Original Article

A novel surgical procedure: scaffold-pulmonary autograft transplantation

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Abstract: Mitral valve-related operations are easy to perform and show good results, but to prevent severe thromboembolism or a high ratio of prosthetic valve destruction by tissue, lifetime anticoagulant therapy is essential after the operation. Thus, identifying a new type of surgical procedure and prosthetic valve to cure mitral valve diseases is necessary. Pulmonary valve autograft transplantation (Ross II) with the “top hat” transplantation technique was first reported by Ross DN to cure mitral disease. Because the “top hat” procedure has some shortcomings, we designed the scaffold-pulmonary autograft transplantation procedure and performed animal experiments to confirm the feasibility and effectiveness of the procedure. A total of 13 minipigs, weighing 20-25 kg, were employed as experimental animals to undergo scaffold-pulmonary autograft valve transplantation in our surgical animal lab. The surgical procedure was performed under hypothermic general anaesthesia and extracorporeal circulation (or cardiopulmonary bypass, CPB). Briefly, the chest cave was opened through the left intercostal, the pulmonary valve autograft was harvested during on-pump beating heart, and the pulmonary valve autograft was mounted in a self-made pulmonary valve scaffold and transferred to the mitral valve annulus without removing the mitral instruments. Finally, the outflow tract of the right ventricle was re-established with a pig pulmonary homograft. After finishing data collection, all animals were executed 1 hour after removal from the CPB. For the 13 minipigs that underwent the operation, the CPB time was 182.4 ± 23.4 min. Two of the thirteen cases died of bleeding during the operation and of a post-operative pulmonary embolism, and the remaining eleven survived for one hour. The pressure of the left atrium did not increase significantly (P = 1.00), and the ultrasonic cardiograph (UCG) showed good function of the new mitral valves, with mean ejection fraction (EF) values of 63.6%. The mitral valve orifice areas were 1.10 ± 0.13 cm² (pre-operation) and 1.01 ± 0.08 cm² (post-operation) (P = 0.013). The function and structure of the new mitral valves were normal. We preliminarily consider scaffold-pulmonary autograft valve transplantation to be a new alternative to cure mitral valve disease, but advanced chronic animal experiments will be needed to confirm the long-term results of the operation. The results showed it could be a new alternative to cure mitral valve disease.

Keywords: Mitral valve disease, scaffold-pulmonary autograft valve transplantation, minipig

Introduction

Mitral valve prosthesis has been performed since 1960’s, and clinical trials have shown that the operation is easily performed by cardiac surgeons. However, preventing severe thromboembolism with lifetime anticoagulant therapy has proven to be essential for a mechanical prosthetic valve by clinical experience, and although tissue valve prosthesis has significantly developed, its fatal shortcoming of auto-destruction has not yet been overcome. Around the world, rheumatic mitral valve disease is still the most common indication for mitral valve replacement, especially in developing countries. Therefore, identifying a new type of surgical procedure and prosthetic valve to cure mitral valve diseases is necessary. In
2005, Ross DN and Kabbani first reported pulmonary valve autograft transplantation (Ross II) with the “top hat” transplantation techniques to cure mitral disease [1]. Because the “top hat” procedure has some shortcomings, we designed a novel surgical procedure, the scaffold-pulmonary autograft transplantation procedure, to cure mitral valve disease and initially performed related animal experiments.

Materials and methods

Thirteen minipigs were treated with the experimental surgical procedure, scaffold-pulmonary autograft transplantation to replace the mitral valve. The experiment materials and methods are as follows.

Experimental animals

A total of 13 minipigs, 6-8 months of age and weighing 20-25 kg, were purchased from Chinese Agriculture University Animal Center (Beijing, China). This study was conducted in strict accordance with the recommendations in the Guide for the Care and Use of Laboratory Animals of the National Institutes of Health. The protocol was approved by the Committee on the Ethics of Animal Experiments of Anzhen Hospital, Capital Medical University. All surgery was performed under sodium pentobarbital anaesthesia, and all efforts were made to minimise suffering.

Experimental instruments and drugs: Bird VIP respirator (USA), Sarns800 heart-lung machine, COBE children’s model hollow-filter membrane oxygenator, Hewlett-Packard Hp multifunction electrocardiogram monitor (USA), and polyformaldehyde (to make the hollowed-out pulmonary valve scaffold).

Surgical procedures

Minipigs were employed as the experimental animals for the scaffold-pulmonary autograft valve transplantation operation in our surgical animal lab. The surgical procedure was performed as follows. Under hypothermic general anaesthesia and extracorporeal circulation (or cardio pulmonary bypass, CPB), the chest cave was opened through the left intercostal, the pulmonary valve autograft was harvested during on-pump beating heart, and the pulmonary valve autograft was mounted in a self-made pulmonary valve scaffold (made from polypropylene) (Figure 1). The method used to make the “tissue mitral prosthetic valve” is described in detail as follows: select a self-made pulmonary valve scaffold that matches the diameter of the pulmonary valve autograft, adjust and trim the pulmonary valve autograft to match the scaffold, and then mount the pulmonary valve autograft in the scaffold with a line suture. On both ends, three mattress sutures with 4-0 Dacron line were used to fix the pulmonary valve, paying attention to avoid a pulmonary twist, and a continuous suture was used on both ends to mount the pulmonary valve in the scaffold (Figure 2). The new tissue prosthetic valve function was checked in vitro with water effusion. Then, the mitral valve replacement was finished with continuous sutures through the left atrium without removing the mitral instruments, and the right ventricle outflow tract was re-established with a pig pulmonary valve conduit homograft. The surgical procedure was finished after closing the left atrium. After the recovery of heart circulation and gradually removal from extracorporeal circulation, we started to collect dynastic data (direct measurement) and ultrasonic cardiograph) results and observed the working state of the new mitral valve by Ultrasonic Cardiograph (UCG). All animals were executed 1 hour after their removal from CPB, and the mitral valve prostheses was removed and examined by macroscopic observation.

Statistical analysis

All data were obtained from the experimental notes taken during the experiment and were expressed as the means ± standard deviation.
Scaffold-pulmonary autograft transplantation

The statistical analyses were conducted using the SPSS 10.0 software for Windows (SPSS Inc., Chicago, USA). The statistical significance for differences between the preoperative and postoperative variables was assessed with Student’s t-test. A P value of less than 0.05 was considered significant.

Results

Experiment surgery results

Two of the thirteen experimental animals died of haemorrhage and pulmonary embolism. The remaining animals successfully underwent the operation.

CPB time

The CPB time was 182.4 ± 23.4 min, the aortic cross-clamp time was 105.5 ± 10.0 min, and the new mitral valve replacement time was 30.5 ± 15.2 min.

Left atria pressure

The left atria pressure was 7.91 ± 2.81 mmHg before the CPB and 7.91 ± 3.12 mmHg one hour after the CPB. These values were not significantly different (P = 1.00).

Mitral valve orifice area

The mitral valve orifice areas were 1.10 ± 0.13 cm² (pre-operation) and 1.01 ± 0.08 cm² (post-operation) (P = 0.013).

Gradient across mitral valve and mitral valve blood flow rate

The gradients across mitral valve were 4.00 ± 1.21 mmHg (pre-operation) and 4.84 ± 1.24 mmHg (post-operation) (P = 0.053). The mitral valve blood flow rates were 1.00 ± 0.09 m/s (pre-operation) and 1.10 ± 0.11 m/s (post-operation) (P = 0.109).

All animals were executed 1 hour after their removal from CPB, and all new mitral valve structures were normal.

Discussion

Mitral valve disease in children is very common, and the mitral valve is very difficult to repair or replace with an artificial heart valve [2]. The pulmonary valve in the most of the patients with mitral valve disease is normal and available, and the long-term follow-up results of the Ross procedure have shown [4-6] that the new aortic valve (pulmonary valve transplant) rarely leads to rheumatic attack and destruction of the new valve. The long-term results of a pulmonary autograft valve transplanted into the mitral valve are satisfactory.

The orifice area of the pulmonary valve matched that of the mitral valve. The inner diameter of the pulmonary valve orifice in normal adults was 21-27 mm (average 24 mm, from the valve database in Anzhen Hospital). Its orifice area was 3.46-5.72 cm², but the native mitral valve orifice area in normal adults was 4-6 cm² and the available mitral orifice area of the mitral prosthesis was 3.1-4.5 cm².

The mitral annulus is large enough for a pulmonary autograft valve to be transplanted into the position of the mitral valve. The external diameter of the new scaffold-pulmonary valve was 25-31 mm, which matched the normal mitral valve annulus well. In addition, the left atria and left ventricles as well as the mitral annulus diameter were enlarged to some extent in the pathological situation; thus, implanting the new scaffold-pulmonary valve in the location of the mitral valve is not difficult.

The pulmonary valve was able to endure the high pressure of the left ventricle over the long term. For patients with mitral lesions combined with secondary pulmonary artery hypertension or primary pulmonary hypertension, the pulmonary valve suffered only slightly from valve incompetence, thereby showing that the pulmo-
The pulmonary valve was able to endure high pressure [3, 4]. The long-term follow-up results of the Ross operation have also shown that the allograft pulmonary valve was able to endure high pressure [5].

The Ross procedure has been widely performed around the world to treat aortic valve diseases and has been regarded the best alternative for isolated aortic valve disease in adolescents until now [2, 5]. Since Ross DN and Kabbani SS first reported that the use of pulmonary valve autograft transplantation (Ross II) to cure mitral disease in London [2, 5], Kabbani SS has reported 97 cases of the procedure with an operative mortality of 4.6% and a late mortality definitively related to the operation of 12.5%. Until now, there have been approximately 345 cases of the Ross II procedure reported around the world, and all cases have been performed with the “top hat” transplantation technique. The “top hat” technique was introduced by Ross DN and Kabbani SS, and the procedure is as follows: the pulmonary autograft is covered with a vascular prosthesis pre-coated with the pericardium autograft to fix the pulmonary autograft shape, its distal end is connected to the mitral annulus, and its proximal end is fixed with the umbrella-shaped pericardium autograft to the wall of the left atrium around the mitral valve orifice to prevent it from swaying [1, 6-11]. The shortcomings of the “top hat” procedure are as follows: 1) pulmonary autograft stenosis induced by a softer vascular prosthesis twist, 2) the rupture of the pericardium autograft, and 3) suture edge breakage resulting from the suture line cutting the tissue.

In our experiment, the pulmonary valve autograft was mounted in a scaffold to replace the Dacron conduit in the “top hat”. Our experiment has proven that this procedure can overcome all of the above shortcomings of the “top hat” procedure.

Evaluation of the new mitral valve: after analyzing the data of the new mitral valves, we observed that the left atrial pressure was not significantly increased after the operation and that no new mitral stenosis and incompetence occurred. Although the new mitral orifice area was decreased ($P = 0.013$), there was no significant increase in the gradient pressure across the mitral valve ($P = 0.053$), and the mitral valve blood flow rate ($P = 0.109$) and postoperative ejective fraction of the left ventricle did not change significantly compared with the pre-operative values. Thus, the decreased size of the post-operative mitral valve orifice did not significantly affect the homeodynamics and cardiac function.

We preliminarily conclude that scaffold-pulmonary autograft valve transplantation is a new alternative to cure mitral valve disease, but advanced chronic animal experiments will be needed to confirm the long-term results of the operation.

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Disclosure of conflict of interest

None.

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