Introduction – Aortic stenosis, a common disease

The aortic valve is the one of the four valves in the human heart, and probably its most important. It is the valve which sits between the left ventricle, which is the major pump of the heart, from the aorta, which is the major conduit which delivers blood to the rest of the body (Figure 1). Hence all the blood leaves the heart passing through the aortic valve. It normally consists of three thin leaflets which opens wide when the left ventricle pumps, allowing unrestricted flow to blood to the aorta. When the left ventricle relax, the leaflets flow shut to prevent blood from re-entering the heart (Figure 2A).

With aging, and sometimes other diseases, the aortic valve leaflets can become thickened and infiltrated with calcium. When this happens, it does not open wide when the heart pumps (Figure 2B). This disease is called aortic stenosis. It is the most common degenerative disease affecting the human heart valves. As this process occurs with aging, it is also more common in the elderly and is seen in 2% of the Western population over 75 years of age. Because it restricts the flow of blood out of the heart, it puts a stress on the heart eventually leading to very debilitating symptoms which can include shortness of breath (due to blood banking up in the lungs), chest pain (due to insufficient blood flow to the heart) and dizziness (due to insufficient blood flow to the brain). Initially patients afflicted may experience these symptoms on heavy exertion (and commonly attribute them to getting older). However once the symptoms start, the expected survival is only 2 years, with a rapid deterioration in exercise intolerance and significant hampering in quality of life before death. The disease is very easily identified as it produces a classical murmur (noise) which a doctor can detect by listening to the chest, and confirmed by an echocardiogram (ultrasound of the heart). However it is also commonly missed especially in elderly patients because the early symptoms are attributed to old age.

Unfortunately it is also a disease without any effective medical therapy. The natural history has been known since the 1960’s, and until now there has not been any medication which can effectively treat the symptoms or prolong the survival. The only effective treatment is to replace the valve. Traditionally it is by open heart surgery in a operation called surgical aortic valve replacement (SAVR). At this operation, the surgeon cuts down the front of the chest through the breastbone. The heart is stopped and the blood diverted to a “heart-lung” machine to take over temporary function of the heart and lungs. The native diseased valve is excised, and a new artificial valve sewn in its place. Commonly in the elderly (over 65 years) the valve used will be a “tissue valve” which is made from animal tissue. The heart is then disconnected from the heart-lung machine and restarted. The wounds are closed with stitches and wires (Figure 3).

Surgical aortic valve replacement has a very good outcome in experienced hands and has remained the gold standard for treatment of aortic stenosis in the last 40 years.
However it is still a very major operation and in the elderly population, especially those with multiple co-morbidities, it may have a 5-10% or higher risk of mortality and be associated with significant morbidities such as stroke and prolonged rehabilitation. As a result, it is estimated that between 30% and 60% of elderly patients with severe AS are either not referred for surgery or are declined by surgeons for valve replacement. There is hence a demand for lesser invasive options to treat this disease.

**What Is TAVI? – The Technology and Procedure**
Transcatheter aortic valve replacement, commonly abbreviated to TAVR or TAVI, is the new percutaneous option to replace the aortic valve. It is first performed in 2012, though there are over 250,000 cases done worldwide since. The two most widely used transcatheter valves are the SAPIEN valve (Edwards Lifesciences, Irvine USA) and the CoreValve / Evolut valve (Medtronic, Minneapolis USA), though there are new designs emerging and establishing in the market. They all consist of a stent-like metal alloy frame on which are attached tissue leaflet valves (Figure 4A and 4B). They are mounted on a delivery catheter (a thin tube).

In the most common version of this procedure, called the “transfemoral approach” this catheter will deliver the valve to your diseased heart valve through the femoral artery which is a blood vessel found at the groin (Figure 5). At the diseased diseased heart valve, the new valve will be expanded to its full size whereby the metal frame will push your existing heart valve aside and the new prosthetic valve will begin functioning immediately. The catheter which is inserted to your artery is currently relatively large (5-6mm in diameter) and in most cases will be removed using a special device and technique to suture the hole created in the femoral artery without the need for surgery.

An uncomplicated procedure takes around one hour by an experienced operator. They can even be done under local anaesthesia without being “put to sleep”. Post-procedure most patients can get out of bed after 4-6 hours. Commonly in an uncomplicated procedure, patients only need to stay in hospital between 1-3 days. There are no strong blood thinner required for this valve.

In 5% of patients, the transfemoral approach is not technically feasible due to technical factors such as the femoral artery is too small to accommodate the large delivery catheter. There are “alternate access” options which include such as via the subclavian artery (blood vessel near the shoulder), direct aortic (through an puncture at the aorta via a small cut in the chest wall) or transapical approach (through a direct puncture in the left ventricle via a cut on the chest wall). These are hybrid procedures performed by a joint team of interventional cardiologists and cardiac surgeons.

**How does TAVI perform?**
Currently TAVIs are typically performed in “medium to high risk” surgical patients patients, which are patients with expected mortality risk of open heart surgery of over 4%. In these patients, contemporary series, risk associated with TAVI include
- Risk of death from procedure and first month – 1-3%
- Risk of stroke – 3-5%
- Risk of bleeding, needing blood transfusion or of injury to blood vessels – 5-10%
- Risk of damage to the heart’s native electrical conduction system leading to need for a permanent pacemaker – 10-15%

Studies have compared the outcomes of TAVI compared to SAVR in high and medium risk patients. TAVI is associated with equivalent or lower risk of death, stroke, bleeding, damage to kidneys, but higher risk of pacemaker and damage to blood vessels. There is also a higher rate of “paravalvular regurgitation” which is back leaking of blood from around the TAVI valve back to the heart, with significant regurgitation being 2-3% with current technology. In surgery as the surgical valve is physically sutured in rather than just anchoring in the native valve, it is extremely rare to find paravalvular regurgitation. Finally there is significantly shorter hospital lengths of stay with TAVI.

**Who would be suitable for TAVI? - Patient Selection And Assessment**
Currently it is recommended that the patients be assessed by a "Heart Team" comprising of cardiologists, cardiac surgeons, imaging specialist, and other multidisciplinary professionals before being considered for TAVI. A lot of factors are considered including cardiac and general co-morbidities which affect the risk of TAVI, their surgical risks, and their overall prognosis. It is necessary to technical feasibility of the TAVI procedure, including size of the femoral arteries, the shape of the aorta, and the anatomy around the native aortic valve. Typically the investigations the patients would undergo include an echocardiography (ultrasound of the heart), coronary angiography (imaging of the arteries of the heart) and CT scan of the aorta and femoral arteries.

**Conclusion And The Future…**
TAVI represents one of the most exciting development in interventional cardiology, offering a viable alternative to surgery in severe AS. It also heralds the start of other minimally invasive procedures to treat diseases in the other heart valves.
Dr Gerald Yong
Dr Yong is an interventional cardiologist with special interest in valvular and structural heart disease. Aside from completing formal training in coronary intervention at Royal Perth Hospital, he trained in Chicago and Montreal in specialised percutaneous and minimally invasive operations for heart valve and structural disease.

In 2009, together with cardiac surgeon Robert Larbalestier and a team of other professions, he started the High Risk Aortic Stenosis Service and TAVI program in Western Australia. This was the state program which was the sole program which offered TAVI in WA until 2017. The program commenced at Royal Perth Hospital, and in 2015 moved to the Fiona Stanley Hospital. Overall the program has performed over 400 cases of TAVI, with over 200 in Fiona Stanley Hospital since 2015. It is one of the premier program in Australia, with no 30-day mortality in the patients treated since 2015, and most patients discharged back to home after 1-2 nights in hospital post-op.

Dr Yong is a frequently invited proctor for TAVI in Asia-Pacific to teach and start up TAVI programs in the region. In this region, He has proctored in South Korea, China, Hong Kong, Taiwan, Thailand, Vietnam, Malaysia and Singapore. He has been a frequent invited speaker to the region for conferences in valve and structural heart disease.
Figure 1 – the human heart and aortic valve

Figure 2A – Normal functioning aortic valve
Figure 2B – Aortic stenosis; The valve leaflets are thickened and opening is restricted

Figure 3 – Surgical aortic valve replacement

Figure 4A – Edwards SAPIEN 3 valve: A Cobalt-chromium frame with leaflet tissues made from bovine pericardium (cow tissue)
Figure 4B – Medtronic Evolut PRO valve; A Nickel Titanium frame with leaflet tissue made from porcine pericardium (pig tissue)
Figure 5: Transfemoral TAVI using Edwards SAPIEN Valve – The transcatheter valve is crimped onto a balloon catheter. It is passed to the aortic annulus via a femoral arterial puncture. The balloon is inflated deploying the valve. The balloon catheter is then removed leaving behind the transcatheter valve held by the native diseased valve. The new valve leaflets function as the new aortic valve.