

A FEASIBILITY STUDY OF NEW SELF-EXPANDABLE PERCUTANEOUS PULMONARY VALVE IMPLANTATION USING KNITTED NITINOL-WIRE STENT MOUNTED WITH A TRI-LEAFLET PORCINE PERICARDIAL VALVE

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BACKGROUND

Severe pulmonary regurgitation (PR) and associated right ventricular (RV) dilatation in native right ventricular outflow tract (RVOT) is challenging and self-expandable percutaneous pulmonary valve implantation (PPVI) for native RVOT is still assessed in ongoing clinical trials.

OBJECTIVE

The aim of this study is to report first human cases of a new self-expandable PPV using newly constructed knitted nitinol wire stent mounted with a tri-leaflet porcine pericardial valve developed in South Korea.

METHODS

We reviewed 10 cases of new self-expandable PPV at the Seoul National University Children's Hospital. This self-expandable valved stent was developed by our research team in cooperation with the TaeWoong medical company in South Korea. The valved stent was made of knitted nitinol wire backbone with tissue valve using porcine pericardium with multiple steps for tissue preservation including decellularization and alpha-galactosidase treatment.

RESULTS

Ten patients underwent previous total correction of Tetralogy of Fallot and showed severe PR (mean PR fraction: 44.6%, range: 35.4-56) and enlarged RV volume (mean indexed RV end-diastolic volume: 184.1 mL/m², range: 161.0–209.8). The median age at PPVI was 21.8 years (range: 13-36). Five patients received a 28 mm diameter valved stent and in 5 patients a 26 mm diameter valved stent was implanted via the 18 French delivery system. There were no significant peri-procedural complications. After the procedure, no significant pulmonary stenosis or PR was observed in angiography and echocardiography. Chest X-ray showed good valved stent position at the targeted RVOT area. All patients were discharged 4 days after PPVI without any complications. Six patients completed 6 months follow-up after PPVI until now. Cardiac MRI showed a mean reduction in indexed RV end-diastolic volume from 187.7 to 125.4 mL/m².

CONCLUSION

A feasibility study assessing the first human implantation of new self-expandable percutaneous pulmonary valve using knitted nitinol wire mounted with a tri-leaflet porcine pericardial valve developed in South Korea showed an excellent short-term result without any valve associated serious adverse events.