Global Spotlights

New devices of transcatheter interventions for structural heart disease in China

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Editor-in-Chief, reviews two of the most remarkable papers published in The Chinese Journal of Cardiology (CJC).

Structural heart disease is a spectrum of disorders that are associated with structural abnormalities of the heart and large blood vessels adjacent to the heart. The most significant challenges treating these disorders are their diversity and the minute variations among them. Due to the complex anatomy of structural heart disease, no single device is suitable for all lesions, requiring specialized knowledge to select treatment strategies for optimal percutaneous outcomes. In recent years, there has been extraordinary progress in the treatment of heart valve disease. Specifically, with China's progress in this area, a number of new domestic therapeutic devices have been introduced and entered the clinical research stage.

This was recently reported in The Chinese Journal of Cardiology (CJC) with a contribution entitled 'Comparison on the efficacy of Chinese-made novel-designed mechanical-locked and elastic self-locked transcatheter edge-to-edge repair system in the treatment of patients with mitral regurgitation' by Prof. Xiangbin Pan et al. from Fuwai Yunnan Cardiovascular Hospital, China. In this retrospective non-randomized comparative study, patients underwent transcatheter edge-to-edge repair (TEER) procedure in a total of 60 patients with moderate to severe functional mitral regurgitation to treat extreme mitral insufficiency. The primary outcome was the success rate on the 30 d post-procedure, while secondary outcomes included immediate postoperative technical success rate and the incidence of all-cause mortality, reimbursement rate of acute heart failure, cerebral infarction, severe bleeding, and other serious adverse events rates on the 30 d post-procedure. A total of 60 patients were enrolled, 34 patients were in the Clip2Edge group and 26 in the ValveClip group. The mean age was (63.8 ± 9.3) years and 24 patients (40%) were female. There were no significant differences in baseline data of age, cardiac function, comorbidities, mitral regurgitation 4+ [19(73%) vs. 29(85%)], the end-diastolic volume of left ventricle [(220.8 ± 91.2) mL vs. (210.8 ± 71.7) mL] between the two groups (all P > 0.05). The technical success rate immediately after the procedure was 100%. There were no readmission of acute heart failure, death, cerebral infarction, severe bleeding, and other serious adverse events up to the 30 d follow-up. The device success rate was similar between the ValveClip group [24 cases (100%)] and the Clip2Edge group [27 cases (96%)] (P > 0.05). Both types of novel domestic TEER devices are safe and feasible in treating patients with functional mitral regurgitation.

Another recent publication was 'Preliminary experience of transcatheter pulmonary valve replacement (TPVR) using domestic balloon-expandable valve' by Prof. Yuan Feng et al. from West China Hospital, Sichuan University, China. This is a prospective single-center observational study. Patients with postoperative right ventricular outflow tract (RVOT) dysfunction, who were admitted to West China Hospital of Sichuan University from September 2021 to March 2023 and deemed anatomically suitable for TPVR with balloon-expandable valve, were included. The immediate procedural results were evaluated by clinical implant success rate, which is defined as successful valve implantation with echocardiography-assessed pulmonary regurgitation < moderate and peak trans-pulmonary pressure gradient < 40 mmHg. A total of five patients were included, with four males, aged 14–37 years. The initial diagnosis included Tetralogy of Fallot (two cases), tricus arteriosus (one case), pulmonary atresia (one case), and sub-aortic stenosis (one case and prior Ross procedure). Four patients underwent RVOT reconstruction with homograft or artificial conduit, and one patient was treated with trans-annular patch technique. The indications of TPVR included RVOT obstruction and regurgitation (three cases), isolated obstruction (one case), and isolated regurgitation (one case). Of the four patients with varying severity of RVOT obstruction, the average peak jet velocity of RVOT was 3.5 m/s, and the average peak pressure gradient was 50.0 mmHg. Except for one patient, who had previously been implanted with a covered Cheatham-Platinum (CP) stent due to severe stenosis of the main pulmonary artery, other patients underwent pre-stenting with a covered CP stent before TPVR. Clinical implant success was achieved in all of the five patients, and there were no serious peri-procedural complications. The average trans-pulmonary peak jet velocity and peak pressure gradient derived from post-procedural echocardiography were 2.3 m/s and 21.2 mmHg, respectively. All patients experienced significant symptom relief after the procedure. All patients completed 3-month follow-up, and four completed 6-month follow-up. There was no case of infectious endocarditis during follow-up. All patients were graded as New York Heart Association (NYHA) functional class one at the latest follow-up. Feng
et al. conclude that TPVR using the domestically produced balloon-expandable Prizvalve system is safe and feasible for the treatment of patients with post-surgical RVOT dysfunction and suitable landing-zone anatomy. The safety, effectiveness, and long-term valve durability of the Prizvalve system deserve further research.

Transcatheter interventions for structural heart disease have become the preferred treatment, and the availability of novel devices satisfies the specific demands of each patient. While there is no denying that domestically produced devices have advanced significantly in recent years, using them still comes with some technological risks and potential issues. The way forward will be to carry out further clinical trials to test the safety and efficacy of these devices.

Declarations

Disclosure of Interest

All authors declare no disclosure of interest for this contribution.

References


