Transcatheter valve therapy was first introduced by Gribet et al.2 in 2002. Since then, this therapeutic option has become popular and has proven to be a feasible technique in selected patients. For example, in aortic valve patients who are high-risk surgical candidates due to multiple medical co-morbidities, extensive aortic calcification, prior sternotomies, depressed left ventricular function, advanced pulmonary disease, and advanced age, the mortality rates from a surgical AVR can be as high as 50%.7 In such patients, TAVI can provide a much lower riskier form of therapy compared to standard surgical AVR.

The two most commonly used transcatheter aortic valve implantation (TAVI) techniques on a beating heart.

In the “trans-apical approach”, a small left thoracotomy is made, the sheath is directly inserted into the left ventricular apex and a guidewire is used to cross the aortic valve and deploy the transcatheter valve. The trans-apical approach is usually performed in patients with poor peripheral vascular access, severe carotid artery disease, and a porcelain aorta. As such, it usually comprises a much higher risk patient group. This approach is best performed in a “hybrid operating room” which combines the facilities of both a cardiac surgery operating room and an interventional cardiology catheterization laboratory, thereby enabling multidimensional treatment options.

Important post-procedure complications include para-valvular leaks, vascular injury, device migration, and stroke.8,9 While the technology is still evolving and large scale future randomized studies will be required for follow-up, some of the results from recent studies have been encouraging.

Osten et al.5 reported in 2010 from their series of 46 patients high-risk patients with AS who underwent TAVI with the Edwards Sapien® Valve with the trans-apical approach (30 patients) or trans-femoral approach (16 patients). Procedural success was achieved in 95% of the trans-apical group and 88% of the trans-femoral group. The estimated operative mortality for conventional AVR was 15% or greater in this high risk group. The observed 30 day mortality was only 6.3%, which was less than 50% of the estimated value. The stroke rate was 6.5%. Ninety three percent of the patients were alive at mean followup times of 7.4 months for the trans-apical group and 8.5 months for the transfemoral group. Valve durability was maintained at followup and there were no cardiac-related post hospital mortalities. Bleiziffer et al.9 published in 2009 the results from their series of 137 high-risk patients who underwent TAVI using the CoreValve® (114 patients) or Edwards Sapien® Valve (23 patients). Thirty day mortality was 12.4% in this series. The stroke rate was 3.1%. NYHA class had significantly improved from an average NYHA class II at one month followup. Eighty percent of the patients were alive and there was good hemodynamic function of the prostheses at 6 month followup. Data on the Edwards Sapien valve are available from the European Registry and were reported in 2008.7 These data show a 95% procedural success, a 30-day mortality of 6.4% and presence of 2/4 aortic regurgitation in 26% of the patients. In a study from 2007 on 53 high risk patients undergoing the trans-apical approach, Walther et al.8 reported a 13.6% 30-day mortality with a 95% peri-procedural success. Recently, the first randomized clinical trial on TAVI (Partner trial) debuted its results. There was a 20% absolute reduction in mortality over the 2-year period. One life was saved by treating only 5 patients.9 While the outcomes of transcatheter valve therapy appear very encouraging, long-term follow-up studies will be helpful in determining the full extent of benefits derived from these techniques and the durability of such prostheses.

Vanderbilt Medical Center is among the sites chosen for the US Pivotal trial for the Core Valve trial. This is a multicenter randomized trial with 2 major arms. The first arm involves high-risk surgical patients randomized to traditional surgery vs. CoreValve. The second arm involves prohibitive risk patients randomized to best medical therapy vs. CoreValve. Enrollment in the trial will begin in early 2011.

REFERENCES:

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