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Perceval

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The first surgical aortic valve replacement (AVR) was performed by Hufnagel in 1952 while in 1962; Magovern introduced the concept of sutureless AVR. The procedure was performed on a 43 year old woman with aortic regurgitation-leading to a cardiopulmonary bypass time of 28 minutes. The idea behind the concept was to shorten the procedure time. Both the Hufnagel and Magovern valves were actually sutureless valves (1).

Surgical AVR improved survivability and quality of life in severe aortic stenosis. However almost one third of patients were not eligible for surgery because of comorbidities and higher risk. Medical therapy for those patients was also suboptimal. Transcatheter aortic valve replacement (TAVR) was first introduced in 2002 for these high risk, inoperable patients (2).

The field of surgical AVR made a rapid advance in the early 2000s with the introduction of the transcatheter valve therapy. Until that time surgical AVR was the only strategy for severe aortic stenosis. By 2016, TAVR produced real revolution in the management of severe aortic stenoses especially in high risk patients. This new therapy has been evaluated in major controlled clinical trials comparing surgical AVR (SAVR) versus TAVR. The interventional cardiologists started to push TAVI for all comers regardless of the risk profile.

At the same time surgeons started to develop and adopt new techniques to reduce the surgical trauma, the so called "minimally invasive surgery" (MICS), as an alternative to standard conventional techniques. These developments in the field of SAVR were highly favorable for patients.

Perceval Sutureless valve technology was introduced almost ten years ago as an alternative to standard surgical prostheses. It is the only truly sutureless valve available on the market. Since its first use on human patients in 2007, Perceval has been implanted in over 20,000 patients worldwide. The valve features an innovative superelastic metal alloy stent frame coated with CarbofilmTM with bovine pericardium. It is designed to provide optimal hemodynamics and facilitate the MICS approach. Recent in vitro studies have shown significantly better gradients compared to stented valves, and iv vivo data has shown excellent haemodynamics up to five years. This can be explained by the absence of a sewing ring and an elastic stent that is able to adapt to aortic root movement during the cardiac cycle.

The implantation technique for this valve is easy and has a short learning curve. The shorter cross clamp time and easy implantation with this valve also overcomes the limitations of the minimally invasive aortic valve replacement. The recent clinical data showed us that mortality and morbidity of the surgical AVR with the Perceval valve decreased significantly (3-5).

Durability is a major concern for bioprosthetic valves. While TAVR crimping might reduce the valve's durability, Perceval collapsing does not affect the leaflets. This has also been proven in several histological in vitro studies (6). Compared to the traditional stented tissue valve structural valve deterioration is also similar (0.8%pt/yrs. versus 0.8%pt/yrs.) with this new valve (7).

Another major advantage of Perceval is the rate of pacemaker implantation which is similar to conventional AVR (5.6% versus 3%) and lower than TAVR (5.6% versus 13.2 %) (8). Another important advantage of this valve is its suitability for future valve-in-valve (ViV) procedures. Thanks to its superelastic nitinol frame and radioopaque visibility under fluoroscopy, this valve has unique engineering specifications. Furthermore Perceval's flexible stent design may in fact facilitate the ViV approach and optimize hemodynamics following the procedure.

PERSIST-AVR (Perceval sutureless implant versus standard aortic valve replacement) study is the first randomized multicenter study that is going to compare this new technology with the standard stented surgical bioprosthetic valves. It is also the first multicenter prospective randomized study in the field of valve surgery in the last 30 years. The results of this study will provide us the real data in the area of aortic valve surgery. The study is going to be

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conducted in 60 centers worldwide and enroll over 1,200 patients. The primary endpoint is to demonstrate non-inferiority of major adverse cardiac cerebrovascular events (MACCE) at one year according to VARC-2 criteria. Results are expected as from 2019.

Despite all the favorable results with TAVR, surgical AVR is still the gold standard for the treatment of Aortic Stenosis. But as surgical community, we also have to change our old habits and try to be less invasive to our patients. Less invasive doesn't just mean smaller incision, but also less traumatic surgery thanks to a reduced cardiopulmonary bypass and aorta cross clamping. In the future we will need to do safer operations for older and frailer patients. This means that we need an advanced technology in this field. The combination of Sutureless valves like Perceval and minimally invasive techniques will allow us to prepare for the future.

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