The Novel Hydra Transcatheter Aortic Valve Demonstrates Favourable Hemodynamic and Low Pacemaker Rate

Study pointers

- The Hydra CE study demonstrates high efficacy with favourable hemodynamic and low pacemaker rate.
- The study included 157 patients with symptomatic severe aortic stenosis and high or extreme surgical risk, who were treated with the self-expanding Hydra THV.

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SMT (Sahajanand Medical Technologies), leading medical device company of India, focussed on innovative patient care in cardiovascular segment, today announced late-breaking data of its TAVR device Hydra transcatheter heart valve at PCR Valves E-Course 2020. The retrievable, self-expanding Hydra THV with supra-annular position of leaflets for optimize hemodynamic performance is designed for high flexibility, easy access to the coronary arteries, and low interference with the conduction system.

Prof. Lars Søndergaard from Rigshospitalet, Copenhagen, Denmark presented the study, which led to approval for commercial use of the Hydra THV for TAVR in Europe. The study was conducted at 18 participating sites in Greece, Hong Kong, India, Kazakhstan, Lithuania, New Zealand, Poland, and Thailand. It was a prospective, single-arm study to evaluate the 30-day and 1-year performance and safety of the Hydra self-expanding transcatheter aortic valve in the treatment of 157 patients with symptomatic severe aortic stenosis in patients at high or extreme surgical risk.

The key findings at 30-day were significant improvement of effective orifice area (from 0.7±0.2cm^2 to 1.9±0.6 cm^2), mean aortic valve gradient (from 49.5±18.5mmHg to 9.2±4.5mmHg), and 6-minute walk test distance (from 231±100m to 268±119m), which were sustained up to 1-year. The rate of new permanent pacemaker implantation was 11.7% at 30 days and 12.4% at 1 year. Stroke rate was 0.6% at 30-day and 1-year.

Speaking more on the trial, Prof Lars Søndergaard, Senior Intervention Cardiologist, 'TAVR has become the default treatment for elderly patients with symptomatic severe aortic stenosis across all risk profiles. Based on the recent evidence from the low-risk trials, it is expected that TAVR will expand to even younger patients with longer life-expectancy, which raises even higher demands to transcatheter aortic heart valves, e.g. durability, conduction abnormalities and future access to the coronary arteries. The Hydra CE study indicates that this THV addresses these requirements by providing large effective orifice area and low pacemaker rate. Large-scale studies with longer-term follow-up are currently underway to validate the results of the Hydra CE study'.

SMT is advancing in science and innovative technology to ensure people living with structural heart diseases have safe and effective treatment options.

*The CE Mark indicates that the product satisfies requirements of EU Directives (EU ： The European Union) and all products need to be CE certified to be sold in Europe.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 75 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of Coronary healthcare. SMT also pioneered the introduction of biodegradable polymer in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

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