Vena cava as autologous tissue for pulmonary valve substitute

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Abstract

In this study, we report on our first experience with the construction of a valve using autologous vena cava tissue for right ventricular outflow tract reconstruction. Simulating the clinical situation, valves were built from tubular pieces of porcine inferior vena cava placed in a PTFE tube and investigated in a pulsatile flow simulator. Based on the given vena cava dimensions, conduits were constructed with diameters of 19 mm in bicuspid or tricuspid and 22 and 24 mm in bicuspid configuration. The lowest pressure gradients were observed in the 22 mm vena cava valves in bicuspid configuration (8.6 ± 0.5 mmHg) compared to 24 mm valves (10.6 ± 0.9 mmHg, P = 0.0004) and 19 mm valves (13.4 ± 1.5 mmHg, P = 0.005). No differences could be found between 19 mm bicuspid and tricuspid valves. Concerning valve opening movements, a complete opening in the 19 mm and a nearly unhindered opening in 22 mm valves were registered. In 24 mm valves opening was incomplete. Leakage was increased in 19 mm bicuspid valves due to leaflet prolapse. In conclusion, construction of a valve mechanism from vena cava tissue is feasible. The in-vitro hemodynamic results are encouraging, animal experiments are ongoing to investigate the midterm function of these valves.

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Keywords: Pulmonary valve; Bioprosthesis; Hemodynamics; Veins

1. Introduction

The first choice for pulmonary valve replacement in the Ross procedure, as well as in other heart defects involving a diseased pulmonary valve, is a homograft or a bioprosthesis. These substitutes are subjected to several shortcomings such as degeneration, including development of increased transvalvular pressure gradients due to shrinkage or calcification, susceptibility to infection, and immunological reactions [1]. One aspect of the restricted durability of these substitutes is the lack of viability and autologous origin. Theoretically, an improvement might be achieved by the use of an entire autologous tissue valve. However, results of previous autologous tissue valves made from pericardium or fascia lata were not satisfying [2, 3]. Tissue from the great veins offers a promising alternative because the intima of this material comprises a desaturated blood tissue surface and its structure bears some resemblance to the pulmonary valve [4, 5]. Therefore, the aim of this study was to develop an autologous valve built from vena cava tissue. In-vitro hemodynamic investigations of these valves were reported.

2. Material and methods

2.1. Preparation

Valves were constructed from tubular pieces of the vena cava inferior (length 16.1 ± 0.7 mm, diameter 17.9 ± 0.7 mm)

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Measurements were performed in a pulsatile flow simulator, details of which have been described previously [6]. The valve conduits were mounted between two spigots in vertical position and then tested at a heart rate of 64 cycles per minute with a stroke volume of 58 ml, resembling that of the average-sized human being.

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and thus the largest prosthesis diameter warranting coaptation of the leaflets is equal to 1.05 (one-third of the Archimedes’ constant). For a bicuspid valve configuration the available length of a leaflet is half the circumference, thus allowing for greater diameters, although these valves will not completely open.

In a first series \( (n=4) \), valves were constructed in both tricuspid and bicuspid fashion using 19 mm prostheses, approximating the diameter calculated for the tricuspid configuration. In a second series, two groups of bicuspid fashioned valves were built with prosthesis diameters of 22 mm \( (n=13) \) and 24 mm \( (n=11) \), respectively, to achieve greater orifice areas for lower pressure gradients.

Pressure measurements were performed using Envec Ceracore M pressure transducers (Endress + Hauser, Maulburg, Germany) at the inflow and outflow spigots. The flow through the valves was measured with a TS-410 ultrasonic flow-meter (Transonic Systems Inc., Ithaca, NY, USA) positioned upstream the valve. Data were collected digitally and mean pressure gradient, closing and leakage volumes were determined from ten consecutive cycles each.

Additionally, valve movements were recorded with a Motionscope HR-1000 high-speed camera (Redlake Imaging Corp., Morgan Hill, CA, USA) positioned straight above the valve at a rate of 500 frames per second for qualitative analysis.

2.3. Statistical analysis

Comparisons between the groups were performed using the one-way analysis of variance and the Bonferroni adjustment for multiple tests was used for significant differences. Data were expressed as means \( \pm \) S.D. of the mean.

3. Results

Details of the hemodynamic measurements are depicted in Table 1. In comparison, mean pressure gradients were lowest in 22 mm bicuspid vena cava valves compared to 24 mm valves \( (P=0.0004) \) and 19 mm valves \( (P=0.005) \). Bicuspid or tricuspid configuration does not influence pressure gradients in the 19 mm group.

Closing volumes were similar for 22 and 24 mm valves but elevated for the 19 mm valves in both configurations. Leakage was negligible for the larger bicuspid valves (22 and 24 mm) and for the 19 mm tricuspid valves. In bicuspid configuration the 19 mm valves became insufficient due to valve prolapse.

Regarding hemodynamics, dimensional evaluation of the tested bicuspid valves revealed an optimal relationship between available vena cava diameter and selected tube size to be 1.25 \( \pm \) 0.04 of primary diameter, thus for the given 17.9 mm mean vena cava diameter a 22 mm tube.

High-speed video visualization of valve movements demonstrated a complete opening in the 19 mm and a nearly

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Results of the hemodynamic measurements of the vena cava valve</th>
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<tr>
<td></td>
<td>Tricuspid</td>
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<td></td>
<td>19 mm</td>
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<td></td>
<td>19 mm</td>
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<td>( n )</td>
<td>4</td>
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<tr>
<td>Mean pressure gradient (mmHg)</td>
<td>13.5 ( \pm ) 0.5</td>
</tr>
<tr>
<td>Closing volume (ml)</td>
<td>6.1 ( \pm ) 2.2</td>
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<tr>
<td>Leakage volume (ml)</td>
<td>1.1 ( \pm ) 1.1</td>
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</tbody>
</table>
Fig. 2. Opening of the vena cava valves. The 19 mm valves (upper row) open completely in both tricuspid and bicuspid fashion. 22 mm and 24 mm bicuspid valves open incomplete, which will lead to a restriction of flow area in the 24 mm valve (below right).

unhindered opening in 22 mm valves. In the 24 mm valves opening was incomplete, leading to a restriction of the flow area (Fig. 2). Leakage was increased in 19 mm bicuspid valves because of a clearly visible prolapse of one leaflet (Fig. 3).

Fig. 3. Closing of the vena cava valves. Valve closure demonstrates sufficient leaflet coaptation in all configuration except of the 19 mm bicuspid valve because of prolapse of one leaflet (above right, the arrow indicates the prolapsed leaflet).

4. Comment

The reconstruction of the right ventricular outflow tract is an obligatory component of the Ross procedure and also for the repair of several congenital heart defects. However, a fully satisfactory material for pulmonary valve replacement is not yet available.

To improve the function of prostheses in the right ventricular outflow tract, one might assume that an autologous valve replacement may be favorable. Theoretically such prostheses provide the advantage of avoiding foreign tissue reactions due to their autologous origin and possible regenerative capabilities of viable tissue. Senning was the first who used autologous fascia lata for repair and replacement of aortic valves [7], Bjork and Hultquist introduced pericardial aortic valve prostheses [8] and Zerbini utilized dura mater preserved in glycerol as valve replacement [9]. Initial results with fascia lata were excellent, however, within 5–10 years increasing stenosis and insufficiency occurred due to progressive fibrosis and contraction of the tissue [2, 3, 9].

The continuous search for preserving viability of valves led us to vena cava tissue which provides some beneficial aspects. The endothelial surface might prevent thrombus formation and shrinkage. Also, the structure of the layers of the vena cava bears some resemblance to the layers of the pulmonary valve [5], with the potential of functional remodelling. It is available in patients and particularly the superior vena cava is replaceable during cardiac surgery, although this is not a common procedure and there may be some doubts if there are appropriate vascular prostheses to replace the vena cava. In this respect we have constructed the valve conduits with vena cava pieces as short as possible, assuming that the vessel could be mobilized for such low distances of about 1.6 cm to allow for readaptation without the use of a vascular prosthesis.

Polytetrafluoroethylene vascular prostheses used for the conduit in this investigation are also readily available. They were shown to less likely develop significant pseudointima or early obstruction compared with Dacron conduits and were more pliable [11, 12]. Allen et al. reported on Gore-Tex conduits as right ventricular outflow tract replacement in pediatric patients with no evidence of failure or deterioration [13].

The present study demonstrates that the construction of a functional valve from vena cava tissue seems to be possible. Depending on the diameter of the available vena cava such valves could be constructed either in tricuspid or bicuspid fashion, at which the bicuspid configuration reached the lowest transvalvular pressure gradients and regurgitation, at a prosthesis diameter of about 25% greater than the original vena cava diameter. On the other hand, bicuspid vena cava valves became insufficient in prosthesis sizes of nearly the primary diameter as the consequence of redundant material, resulting in valve prolapse, but not tricuspid valves. Thus, the individual conduit size as well as the configuration of the valve have to be well adapted to the available diameter of the patient’s vena cava and in some cases may restrict the usage to avoid prosthetic mismatch. Ultrasonic studies of the vena cava at humans, however, reveal mean diameters similar to the porcine...
vena cava used in this study, but vary in a wide range, regardless of ventricular function or body surface area [14, 15].

With regards to limitations in the concept of building a valve from the patient's own vena cava, the usage of homologous (and even xenologous) vena cava material should also be considered. These materials are widely available in a range of dimensions and there is no need of reconstructing others than the malfunctioning patients valve. However, like other bioprostheses the durability of such constructs would be limited due to the foreign material nature of the homologous (or xenologous) tissue, which was the primary stimulus to conduct this study with creating genuine autologous valves.

5. Conclusions

In this study, we report on our first experience with the construction of a valve using autologous vena cava tissue as an alternative for right ventricular outflow tract reconstruction. The in-vitro hemodynamic results are encouraging, so animal experiments are ongoing to investigate the midterm function of these valves and possible adaptation processes. However, since the usage of patients vena cava material has its limitations, also homologous or xenologous vena cava should be considered for valve construction.

References