APPLICATION OF A TWO-STAGE STENT FOR THE DEVELOPMENT OF TRANSCATHETER AUTOLOGOUS TISSUE-DERIVED PULMONARY VALVE IMPLANTATION.

Yoshiaki Takewa (1), Yusuke Inoue (1), Takeshi Terazawa (1), Yasushi Sato (1), Tomoki Nagayoshi (1), Kazuto Fujimoto (2), Isao Shiraishi (2), Ken Takamatsu (3), Kunio Ohta (3),

1. Advanced Medical Engineering Research Center, Asahikawa Medical University, Japan;
2. Department of Pediatric Cardiology, National Cerebral and Cardiovascular Center, Japan;
3. Tamachi Industries Co. Ltd., Japan

Introduction

We have been developing a novel autologous biological heart valve (biovalve) using a unique technique, called in-body tissue engineering, in which tissue is formed by applying the encapsulation reaction of connective tissue [1, 2]. The biovalve has the potential to grow as we have previously reported [3], and thus has potential application in pediatric valvular heart disease with congenital heart disease. To be used in such patients, the valve must be implanted in a noninvasive method, i.e., transcatheter technique. To achieve this, the diameter of the crimped valve with a stent must be small enough to allow insertion through a peripheral blood vessel. For this purpose, we devised a two-stage deploying technique of stent-combined devices. In this study, we evaluated the feasibility of the device to achieve transcatheter implantation into the pulmonary valve position in a large animal experiment using an adult goat.

Methods

The device developed in this study is divided into two parts: one part consisting of the conduit and stent, and the other part consisting of the valve leaflet and stent, allowing for a reduction in outer diameter when crimping into the vessel. To obtain both parts, The biovalve molds were made of acrylic and metal, implanted with a self-expandable stent each subcutaneously in the back of an adult goat. Around 8 weeks after implantation, the molds with stent were extracted along with the surrounding connective tissue and only the molds were removed, resulting in the final two parts with the stent each. In this way, the minimum outer diameter of each device was reduced from 16 mm to 12 mm, respectively. Using transcatheter technique, a stent with a conduit was first deployed at the pulmonary valve position of an adult goat, followed by a stent with a valve leaflet in the former stent.

Results

The device could be implanted in the pulmonary valve position by conventional transcatheter valve implantation. Postoperative angiographic and echocardiographic monitoring showed good movement of the valve leaflets and no significant stenosis or regurgitation. The goat implanted the biovalve has been well condition (no thromboembolic event or heart failure) beyond 3 months without any anti-coaguration therapy after implantation. We plan to observe the goat's condition and monitor the device function for up to 6 months, after which the valve will be removed to examine its histologic structure and histocompatibility.

Conclusions

The biovalve could be implanted in the pulmonary valve position by our two-stage stenting method. It is expected to be a promising alternative valve for pediatric valvular heart disease with congenital heart disease because of its good histocompatibility in regenerative medicine, ease of application in transcatheter technique, and the advantage of being able to fabricate planned shapes.

References

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