more likely (Reynolds et al., 2016). Because TAVI is less invasive and requires only a small incision to be made, there is no need to have intense physical therapy sessions. SAVR on the other hand, deals with sawing the sternum open in order to conduct open heart surgery therefore it requires more time for hospital stay and rehabilitation.

Despite having a shorter hospital stay and rehabilitation, TAVI is found to be less cost effective compared to SAVR. TAVI procedures were found to be approximately $24,000 more expensive than SAVR procedures (Reynolds et al., 2016). This is mainly due to the more technological advances that come with this procedure. One can say that the high procedure costs are negated by the decrease in hospital stay as well as rehabilitation needs but despite these cuts, the total fees for this procedure still remains higher with $11,260 per patient (Reynolds et al., 2016). According to the study by Reynolds et al., the resources used for TAVI patients and SAVR patients are the same but the nonprocedural and admission costs were significantly higher for TAVI.

Conclusion

After reviewing a numerous amount of research articles TAVI has proven to be a great alternative method for SAVR, but there is still much more research that needs to be done. Although TAVI has shown to be less invasive method due to its technological advances, SAVR displays less risks of complications. Much of the risks that occur during SAVR are complications that can happen to any patient undergoing surgery. The risks that follow TAVI are complications that are due to leakage of blood as a result of inaccurate placement of the bioprosthesis. Although there is an overwhelming amount of evidence proving this, there is still not enough research on the effects of TAVI on low surgical risk patients. Controlled trials on low risk patients must be conducted in order for the results found from TAVI to apply to patients of low and high surgical risk.

References

Burrage, M., Moore, P., Cole, C., Cox, S., Lo, W. C., Rafter, A., . . . Camuglia, A. (2017). Transcatheter aortic valve replacement is associated with comparable clinical outcomes to open aortic valve surgery but with a reduced length of in-patient hospital stay: A systematic review and meta-analysis of randomised trials. Heart, Lung and Circulation, 26(3), 285-295. doi:10.1016/j.hlc.2016.07.011

Crouch, G., Bennetts, J., Sinhal, A., Tully, P. J., Leong, D. P., Bradbrook, C., . . . Selvanayagam, J. B. (2015). Early effects of transcatheter aortic valve implantation and aortic valve replacement on myocardial function and aortic valve hemodynamics: Insights from cardiovascular magnetic resonance imaging. The Journal of Thoracic and Cardiovascular Surgery, 149(2), 462-470. doi:10.1016/j.jtcvs.2014.10.064

Généreux, P., Cohen, D. J., Williams, M. R., Mack, M., Kodali, S. K., Svensson, L. G., . . . Leon, M. B. (2014). Bleeding complications after surgical aortic valve replacement compared with transcatheter aortic valve replacement: Insights from the PARTNER I trial (placement of aortic transcatheter valve). Journal of the American College of Cardiology, 63(11), 1100-1109. doi:10.1016/j.jacc.2013.10.058

Hayashida, K., Lefèvre, T., Chevalier, B., Hovasse, T., Romano, M., Garot, P., . . . Morice, M. (2012). Impact of post-procedural aortic regurgitation on mortality after transcatheter aortic valve implantation. JACC: Cardiovascular Interventions, 5(12), 1247-1256. doi:10.1016/j.jcin.2012.09.003

Indraratna, P., Tian, D. H., Yan, T. D., Doyle, M. P., & Cao, C. (2016). Transcatheter aortic

valve implantation versus surgical aortic valve replacement: A meta-analysis of randomized controlled trials. International Journal of Cardiology, 224, 382-387. doi:10.1016/j.ijcard.2016.09.018

Lawrie, G. M. (2012). Role of transcatheter aortic valve implantation (TAVI) versus conventional aortic valve replacement in the treatment of aortic valve disease. Methodist DeBakey Cardiovascular Journal, 8(2), 4-8. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3405806/

Malaisrie, S., Iddriss, A., Flaherty, J., & Churyla, A. (2016). Transcatheter aortic valve implantation. Current Atherosclerosis Reports, 18(5), 1-12. doi:10.1007/s11883-016-0577-2

Reynolds, M. R., Lei, Y., Wang, K., Chinnakondepalli, K., Vilain, K. A., Magnuson, E. A., . . . Cohen, D. J. (2016). Cost-effectiveness of transcatheter aortic valve replacement with a self-expanding prosthesis versus Surgical Aortic valve replacement. Journal of the American College of Cardiology, 67(1), 29-38. doi:10.1016/j.jacc.2015.10.046

Takagi, H., & Umemoto, T. (2016). Worse survival after transcatheter aortic valve implantation than surgical aortic valve replacement: A meta-analysis of observational studies with a propensity-score analysis. International Journal of Cardiology, 220, 320-327. doi:10.1016/j.ijcard.2016.06.261