

**Title:** TAVR USING THE HYDRA SELF EXPANDING BIOPROSTHESIS- A SINGLE CENTER, 6 MONTHS FOLLOW UP STUDY

**Category:** Valvular Heart Disease

### **Abstract**

**BACKGROUND:** This study was aimed to analyse and document the initial experience with transcatheter aortic valve implantations using the Hydra self-expanding aortic bioprosthetic valve in patients with symptomatic, severe aortic stenosis.

**METHOD(S):** Implantation of the Hydra aortic valve was performed in patients with symptomatic, severe calcific aortic stenosis with tricuspid morphology in a tertiary care centre. Hydra has a self-expanding Nitinol stent frame, with a bovine pericardial tissue valve. It has non-flared inflow section of the frame and a supra-annular valve leaflet design. The valve has got 3 tentacles or antenna for better anchorage and larger cells (10mm). The delivery cable is highly flexible and 18 F compatible, and the device can be recaptured/ repositioned after around 85%-90% deployed.

**RESULT(S):** In the study cohort, surgical aortic valve replacement was deferred based on heart team assessment of an estimated high and intermediate surgical risk. The valve was implanted in 9 patients with mean Society of Thoracic Surgery score 5.1%, mean age 76.5 years, mean aortic valve area 0.68 cm<sup>2</sup>, mean aortic pressure gradient 61.33 mmHg. In 7 patients, the procedure was performed under general anaesthesia with online TEE monitoring, while conscious sedation was used in the rest. Surgical femoral arteriotomy was used in 7 patients, whereas the remainder had a percutaneous transfemoral approach. All but one valves were predilated. All valves were post dilated.

Valve deployment was successful in all patients in one attempt. There was one procedural death due to refractory hemodynamic collapse from right ventricular perforation, after a successful valve deployment. There was no coronary occlusion, major bleeding or major vascular complications. One patient developed transient complete AV block which recovered in 4 hours and was managed conservatively. No patient required new permanent pacemaker implantation. At 30-day follow-up, the median aortic valve area and mean pressure gradient were 1.83 cm<sup>2</sup> and 8 mmHg, respectively. The prevalence of more than mild paravalvular leakage (PVL) and new complete left bundle branch block was 11.1% (1 patient) and 33.3% (3 patients), respectively. None of the patients suffered from stroke or TIA. At 6 month follow up, there was no additional mortality or heart failure. There was significant gain in 6 Minute Walk Test, and Echocardiogram revealed sustained valve performance at 6 months, gradients and aortic valve area remained the same as in 30 days. PVL, though insignificant, persisted at the same grade.

**CONCLUSION(S):** The new Hydra aortic bioprosthetic valve appear safe and useful for transcatheter treatment of severe calcific aortic stenosis with tricuspid valve morphology. The study results showed a good hemodynamic performance and complication rates comparable to those reported for second-generation transcatheter aortic self-expanding bio prostheses