Transcatheter Aortic Valve Replacement:

A New Method for the Treatment of Aortic Valve Disease

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Abstract

As heart complications increase among the elderly population, transcatheter aortic valve replacement is a new procedure that can treat many aortic stenosis and congestive heart failure patients. Transcatheter aortic valve replacement is a common medical procedure across Europe; this investigates the possibility of the procedure's adoption as common practice in the United States. Several factors have been identified as key components for adapting to this procedure. Medical institutions must update their catheterization labs and operating rooms as well as train all surgical staff members on the transcatheter valve technology and standard procedures. Intensive care unit and surgical recovery staff must also be adequately prepared to care for patients who undergo transcatheter aortic valve replacement. These changes by medical facilities could potentially allow a great expansion in the number and type of patients the facility is able to treat. Furthermore, patients who are eligible to undergo this surgery are shown to benefit in their post-surgery recovery time and in their overall health. Based on extensive research, medical professionals should be considering adoption of transcatheter aortic valve replacement as a common method for treatment of aortic valve disease.

Keywords: transcatheter aortic valve replacement, aortic replacement

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Few individuals would respond negatively to the idea of elongating the life expectancy of humans through medical means. This fact has been reinforced as the elderly population has grown immensely in the last 100 years. As humans age, wear and tear upon the heart valves is expected but is not without consequences. The aortic valve is the largest valve in the cardiovascular system and is responsible for maintaining blood flow from the heart to the rest of the body. Aortic valve disease is common in patients over the age of 65 and can be caused by stiffening of the aortic valve and inability of the valve to close completely. These patients are often referred for aortic valve replacement. Many patients are ineligible for surgical valve replacement due to an increased risk from age or other coexisting medical disorders (Smith et al., 2011). A large population suffers from a serious medical ailment in which they cannot receive curative treatment.

Furthermore, patients who are good candidates for surgical aortic valve replacement must accept the known risks and life changing consequences of electing to undergo open heart surgery. Some of the common risks from open heart surgery include heart attack, kidney failure, and a mild fever and chest pain for up to six months. To add insult to injury, for each aortic valve replacement surgery the mortality rate ranges from 2.5% to 4.0% (Thomas et al., 2010). One of the two varieties of valves used in open heart surgery requires a patient to take blood thinners for the rest of his or her life. This procedure was once a medical marvel; however, the risks and long-term results are no longer accepted by elderly individuals who desire to maintain active lifestyles. There is a longstanding need for new procedures that correct aortic valve disease in a way that is long lasting and minimally invasive.

For several decades, doctors have possessed the ability to diagnose congestive heart failure and aortic valve stenosis. However, effective treatment has not been offered to every patient with a confirmed heart disorder diagnosis. Clinical trials and preliminary surgical success have introduced the surgical procedure, transcatheter aortic valve replacement (TAVR), as a new treatment option. Transcatheter aortic valve replacement, also referred to as transcatheter aortic valve implantation (TAVI), is completed by placing a new valve within the native aorta. This is a change from the complete removal and replacement of the aorta that occurs in open heart surgery. TAVR was first successfully performed in 2002 and has evolved to become a valid treatment option for patients who require aorta restoration. The procedure originated in Europe, where it is now an established procedure for treatment of aortic stenosis (Palacios, 2012). Since 2002, at least 80,000 TAVR procedures have been completed (Liu & Wang, 2013). Recent FDA approval has allowed for many studies of TAVR in the United States with positive results. Initial research and clinical trials have indicated great patient benefits of undergoing TAVR rather than surgical aortic valve replacement (SAVR). TAVR has proven to have higher rates of survival and decreased hospitalization visits (Adams et al., 2014). However, TAVR has yet to be established as a standard method of treatment.

Initially, TAVR appears as though it is a medical miracle that all of the medical world should openly embrace. However, transition to this procedure has been a slow process. Of course, standardization of new medical treatments includes a very long timeline, which will be considered throughout this investigation.

Since the procedure has not been widely accepted, the reality of the ease of transition to this surgical method is still unexplored. The patient benefits of TAVR vs. SAVR are documented but not well known amongst the wide medical community. Initial research of this medical procedure did not provide an in-depth investigation and/or analysis of what must occur in order for a standard hospital facility to transition or adapt to carry out this procedure on a regular basis.

TAVR is an established procedure that has a proven success rate outside of the United States. While its existence is known throughout the U.S. medical community, this country's health care system has yet to include this procedure as a standard of care for aortic stenosis. The objective of this paper is to investigate the methods, technology and personnel associated with offering transcatheter aortic valve replacement as a treatment for heart disease. This research will also attempt to provide an in-depth discussion of the patient benefits of the procedure that include its effects on survival and mortality rates. Some of the questions that will be used to guide research and analysis include: What methods are used to execute transcatheter aortic valve replacement? After clinical trials and initial use of procedure, are their significant benefits to the patient that outweigh the benefits of other clinical options? What technology is in place and what technological advancements are required to establish this procedure as a standard treatment option? How will medical personnel teams be affected in care of TAVR patients and what training would be necessary to make this a standard treatment option?

Current literature available from investigation of the actual procedure, the treatment outcomes, and the facilities that have completed the procedure will be essential elements in answering the research questions outlined in the introduction. This inquiry will largely rely on published articles from the medical community to gather data, and qualitative findings to scrutinize the implications associated with using this procedure regularly in the U.S. healthcare system.

Discussion

Any opportunity to prolong and improve life expectancy is an opportunity worth investigating. Medical professionals have made great progress in the last decade in treatment of aortic stenosis but there is still work to be done. TAVR has proven to be a legitimate treatment for heart disease. This research initiates with the knowledge that it will be a significant undertaking on the part of the facilities and professionals who are interested in performing transcatheter aortic valve replacement. The major objective of this research project is to realistically illustrate how the procedure can be carried out, what will be expected of medical professionals and facilities, and to analyze the benefits of transitioning to TAVR as a standard procedure.

The two methods used to perform TAVR

Transcatheter aortic valve replacement uses percutaneous catheters to insert prosthetic aortic valves within the native aorta. Two distinct methods are used to perform TAVR and are named for the access point used for catheter implantation. The two methods used are termed as transfemoral TAVR (TR-TAVR) and transapical TAVR (TA-TAVR) (Palacios, 2012). Percutaneous catheters are surgical tubes that are inserted by needle puncture to allow access to tissues and organs within the body cavity. This prevents the need to expose tissues and organs within the body cavity to outside environments during the replacement. TAVR is carried out completely by use of percutaneous catheters, thus, it is less invasive than open heart surgery that requires opening the entire abdominal cavity (Palacio, 2012).

The first focus in this research is with the insertion site of the catheters in each procedure and in the unique course of action for each of the two types of replacement. Transfemoral insertion is carried out by accessing a femoral artery in the groin and guiding the catheter all the way to the aortic arch of the heart. Dr. Morton Kern explains the steps of TR-TAVR in his article for *Cath Lab Digest*. Dr. Kern explains the insertion site of the catheter and the catheter insertion through arteries to the aorta. After catheter insertion, the guide wire of the catheter is used to insert an aortic balloon to expand to the correct dilation of the aorta to allow insertion of the new valve. The balloon catheter can then be replaced with the prosthetic valve. The balloon is removed as the new valve system is inserted as a simultaneous action (Kern, 2013).

TR-TAVR is the most common of the two procedures used in today's society. Transfemoral insertion is often considered less invasive because of the reduced size of the incision. However, as Walther and Kempfert (2012) point out in their study of TAVR methods, significant consideration should be given to the longer distance the catheter must travel through the body in TR-TAVR. TR-TAVR surgery involves an almost ten-fold increase in the distance the catheter must travel in comparison to TA-TAVR. TR-TAVR requires a catheter navigation distance of 70-100 cm while TA-TAVR requires only a 7-10 cm navigation distance (Walther & Kempfert, 2012). Increased distance the catheter must be maneuvered to reach the aorta does add more risk factors in regards to damage to arteries within the body. Walther and Kempfert also point out the serious risk taken in touching the aorta with surgical equipment to inflate the valve (Walther & Kempfert, 2012).

Transapical insertion TAVR is performed by making a small incision near the ribs (Palacio, 2012). The anatomical position of catheter insertion requires what surgeons refer to as a "minithoracotomy." In this procedure, a 5-8 cm incision is made near the sixth intercostal space of the left side of the thoracic cavity for insertion of the catheter. The prosthetic valve, balloon and catheter are all inserted into the aorta as a unit as the prosthetic valve is crimped around the balloon and catheter (Lichtenstein et al., 2006). One major benefit to TA-TAVR is in that the aorta is not directly touched by surgical equipment, only by the replacement valve. However, there is also a negative implication in that the incision size is up to five times larger than in TR-TAVR, which increases the patient's chance for post-surgical infection and the resulting complications associated. Walther and Kempfert provide a very useful summary table of each surgical method for executing TAVR. The table shown in Figure 1 could be a useful tool for introducing both methods of transcatheter aortic valve replacement to medical teams who are considering the procedure as a means of treatment. This table could also be translated to include more largely understood clinical/medical terms that could inform patients of their options in choosing transcatheter aortic valve replacement.

	Transfemoral (TF)	Transapical (TA)
Access	Femoral artery	Left ventricular apex
Access mode	Retrograde	Antegrade
Incision length [cm]	1-2	~5
Distance to aortic valve [cm]	~70-100	~7-10
Wire insertion	Through the aortic arch, retrograde	Through the aortic arch, antegrade
Wire positioning	Arbitrary, across iliac vessels and aortic arch, irregularities, slack	Coaxial, straight
Valve insertion	Through the aortic arch, retrograde	No touch aorta
Valve orientation	Arbitrary	Commissural (anatomical) alignment possible
Valve implantation	Some mobility during implantation	Little mobility, stepwise and controlled implantation usually feasible
Application system retrieval	Across the aortic arch, relatively long distance	Direct and straight
Access closure	Complication rates as high as 10%	Very low complication rate, ~1%
Perspectives	Smaller systems will become available	Allows access to almost any diameter of the devices – this may lead to potentially better tissue longevity
Future developments	Improved vascular closure systems	Percutaneous access and closure systems

Figure 1. A comparison between transfemoral and transapical aortic valve implantation (Walter & Kempfert, 2012)

Two Commercially Available Valve Systems for Aortic Replacement

Overall, the most important piece of this procedure is the replacement valve used to restore heart function. Currently, there are two leading valves on the market for TAVR. These include the Edwards SAPIEN valve and the CoreValve Prosthesis. These valves must be durable and reliable for both the surgeon placing them and for the patient's lifetime use of the technology. The most significant difference between the two valves is diameter, thus affecting whether or not the valve will fit within a patient's aorta. In a study done by Godino et al., both valves were used in a clinical trial, and at the thirty day post-surgery date, only one death occurred (Godino et al., 2010).

In depth analysis of the two valve types has shown a few inequities. Godino et al. completed one of the first studies to compare the Edwards SAPIEN valve and the CoreValve Prosthesis. In the study, patients who were selected to receive a specific valve had the same clinical characteristics and presented with similar symptoms. The patients only differed in the diameter of their native aorta (Godino et al., 2010). The study implies that a physician chose the type of valve for implantation based only upon the artificial valve that best suited the patient's natural aorta diameter. This is evidence that both valve types are considered suitable by medical professionals for treatment. However, one valve far exceeded the other in terms of procedural success. The CoreValve technology had a substantially lower rate of surgical success in comparison to the Edwards SAPIEN valve. This is indicated by the increased need for a second replacement valve after initial surgical failure and a higher rate of valve embolization (Godino et al., 2010). This indicates that more patients underwent prolonged surgery for a second valve or experienced significant vessel blockage after initial replacement. Routine TAVR with both the Edwards SAPIEN valve and the CoreValve Prosthesis were deemed to have high overall success rates specifically in regards to 30-day and 6-month outcomes (Godino et al., 2010). While one valve type may require further study and improvement, the existence of two reliable technologies that work for a variety of patients will make the procedure easier for medical professionals.

The steps of treatment starting from patient preparation to surgery and post-operation care are essential for the success of patients' health. Both available valves are targeted to reduce the incidences of paravalvular leakages occurring, as well as reduce the necessity pacemaker implantations. There are newer generations being developed of these two valves to ensure the longevity of a patients' life. With the growth of technology, there will be higher rates of success and less complications allowing TAVR to become the alternative procedure to SAVR in patients that have less severe aortic stenosis (Liu & Wang 2013). As the procedural success of TAVR increases, the cost of insertion of these valves will decrease and become more reasonable for patients that have a harder time affording operational costs.

The durability and reliability of these valves are essential factors for both the surgeon placing them inside of the patient and the patient who will live with the valve. With surgical aortic valve replacement, it is more common to have major bleeding and atrial fibrillation but the smaller catheters used in TAVR help reduce vascular complications (Smith et al., 2011). The Edwards SAPIEN valve uses an expandable balloon whereas the CoreValve is a self-expandable valve. Technological expansion has produced newer generations of devices such as the SAPIEN XT. The Edwards SAPIEN valve is available in 23 or 26 mm valve sizes depending on the patient. Figure 2 illustrates the positioning and deployment of the Edward SAPIEN valve (Cheung & Lichtenstein 2012). According to Dr. Palacios, the SAPIEN XT is 40% smaller and has better durability than the generations before it. The CoreValve, along with the SAPIEN

XT,will help reduce bleeding complications that a patient might have and with the smaller diameter of the valves, TAVR will become more commonly used (Palacios, 2012).

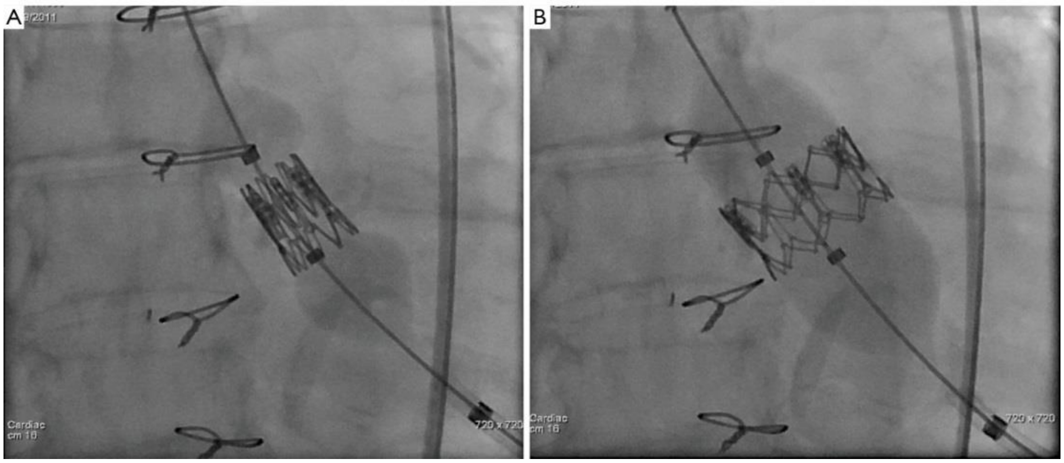

Figure 2. Positioning of Edward SAPIEN in aortic valve. The left picture shows proper positioning of the Edward SAPIEN valve. The picture on the right demonstrates the Edward SAPIEN being fully inflated within a patient's aortic valve. (Cheung and Lichtenstein, 2012, p. 238)

These newer generations of valves are targeted to reduce the common complications associated with TAVR such as paravalvular leaks, frequent pacemaker implantations, and strokes. Wang and Liu state in their 2013 journal that with technology advancing, the experience required of the operator will also increase . The accumulation of evidence demonstrates that the procedural success will be higher and less complication rates will make TAVR the alternative to SAVR in patients that are younger and range from low to intermediate risk for AS (Liu & Wang 2013). Increasing evidence and advancing technology indicate that

TAVR should be able to compete with SAVR in patients that are not only over the age of 75 or have severe symptomatic aortic stenosis and are refused surgery due to the increased risk related to age. The existence of two reliable technological valves that have proved to reduce complications in a variety of patients will make TAVR an easier procedure for medical professionals in the upcoming years.

Research has indicated that multiple methods for implanting a new aortic valve and multiple valve options with varying diameter choices are associated with successfully carrying out transcatheter valve replacement. Publications about clinical trials and use of TAVR in multiple cardiovascular and cardiothoracic journals indicate ample interest in advancing the procedures' success and use in healthcare. Furthermore, acknowledgements of the failings of current heart valve replacements and new prototypes that have already been developed display drive by the medical community to make this procedure a common place treatment.

Patient Benefits

Additionally, TAVR could be regularly used because it allows more patients to be treated and shows to be advantageous over open heart surgery. According to an article in *Perfusion*, a journal about cardiac surgery, authors Rozeik, Wheatley and Gourlay say that, "33% of patients over the age of 75 with severe symptomatic aortic stenosis are refused surgery due to the increased risk related to age and left ventricular function" (Rozeik, Wheatley, and Gourlay, 2014). The patient benefits from a less invasive surgery are numerous. The same article in *Perfusion* mentions that a major benefit of TAVR is that the new valve is inserted over the original valve without the need for open heart surgery (Rozeik et al., 2014). Transcatheter aortic-valve implantation is a less evasive surgery that lowers mortality rates and will increase the longevity of many elderly individuals.

A significant benefit of transcatheter replacement is a shorter stay in the hospital and the intensive care unit (Smith et al., 2011). Thirty days after surgery, Craig Smith and his associates report that, "among patients who could perform 6-minute walk tests, patients in the transcatheter group walked father than those in the surgical group (Smith et al., 2011)." Figure 3 lists clinical outcomes for thirty days and one year post-surgery. This indicates any medical complications for two study groups, those who underwent transcatheter replacement and those who underwent surgical replacement.

Table 2. Clinical Outcomes at 30 Days and 1 Year in the Intention-to-Treat Population.*

Outcome	30 Days			1 Year		
	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
From cardiac causes	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Repeat hospitalization	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or repeat hospitalization	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
Stroke or transient ischemic attack						
Either	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
Transient ischemic attack	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Stroke						
Minor	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Major	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Death from any cause or major stroke	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Vascular complication						
Any	59 (17.0)	13 (3.8)	<0.001	62 (18.0)	16 (4.8)	<0.001
Major	38 (11.0)	11 (3.2)	<0.001	39 (11.3)	12 (3.5)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)	4 (1.2)	4 (1.2)	0.95	12 (3.9)	8 (2.7)	0.41
Renal-replacement therapy	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Major bleeding	32 (9.3)	67 (19.5)	<0.001	49 (14.7)	85 (25.7)	<0.001
Endocarditis	0	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New-onset atrial fibrillation†	30 (8.6)	56 (16.0)	0.006	42 (12.1)	60 (17.1)	0.07
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

Figure 3 – Clinical Outcomes for TAVR and Surgical Replacement (Smith et al., 2011)

One study by Codner et. al, examined the post-surgical outcome of 153 TAVR treated individuals. One significant measure analyzed was the prevalence of stroke post-surgery. In this study, the 30-day stroke rate was only 3.9%. This low value indicates diminished negative outcomes from prosthetic valve complications. Low stroke occurrences are a major indicator of the procedure's success rate (Codner et. al, 2013)

Aortic stenosis is one of many valvular heart diseases that causes other problems for patients such as decreased left ventricular ejection fraction (LVEF). LVEF is the amount of blood that is pumped from the heart with each heartbeat. Patients that had severely impaired LVEF have lower amount of blood being pumped from the heart and cardiac function from their heart, which is a reason for why TAVR is the prominent procedure used as treatment. In a study conducted by Pilgrim et al., patients that have left ventricular (LV) problems as well as aortic stenosis were investigated to compare whether patients with less than 30% LV function had a more rapid recovery than those that had greater than 30% LV function (Pilgrim et al., 2011). The patients that had severe LVEF and underwent TAVR had rapid improvement in their LV function compared to patients in the SAVR group. The patients also had similar improvements to those that had normal or reduced LVEF. This demonstrates that TAVR can produce faster recoveries for patients with severe LVEF than SAVR (Pilgrim et al., 2011).

The use of TAVR includes many post-surgical benefits over open heart surgery. A comparison of TAVR versus surgical valve replacement concluded that 30 days after surgery 6.5% of the group that underwent surgical replacement was deceased while only 3.4% of the TAVR study group was deceased (Smith et al., 2011). An additional study by Makkar et al. in 2012, resulted in similar conclusions with lower mortality rates in TAVR. The study compared patients with severe aortic stenosis who underwent either TAVR or SAVR on the basis of hospitalization and mortality rates along with decrease of any symptoms the patients had prior to the operation. Based on the results, patients that underwent TAVR had lower rates of death from any cause (43.3%) when compared to those in the SAVR group (68.0%) after 2 years post operation. The causes of death included cardiac problems such as heart attacks or strokes ((Makkar et. al, 2012). The simple evidence of a lower mortality rate is enough to convince many individuals that the new procedure is beneficial. Benefits to patients will also aid medical professionals as they will be responsible for fewer invasive surgeries and will have less at-risk patients residing within the ICU for extended stays. Without this new procedure, continued prevalence of high mortality rates will be present for all patients with any type of vascular complication.

Patient benefits listed in the data reviewed show a very high success rate. The varying post-surgical benefits show the wide range of gains by patients who suffer from aortic stenosis and opt to undergo TAVR. Multiple studies show very minor mortality rates for both transfemoral and transapical transcatheter aortic valve replacement.

Procedure Room and Equipment

Hospitals and clinics must be prepared to handle every aspect of the procedure if transcatheter aortic valve replacement is going to be successful. This includes all steps of treatment from patient preparation to surgery and post-operation care. The primary concern for facilities is the technology in the operating room. According to Walther et al., the TAVR should be performed in an operating room with high tech imaging, a large image intensifier, and replay capability. The imaging arm should be positioned on the right side of the patient's body to allow maximum space for the surgical team (Walther et al., 2009). The operation room should also be able to quickly transform into a bypass surgical area in case of emergency (Tomasso et al., 2014). All of the intricate equipment necessary for the procedure requires a very specific set-up for the physical operating space. Tomasso et al. suggests a room of no less than 800 square feet and reminds clinics to take special care in their choice of ventilation, power receptacles, and lighting (Tomasso et al., 2014). Proper groundwork done by a hospital or clinic to provide the optimal surgical environment will increase procedural success.

A clinic must have much more than a well-stocked operating room to advance in cardiology. In order to further aid patient success in TAVR, health institutions must also have high-tech imaging center and post-operation care facilities. Advanced diagnostic imaging in cardiology includes a cardiac catheterization laboratory with an imaging system (Tomasso et al., 2014). This technology is essential because it allows the surgical team to assess heart damage, valve size, and precise vessel location before the operation (Tommaso et al., 2014). During this procedure, a contrasting dye is injected through the catheter so that the surgeon can visualize the heart as well as the major arteries. After the dye has been inserted there are x-ray images that are taken of the heart and arteries to assess if there are any complications such as heart damage before TAVR is performed (Tommaso et al., 2014). This procedure is beneficial because the cardiologist is able to evaluate the heart before he or she performs TAVR so that preexisting conditions are fixed surgically to ensure that the patient and the transplant valve remain stable. The groundwork done by a hospital or clinic will provide the optimal surgical environment to increase procedural success.

Transcatheter aortic valve replacement is a procedure that requires specialized facilities for every aspect of pre and post-operation care. The hospital should take special care in their choice of ventilation, lighting, and power receptacles as well (Tommaso et al., 2014). Imaging such as transeophageal echocardiography (TEE) or intracardia echocardiography (ICE) needs to be easily accessible for the surgeon to regulate the valvular and ventricular functions.

TEE helps position the transcatheter valve prior to being deployed in the aortic valve (Cheung & Lichtenstein, 2012). It also is essential for the detection of complications that can occur during the procedure such as thrombus formation (clotting) and the reoccurrence of aortic stenosis regurgitation (backward flow of blood). Since TAVR can be performed under a local anesthetic and sedation, TEE is sometime omitted since it can interfere with fluoroscopy and ICE does not (Bartel et. al, 2011). Another aspect of the study conducted by Bartel et. al (2011) demonstrated that ICE was the better choice of imaging due to the fact that in TEE when inserting the valve, the stent containing both the valve and balloon became hard to differentiate between. This was due to the probe being used was at a lower frequency than the one used during ICE so the image resolution was limited. During TEE, the image viewing is interrupted throughout the valve deployment which is one of the most crucial steps so that the surgeon could have the most optimal fluoroscopic viewing of the aorta. Any major or minor readjustments that were made during this procedure were recorded, but the ICE imaging proved to have the least amount of readjustment when compared to TEE imaging. Because of this, the surgeon was able to perform continuous ICE imaging throughout the patients' procedure which allowed for easier insertion and withdrawal as well as depiction of paravalvular leakages (Bartel et al., 2011).

Advanced medical equipment is required of any facility that intends to perform TAVR as described in detail by several authors included in the literature review. With advanced medical technology comes the necessity of advanced and experience professional teams to run, maintain, and service all of the equipment. This could be considered a limitation of spreading the procedure throughout all of healthcare, even within the United State healthcare system. Rural areas often do not have access to the funds that are required to purchase and maintain medical equipment, especially top of the line cardiology machinery. Transcatheter aortic valve replacement may be a procedure that is restricted to a finite number of medical facilities in mostly urban areas within the U.S.

Training and Implementation

As a newly introduced procedure, transcatheter aortic valve replacement requires specific training and experience for the medical professionals involved in this treatment. The recentness of the procedure's FDA approval has not allowed for the establishment of mandated operator experience and success rate. However, many key concepts should be understood by the surgical team. Physicians performing TAVR "should possess extensive knowledge of valvular heart disease, including the natural history of the disease, hemodynamics, appropriate diagnostics, optimal medical therapy, the application and outcome of invasive therapies, and procedural and perioperative care" (Tomasso et al., 2014).

Furthermore, many key concepts have been agreed upon by professional societies for both the facility and the operator. Some cardiologists suggest a required number of procedures per year for both the surgical team and the institution. For example, physicians have suggested that a surgeon should be required to complete 10 mitral valve repair surgeries a year to maintain the privilege of performing TAVR (Tommasso et al., 2014). These requirements will help ensure practical skills and success rates of TAVR. In The Journal of The American College of Cardiology, a group of experienced physicians state that is it essential to have a, "post-procedure intensive care facility with personnel experienced in managing patients who have undergone conventional open-heart valve procedure" (Tomasso et al., 2014).

One group of physician sstressed their own belief in the use of a multidisciplinary team. Not only does the multidisciplinary team (MDT) consist of the interventional cardiologist and cardiac surgeon, it also consists of a multitude of people such as radiologists, nurses, anesthesiologist, and cardiac imaging team. Through a MDT program, interventional cardiologists and cardiac surgeons are able to jointly evaluate and examine the patient prior to the procedure. Before the operations begin, the MDT use ‘pre-procedure briefings’ where the patient is educated on the steps of the procedure intended for he or she, equipment and tools used, as well as the complications that could potentially arise during surgery (Tommaso et al., 2014). If all members of the MDT have a common understanding of the planned procedure, then everyone will know what to do if the plan is subjected to change. The personal attention patients receive from the MDT helps ensure the patient that the procedure will be successful.

These recommendations from multiple physicians reinforce the importance of proper procedure rooms and equipment. If extensive training and practice is done by medical professionals, transcatheter aortic valve replacement can be a viable option within hospitals and clinics. However, curative facilities will be held to the highest standards in regards to the professionals they employ and the training and continued education they offer. Implementing a program will also require means to recruit advanced surgical staff members who have performed the procedure or similar procedures previously.

Conclusion

Aortic stenosis is a very common illness among elderly individuals in the United States. The heart is arguably the most precious organ in the body and requires special care when illness has damaged or disabled it. Treatment of cardiac disease is the focus of many research groups around the world. Blood vessel replacement is a necessity for many and thus has resulted in the creation of several treatment methods. A new procedure, transcatheter aortic valve replacement, has potential to become the leading method for aorta restoration.

Research conducted was focused on three primary subjects; the methods used to perform TAVR, the technology placed within the body and the technology required for the surgery, and the demands of the medical staff treating the patient during and post-surgery. Cardiology journals were the most prevalent source consulted for reliable, peer-reviewed studies of transcatheter aortic valve replacement. Review of acquired literature required intermediate-level knowledge of cardiology as it relates to medical terminology and associated acronyms. Information on the subject investigated did not prove to be difficult to obtain.

Investigation into the two methods, transapical and transfemoral insertion, that are used for TAVR were both well analyzed and used in the small population within the medical community that has accepted this medical procedure as a standard or potentially commonplace treatment. Furthermore, ample material has been published about the medical supply companies that manufacture the two prosthetic valves that are currently on the market. These prosthetic valves have progressed through several prototypes and rounds of advancements. Manufacturing supply companies appear to have received enough demand for and feedback on the prosthetic valves that they continue to be readily assembled while the companies investigate advancements to enhance the efficiency of the valves. In the realm of patient benefits, all research pointed toward outstandingly positive outcomes for individuals who opt to undergo TAVR through either transfemoral and transapical insertion.

In order to make TAVR a standard procedure in the United States, technological advancements are required in many hospitals. Each institution performing the procedure must have advanced operating rooms and intensive care units for post-surgery treatment. Furthermore, surgical teams must receive the appropriate training on new surgical equipment and surgery procedures. These updates will allow medical professionals to treat more patients. The procedure will also allow them to offer a less invasive treatment that lessens the patient's risk of death and other surgical complications.

Dr. Neil Ruperelia and Dr. Bernard Prendergast (2015) artfully summarize their opinion on the future of transcatheter aortic valve replacement in an article for the general physician:

> The prevalence of AS will continue to rise in the increasingly elderly population. TAVI is a revolutionary treatment for patients who previously would have been considered inoperable or high risk for conventional surgery. TAVI is now established for the treatment of these patients, and longer-term data concerning valve durability and clinical outcomes are eagerly awaited to ascertain whether TAVI should be routinely offered to lower risk populations. Outcomes and complication rates are set to improve further with accumulating operator experience and technological advances. Not only is TAVI here to stay, but it has also galvanised a revolution in the management of valvular heart disease, and encouraged a new collaborative approach to the management of complex cardiovascular disease. (p.424)

TAVR has the initial success rates of a procedure that could be adopted as a treatment in order to treat more patients and to improve the prognosis for those seeking treatment for aortic valve disease. The quotation from Dr.'s Ruperelia and Pendergast largely summarizes the conclusions drawn from this literature investigation. Transcatheter aortic valve replacement is a procedure that will not soon disappear from the forefront of new cardiology treatments within the United States healthcare system.

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