In-vitro study on the relationship between progressive sinotubular junction dilatation and aortic regurgitation for several stentless aortic valve substitutes

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Abstract

Objective: Stentless aortic valves are widely used due to their excellent hemodynamic properties. However, if the subcoronary implantation technique is used later dilatation of the sinotubular junction (STJ) can cause regurgitation. The aim of the study was to determine the dilatation tolerance of two commercially available stentless xenografts and fresh aortic and pulmonary roots against such dilatation.

Methods: Four groups each comprising five specimens of fresh porcine aortic roots, pulmonary roots, Medtronic freestyle or Toronto SPV Xenografts were tested in a mock circulation using a special device for gradually increasing the diameter of the sinotubular junction. The smallest diameter where regurgitation occurs was measured and correlated with the starting diameter and expressed as per cent values. Opening and closing patterns were obtained by a high speed camera and flow characteristics were determined.

Results: The highest dilatation tolerance of STJ was found in the fresh porcine aortic roots (165%\( \pm \)10) followed by fresh pulmonary roots (146%\( \pm \)12), the Freestyle (143%\( \pm \)4) and the SPV (132%\( \pm \)5) bioprostheses. All differences were significant with \( P\% 0.05 \) except that between the fresh pulmonary roots and the two commercial available bioprostheses.

Conclusions: Our results indicate that aortic homografts provide higher resistance against regurgitation induced by dilatation of the STJ than an autograft or the stentless xenografts, Freestyle xenograft followed by the Toronto SPV. The use of the full-root technique should be considered if aortic dilatation seems to be likely.

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1. Introduction

First aortic xenografts were implanted in a stentless fashion [1] prior to the introduction of stented bioprostheses which have been used for more than three decades with excellent results [2,3]. One shortcoming of stented bioprostheses is the fixation of the commissures which does not allow cyclic change of the commissural dimension as it normally occurs. This cyclic expansion of the commissural area serves reduction of stress on the leaflets. The principle of stentless implantation was clinically revived by Sievers et al. [4] who implanted stentless bioprostheses with different design features [5]. In the following years, the implantation of stentless bioprostheses was used more and more commonly. The advantage of stentless bioprostheses in comparison to stented bioprostheses is not only the distensibility at commissural level but also the smaller suture ring resulting in lower pressure gradients. However, the commissures of the stentless bioprostheses free-hand implanted in subcoronary technique have to follow the dimensional changes of the aortic root not only in a cyclic mode but also concerning the naturally occurring increase of the aortic diameter [6]. This increase in dimension at commissural level pulls apart the commissures leading to reduction of coaptation area of the leaflets and finally regurgitation. The tolerance of the different stentless implants against regurgitation in relation to dilatation of the sinotubular junction (STJ) is still not clearly defined. David recommended not to use the Toronto SPV in case the STJ diameter exceeds the annular diameter by more than 3 mm [7]. The pulmonary autograft is of special interest because a ‘low pressure graft’ is implanted in a high pressure environment which is the main characteristic of the Ross
procedure [8]. The aim of this in vitro study was to investigate at which increase of STJ diameter regurgitation starts to occur.

2. Methods

2.1. Experimental protocol

Four different types of stentless valve implants were used, firstly five fresh porcine native aortic roots (NAV) which were used at the latest within 2 h after harvesting, five native pulmonary roots (NPV) of the same origin, also used within 2 h after harvesting, five commercially available Medtronic stentless bioprostheses (Medtronic Freestyle®, Model 995, Medtronic, Minneapolis MN) (MF) and five also commercially available SJM bioprostheses (Toronto SPV®, Model SPA-101, St Jude Medical Inc, St Paul MN) (SPV). The diameter $D_s$ of the native aortic and pulmonary roots were measured with a caliper by pressure rising the roots to 80/25 mmHg, respectively and was measured to be $26.0 \pm 0.26$ and $25.98 \pm 0.21$ mm, respectively. The diameters of the prosthetic xenografts were labeled to be 25 mm. The experimental setup consisted of a mock circulation with an integrated video camera system taking 500 pictures per second to visualise the opening and closing mechanisms of the implants and especially to detect the loss of coaptation, determining the onset of regurgitation. The STJ diameters were gradually increased using a special device in a pulsatile circuit.

2.2. Mock circulation

An open reservoir with its fluid level adjustable above valve position provides the atrial pressure. The pulsatile flow is generated by a short-stroke piston pump driven by waveform adapted cam plates at various frequencies and stroke volumes. To minimize negative pressure while filling the pump in diastole the input of the pump is built with two specially designed disc valves representing the mitral valve with little inertia during opening and nonleakage closure. An adjustable air compliance chamber at the pump outflow simulates ventricular impedance to avoid pressure and flow oscillations in systole. The composite graft was mounted in front of the pump, standing free between two holders in a fluid reservoir to keep the material moist. Above the aortic root section a box with an optical window at the upper side is mounted, permitting a view on the investigated valve.

The afterload system consists of three elements: a fluid column of variable height providing constant diastolic pressure, an adjustable air compliance chamber to provide the characteristic aortic compliance, and a nonlinear resistance element to simulate peripheral resistance. The pump rate was $60 \text{ min}^{-1}$ and the stroke volume were $60 \text{ ml}$. The fluid consisted of physiological saline solution with a density of $1.05 \text{ g/ml}$. A near normal pressure wave form with systolic pressures of $120 \text{ mmHg}$ and a diastolic pressure of $80 \text{ mmHg}$ was initiated.

2.3. Device for gradually increasing sinotubular diameters

A special device (Fig. 1) was mounted at the area of the STJ and allowed a gradual increasing in sizes of the sinotubular area equilaterally. The stentless grafts were implanted in a prosthetic tube. The prosthetic tube included a redundant patch material in the sinuses which allowed diameter increase at the STJ.

2.4. Data collection and analysis

Valve motions were recorded with a Motionscope HR-1000 high-speed camera (Redlake Imaging Corp., Morgan Hill, CAL) at a rate of 500 frames per second, positioned right above the valve outflow. Video data were digitalized and analysed with a custom-designed motion evaluation software. Both video and data recording were started simultaneous and were synchronized by trigger signals of the high-speed camera. Time delay between measured data and video recording was less than $3 \text{ ms}$. For every investigated valve each video sequence was carefully evaluated to assess the smallest STJ-diameter $D_s$ at which a loss of central coaptation of the leaflets was observed. In every series the frame with the best coaptation was chosen. These diameters were compared to the initial values $D_s$ of the industrial prostheses, or respectively of the aortic and pulmonary roots. The Figs. 2 and 3 illustrate original pictures of a valve at a STJ diameter with first coaptation loss (Fig. 2) and under considerably higher distension of the STJ, causing severe regurgitation (Fig. 3). The pictures were obtained during diastole.

Statistical analysis was performed with the statistical language R 1.8.1 [9]. Data were expressed as mean $\pm SD$. The minimum diameter of the STJ causing insufficiency was assessed by visually analysing the video records and was expressed as percentage of the initial diameter. Initially a Kruskal–Wallis rank sum test was performed and subsequently the differences between the groups were proven with the Wilcoxon rank sum test. Any difference was considered significant for $P < 0.05$. Effect sizes were computed according to Cohen J. [10] and considered to be large if $d > 0.8$ [10].
3. Results

Native aortic valves exhibited the highest resistance against STJ-dilatation (165% ± 10). A significantly lower ($P=0.03$, $d=1.75$) but fairly high resistance can be demonstrated for the NPV-group, but however with a high variability (146% ± 12). The prosthetic specimens are tolerating dilatation to a significantly lesser extent than NAV ($P=0.008$ for both and $d_{MF}$ vs NAV $=2.87$ and $d_{SPV}$ vs NAV $=4.15$), the freestyle showing the better values (143% ± 4 vs 132% ± 5; $P=0.004$, $d=2.28$). The differences between SPV and NPV as well as between MF and NPV are not significant. A boxplot of the percentage of the $D_r/D_a$-values is provided in Fig. 4. The absolute, relative and basic values are given in Table 1.

4. Discussion

In this study we provide evidence that the commercially available glutaraldehyde treated stentless xenografts have a reduced tolerance against of regurgitation with respect to dilatation of the STJ in comparison to native porcine aortic and pulmonary roots. In the field of bioprosthesis replacement of the aortic valve, stented bioprostheses were considered as the ‘Gold Standard’ for several decades. More or less fix commissures, however, induce abnormal stress on the leaflets which might have contributed to the limited durability of these implants. To overcome this problem, stentless bioprostheses were re-introduced 1985 by Sievers et al. [5,11] In the mean time, several commercially available stentless bioprostheses are on the market and have proven to be superior to stented bioprostheses with reference to pressure gradient and effective orifice area [12,13], as well as survival [14]. This is not only related to the more flexible commissures but also to the little amount of fabric tissue at the proximal suture line. Since the stentless valves are sutured to the native wall of the recipient aortic root, however, there exists a risk for the development of aortic regurgitation over time with increasing diameter at the STJ which occurs naturally during life to a greater or lesser extent [7,15-17]. If size increase exceeds certain limits, aortic regurgitation may occur after implantation of stentless implants, because the prosthesis commissures have to follow the dilatation of the root. This could implement a limiting factor for improved durability of stentless bioprostheses compared to stented bioprostheses.

Table 1

<table>
<thead>
<tr>
<th>Valve type</th>
<th>$D_a$ (mm)</th>
<th>$D_r/D_a$</th>
<th>$D_r$ (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh aortic valve</td>
<td>26.0±0.26</td>
<td>1.65±0.10</td>
<td>42.94±2.64</td>
</tr>
<tr>
<td>Fresh pulmonary valve</td>
<td>25.98±0.21</td>
<td>1.45±0.12</td>
<td>37.84±3.13</td>
</tr>
<tr>
<td>Medtronic Freestyle</td>
<td>23</td>
<td>1.43±0.04</td>
<td>35.66±1.11</td>
</tr>
<tr>
<td>Toronto SPV</td>
<td>25</td>
<td>1.32±0.05</td>
<td>32.97±1.25</td>
</tr>
</tbody>
</table>
We found a significant difference of tolerance against aortic regurgitation with respect to dilatation of the STJ between native porcine aortic and pulmonary roots on the one hand and stentless bioprostheses on the other hand. Most likely this is related to the fixating procedure of the bioprostheses which stiffens and shrinks the leaflet material, preventing adaptive mechanisms and the natural tolerance against STJ dilatation. We found also a difference in the onset of regurgitation between the two commercially available bioprostheses from Medtronic® and SJM®. Whether the different fixation processes relate to this finding is speculative, but could have an important influence in this respect. The Medtronic® valve is fixated with zero pressure, the SJM® valve is fixated with low pressure. The different characteristics of these stentless bioprostheses might have an influence regarding late onset of regurgitation when undue dilatation of STJ occurs in the patient. These findings also emphasize the need for exact sizing of the STJ and valve during implantation of stentless bioprostheses. Undersizing of a stentless bioprosthesis could promote early occurrence of regurgitation and should be avoided. On the other hand, oversizing could be a protective measure to get more tolerance against dilatation related regurgitation but it will also increase the stress on the leaflets due to bending and flexion. The lower tolerance of native pulmonary grafts against STJ dilatation compared to aortic grafts may be conditional upon the usage of a ‘low pressure graft’ in a high pressure environment which consumes part of the distensibility after being subjected to systemic diastolic pressure of 80 mmHg [8]. Whether the lower resistance of pulmonary roots against coaptation loss under STJ distension is of clinical importance remains unclear even though the Yacoub group demonstrated functional and histological modes of adaptation of pulmonary autografts to systemic pressure postoperatively [18].

One limitation of the study is that the experiments are performed under an unvariable diastolic pressure. It can be assumed that with a different diastolic load there may be also a change on distension tolerance for the different grafts. Furthermore, the results presented are valid only on the assumption that the tissue characteristics such as dimension, flexibility, movement during cyclic change of blood pressure and histological integrity of the valves do not change over time. For allogenic and xenogenic material it is likely that tissue alterations might reduce tolerance against dilatation related regurgitation. In addition, we did not use a non-Newtonian fluid. This may have an influence on hemodynamics and valve motion and possibly also on the amount of regurgitant volume.

In conclusion, there is a difference between tolerance towards aortic regurgitation (related to dilatation of the STJ) not only between native aortic and pulmonary porcine roots and stentless bioprostheses in systemic circulation, but also between different commercially available xenografts.

References