Transcatheter aortic valve implantation (TAVI) is an alternative to aortic valve replacement (AVR) for high-risk patients. This novel procedure was introduced by Cribier et al. in 2002 and developed mainly in Europe. Two TAVI devices have been commercially approved in USA: Sapien valve (Edwards Lifesciences, Irvine, CA) and CoreValve system (Medtronic, Inc., Minneapolis, MN). Around 30,000 devices have been implanted to date. This procedure is finally beginning to be performed in Japan in a clinical trial. In this review, I summarize clinical results and problems from some clinical experiences and suggest possible ways to introduce this technique to Japanese candidates, who are different from Western candidates.

Present Situation of TAVI Worldwide

The last International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) and European Association for Cardio-Thoracic Surgery (EACTS) included many reports of operative results and early follow-up data on TAVI, which is becoming widely accepted by both cardiac surgeons and cardiologists. In these meetings, not only the results were reviewed, but also the risk management of these procedures, focusing on teamwork between cardiac surgeons and cardiologists. This is because of cases of catastrophic complications during the procedure when only interventionists were involved in it, such as aortic wall rupture, acute dissection, descending or abdominal aorta injury, and iliac artery injury.

The most recent clinical studies showed that the rate of death from any cause at 1 year among patients treated with TAVI was 25%–30%. Wendler et al. described the early results from the multicenter SOURCE registry of European countries for Sapien valve implantation. He reported a 92.7% success rate with 2.1% reoperation, 7.3% pacemaker implantation, 7.1% dialysis, and 2.6% major vascular complications. The total 30-day mortality rate was 10.3%, which is still very high, despite the candidates being high-risk.

On the other hand, the outcomes of aortic valve replacement have been improving year by year, with about 3% mortality in the worldwide database and less than 2% in Japanese cardiovascular database in 2008. Even for the elderly patient group, for example, older than 85, the mortality was not as high as expected, although this group of patients had the procedure in spite of their advanced age. Moreover, minimally invasive cardiac surgery has also been developed to achieve satisfactory results with fewer postoperative complications like infections and respiratory dysfunction.

The mortality of the patients converted to surgery during TAVI procedure was high with complication of annular rupture, aortic dissection or embolization of coronary arteries. The comments on this problem from some of interventionist were that they were not patients where TAVI was not feasible and who were planned for conventional surgery, which means that even in Europe, the concept has already been reinterpreted from the initial idea: that TAVI was designed for contraindications of AVR, as a palliative procedure.

Possible Problems of TAVI for Japanese Candidates

The basic indications for TAVI include contraindications for extracorporeal circulation and severe calcification of the ascending aorta for cross clamping. Still, the devices have no evidence of durability, and many
perioperative complications are found, such as paravalvular leakage and AV blocks. We must realize that this procedure is completely different from aortic valve replacement; implantation is only on the aortic annulus where natural valve leaflets are pushed to the aortic wall. Cardiac surgeons should precisely communicate the risk; otherwise, patients will misunderstand that this is a non-invasive procedure for which the chest does not need to be opened for the aortic valve procedure. Although cardiologists might intentionally misinform patients, a cardiac surgeon must understand the reality of this procedure, including the advantages and disadvantages so as to inform other cardiologists and patients. In that sense, we had a very bad experience at the boom of coronary artery intervention and peripheral artery intervention. Some interventionists insisted on those procedures in spite of patients being surgical candidates. The patients refused surgery but accepted interventions. However, I personally do not believe that they were given precise information regarding the benefits of surgery. This time, cardiac surgeons have to make this procedure a priority because they know the status of diseased valves and have been involved in this area for a long time. Now, some interventionists are starting to focus on valve disease, and they are performing some procedures on patients.

Sapien valves are only available in 23- and 26-mm sizes, which are too large for elderly Japanese patients, who are normally very small, such as 150 cm tall or shorter. According to data from Edwards Lifesciences, in 2009, 19-mm tissue valves (Magna) were used for 46% and 21-mm valves for 33% of Japanese patients, whereas 19-mm valves were only used for 11% and 21-mm valves for 30% of US patients. Pasic et al. reported their excellent results regarding the TAVI procedure after a previous AVR, called the “valve-in-valve” procedure. In this report, all of the patients had previously taken a prosthesis bigger than 21 mm. Almost all Japanese candidates, who are expected to be much smaller than Western ones, will have limitations because of the aortic annular size.

Pasic et al., validating the precise annular sizes before and after TAVI, revealed that TAVI might be a “palliative approach” for the aortic valve procedure in some patients with smaller annuluses. They insisted that strictly observing TAVI indications is very important because the aortic orifice after TAVI depends upon the orifice of the host. We must understand the limitation of this procedure and understand that this is no replacement but implantation on destroyed natural valves.

That is why that the indication for TAVI must be carefully chosen, especially for small Japanese patients. To prevent the catastrophic history of introduction that we saw with coronary artery intervention, cardiac surgeons must become active in the precise control of indications for TAVI procedures.

**Teamwork**

Dr. Ruel, one of the leading surgeons of this technique, has emphasized the importance of teamwork and role of the cardiac surgeon in the introduction, development, and sustainability of TAVI. Moreover, because the procedural technique involved in TAVI is complex and fraught with risks, it requires learning from both the cardiologist and the heart surgeon, who bring different and complementary skill sets. In addition, involvement of the cardiac radiologist and cardiac anesthesiologist optimizes procedures and perioperative management. By building a collaborative partnership and establishing a TAVI team, the cardiac surgeon and the cardiologist can provide not only didactic, clinical, and ethical leadership to the team, but also the adaptation and progression of TAVI among conventional treatments for severe AS.

**Alternative**

On the other hand, for Japanese candidates, balloon valvuloplasty for aortic valves might be a much better option than TAVI. Sakata et al. reported their novel technique of balloon valvuloplasty with the Inoue balloon catheter (Toray Inc., Japan) using the transatrial septal approach. They investigated the pressure of each chamber to evaluate the hemodynamic status and predict the hemodynamic outcome after valvuloplasty. Because they delivered the balloon intravenously, there were no significant neurological deficits or major vascular complications. Moreover, this procedure might be done a few times or as a trial for an aortic valve procedure in patients with left ventricular dysfunction. This procedure revealed the effect of a pressure gradient between the aorta and the left ventricle and the effect of decreasing the pressure gradient.

TAVI is now being developed as an intravascular valve procedure, and I am confident that this will be a standard procedure in the next decade or two. However, cardiac surgeons and cardiovascular interventionists must understand the concept and reality of TAVI to perform it on our candidates. You must not rush to do it without scientific and academic collaborations with interventionists.
and cardiac surgeons.

Now, for cardiac surgeons to be acceptable collaborators, they must understand our situation: new technologies and inventions must constantly be brought to clinical practice. Otherwise, sooner or later, one will fall so far behind as to lose one’s job. Japanese cardiac surgeons must tackle this issue without any excuses, in contrast to the handling of the introduction of percutaneous coronary artery intervention, two decades ago.

References


