Eight years clinical experience with the replacement of the ascending aorta using composite xenopericardial conduit


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Abstract

Objective: The evaluation of early and late results after ascending aorta replacement with composite glutaraldehyde-treated xenopericardial valved conduit. Methods: From December 1989 to May 1999 the ascending aorta was replaced with 148 composite xenopericardial conduits in 145 patients. Biological valves were inserted in 28 conduits, mechanical valves ± in 116. The age of 40 female (28%) and 105 male (72%) patients ranged from 10 to 60 years (mean, 38.7 ± 12 years). The original diseases were: atherosclerosis in 51 (35%), cystic media necrosis in 50 (35%), Marfan syndrome in 35 (24%), syphilis in three (2%), non-specific aortitis in one (0.7%), Turner syndrome in one and infective endocarditis in four cases. Aortic dissection was found in 67 patients (46%): type I in 14 (23%) and type II in 53 (77%). Twenty-one patients (15%) were operated on during the acute phase of the dissection. The Bentall–DeBono technique was used in 144 operations, in four cases (2.7%) supracoronary resection was performed. Associated procedures included: mitral valve repair (five), CABG (four), resection of the coarctation (two), MV replacement (two). Biological tissues condition was assessed using TTE, TEE and computed tomography (CT) scanning technique. Results: Hospital mortality was 8.3 % (12 patients). The death was caused by: low cardiac output (three), arrhythmia (two), neurological complications (one), sepsis (one), polyorgan failure (four), bleeding (one). Non-lethal complications included: bleeding (four), heart failure (two), persisting A-V block (two), polyorgan failure (three), cerebral (two), mediastinitis (three), and early prosthetic endocarditis in three patients. All three patients with endocarditis were successfully re-operated and conduit replaced with the same type of the device. Late follow-up ranged from 2 months to 8 years (mean, 51 months) and complete in 87% of the discharged patients (115 patients). There were four valve-related deaths due to thrombembolia and five deaths non related to the valve and/or conduit. Clinical and instrumental evaluation did not reveal any signs of tissue degeneration at the conduit and biovalves’ cusps. Conclusions: The xenopericardial valved conduit is an effective and acceptable device for the replacement of ascending aorta in almost all cases, it provides good early and late results. Its pliability and elasticity are especially attractive in situations with frail tissues and high risk of bleeding.

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Keywords: Aortic aneurysms; Surgical repair; Composite xenopericardial conduit

1. Introduction

The use of valved conduit in cases of aneurysm or dissection of the ascending aorta with valvular insufficiency today is the widest-spread method of surgical treatment [1–3]. Most authors use Dacron vascular prostheses. The disadvantages of those prostheses when used in classical Bentall–DeBono procedure are well known. Lately some companies have elaborated and introduced into the clinical practice new types for the processing of the synthetic tube which assure its total hemostaticity [4,5]. Up to 1990 in our center we have used only synthetic conduits. After getting acquaintance with the work of Ardito et al. [6] we created an original xenopericardial conduit for ascending aorta replacement. Its clinical use started in December 1989. The purpose of our investigation consisted in evaluation of early and late results of the operations using this conduit.

2. Materials and methods

2.1. Patients

From December 1989 until May 1999 we performed 148 operations using xenopericardial conduit for the replacement of the ascending aorta in 145 patients. Their age
ranged from 10 to 60 years (mean, 38.7 ± 12 years). There were 40 female (28%) and 105 (72%) male patients. Clinical characteristics of patients and the etiology of their aortic lesions are presented in Table 1.

Aortic dissection was present in 67 patients (67%), in 21 of them (31%) it was acute.

2.2. Method of bioconduit preparation

Xenopericardial conduit and xenopericardial valve are made in the laboratories of biotechnology attached to our institute. Bovine pericardium was cleaned from the friable tissues, then it was treated similarly to Hancock T6 method with 0.625% glutaraldehyde solution, and 1% dodecyl-sulphate solution subsequently and preserved in 4% formaldehyde solution [7].

A tube with the diameter corresponding to the prosthetic valve size was constructed from the pericardium. The prosthetic cuff was fixed to the tube with continuous suture. The longitudinal suture on the tube ended at 2 cm from the proximal end and the was left open (Fig. 1). Xenopericardial aortic valve prostheses (original BIONIKS design) were inserted in 28 conduits, 116 conduits contained tilting-disc prostheses EMIKS (Russia), and four were used without prosthetic valve. Pericardial valves BIONIKS are clinically used in Russia since 1984 and its preparation is similar to conduit. Mechanical valves EMIKS are low-profile tilting disc valves with locking element made from Carbonstal – an analogue of Pyrolyte carbon. Those valves are used in Russia and in CIS country from 1983.

2.3. Surgical technique

All operations were performed under extracorporeal circulation with moderate hypothermia (26–28°C). As a rule, we cannulated common femoral artery and both caval veins separately. After aortic cross-clamping, it was opened with T-shaped incision and cardioplegia was induced by injecting modified St. Thomas solution (every 20 min) or Custodiol (single 3 l infusion) into the coronary ostia. In acute dissection with intact aortic valve (four cases, 2.7%) supracoronary replacement of the ascending aorta was carried out. With this proximal and distal anastomoses were performed using continuous suture with Prolene 4-0.

For the use of valved tube the aortic valve was resected. Proximal anastomosis was performed using mattress sutures with Ti-cron 2-0 on Teflon pledgets. The openings were created in the conduit at the sites of coronary ostia projection, the anastomoses with coronary arteries were performed. The distal part of the tube was cut out at the necessary length and distal anastomosis between the aorta and the tube was made using continuous suture. At this stage of the operation we adjusted the tube diameter to this of the aorta with the use of unfinished longitudinal suture. In two patients with low-positioned coronary ostia and marked atheromatosis of the aortic wall a square xenopericardial flap was fixed by the commissural sutures. The anastomoses with coronary ostia were created from the luminal side. The prosthetic valve was sutured, then the tube and its distal

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Clinical characteristics of the patients</th>
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<tbody>
<tr>
<td>Age</td>
<td>10–60 years</td>
</tr>
<tr>
<td>Male</td>
<td>105</td>
</tr>
<tr>
<td>Female</td>
<td>40</td>
</tr>
<tr>
<td>Etiology of lesion:</td>
<td></td>
</tr>
<tr>
<td>Marfan syndrome</td>
<td>35</td>
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<tr>
<td>Cystic media necrosis</td>
<td>50</td>
</tr>
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<td>Atherosclerosis</td>
<td>51</td>
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<tr>
<td>Aorto-arteritis</td>
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</tr>
<tr>
<td>Turner syndrome</td>
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</tr>
<tr>
<td>Syphilis</td>
<td>3</td>
</tr>
<tr>
<td>Infective endocarditis:</td>
<td></td>
</tr>
<tr>
<td>Native valve</td>
<td>1</td>
</tr>
<tr>
<td>Prosthetic valvea</td>
<td>3</td>
</tr>
<tr>
<td>Trauma</td>
<td>1</td>
</tr>
<tr>
<td>Type of aortic lesion:</td>
<td></td>
</tr>
<tr>
<td>True aneurysm</td>
<td>74</td>
</tr>
<tr>
<td>Chronic dissection</td>
<td>46</td>
</tr>
<tr>
<td>Acute dissection</td>
<td>21</td>
</tr>
<tr>
<td>Type I</td>
<td>14</td>
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<tr>
<td>Type II</td>
<td>53</td>
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* Patients with early endocarditis after conduit implantation.
anastomosis were formed. The heart was deaired and aortic cross-clamp was released. The operation was ended by tight wrapping of the conduit by the remnants of the aneurysmatic pouch and the creation of an anastomosis between the para-conduit space and right atrial appendage. This was not performed during the operations including CABG and in cases with infective endocarditis.

In aortic dissection the false lumen was closed by separate pledged suture. In five cases in order to find the dissected intima, that migrated into the aortic arch, the rate pledgeted sutures. In five cases in order to find the para-conduit space and right atrial appendage. This was not performed during the operations including CABG and in cases with infective endocarditis.

The concomitant procedures included mitral valve replacement (two), mitral valve repair (five), coarctation repair (two), CABG (four). When mitral valve replacement was necessary, the operations were carried out through the aortic root. After the excision of aortic valve leaflets we measured the diameter of the fibrous ring. If left ventricular outflow tract was not 27 mm at least, then the mitral valve leaflets were resected from the LVOT side. Mattress sutures were put on the fibrous ring of the mitral valve from the left atrial side and mitral valve prosthesis was implanted into the infra-annular position. Then the conduit was implanted.

In cases with associated coarctation of the aorta (two patients) the sternotomy was performed, the patients were prepared for extracorporeal circulation. With patients laying on the right side, coarctation was resected through left thoracotomy. Then the procedure on the ascending aorta was performed.

The continuous anticoagulation agent Phenylindionum (Fenylin, Tallinna Farmaamatsiatehas, Tallinn, Eesti) was prescribed in all cases starting from the 3rd post-operative day, the INR was maintained at 2–2.5. This anticoagulant is drug of choice in patients with artificial heart valves in Russia. In patients with biological aortic valve prostheses anticoagulant uptake was stopped 1 year later.

The assessment of late results was made with the questionnaire and at direct investigation using EchoCG, X-ray examination and computer tomography.

In order to process the materials statistically we used ‘Primer of Biostatistics’ software (v.4.03) (McGraw Hill, 1998). The rate of early and late complications was calculated according to Edmunds et al. [8]. The data were expressed as mean ± SD. Differences between groups were evaluated using chi-square analysis. The reliability of the results was assessed with CI 95%. P < 0.05 was considered to be significant.

3. Results

Overall hospital mortality was 8.1% (12 patients). The death was caused by: low cardiac output (three), arrhythmia (two), neurological complications (one), sepsis (one), polyorgan failure (four), bleeding (one). The highest mortality was seen in the group with acute dissection – 19% (four out of 21 patients). In the group with chronic dissection the mortality was 8.7% (four of 46). However the difference between those two groups did not reach statistical significance (P = 0.67). All four deaths caused by polyorgan insufficiency occurred in the group with type I acute aortic dissection and were connected with the underestimation of initial visceral perfusion. The mortality in the group with type I dissection as 29% (four of 14 patients) and was reliably higher than in the group with type II dissection (5.7%) (P = 0.03). The mortality among the patients with true aneurysms and aortic insufficiency reached 4.9% (four out of 81 patients). In one patient after the conduit wrapping the Cabrol anastomosis was not performed. The cutting of the distal anastomotic suture led to acute bleeding, conduit compression and heart arrest. All the cases of acute heart failure were seen in patients with chronic aortic insufficiency, cardiomegaly and circulatory decompensation.

No lethal outcomes occurred in the group with concomitant surgical interventions.

Non-fatal complications were noted in 19 patients (12%) and included: bleeding (four), heart failure (two), persisting A-V block (two), polyorgan failure (three), cerebral (two), mediastinitis (three), and early prosthetic endocarditis in three patients. The development of early prosthetic endocarditis is of special interest. In two patients the infection was localized on aortic valve prosthesis, in one patient there was fester of paraprosthetic area. In all those cases the valve prosthesis was replaced by a similar device.

One hundred and thirty-three patients were discharged from the hospital. The fate of 115 (87%) was followed for 1 month–8 years (mean, 51 months). The late survival (Fig. 2) was 83% by the 9th year (CI 71.1–94.6%). The causes of late mortality are presented in Table 2. A total of 12 patients (8.7%) died. Re-operations were performed in five patients – all for thoraco-abdominal aortic aneurysms. One of re-operated patients died. There were no re-operations for prosthetic valve dysfunction or conduit degeneration. In five patients operated for type I dissection the false lumen persisted distally form the conduit, however aneurysmatic dilatation was absent. In two of them there were signs of chronic mesenteric ischemia, but they refused the operation. According to EchoCG data, the leaflets of the xenopericardial prostheses are thin, without degenerative changes. X-Ray (75 patients) and CT (25 patients) investigations revealed the absence of calcification on the wall of the xenopericardial tube. Its inner surface is smooth.

4. Discussion

The method of ascending aorta and aortic valve replacement with the composite graft sutured into the aortic lumen
was primarily described in 1968 by Bental and DeBono [1]. From this time the number of such operations reached several thousands, there is a marked tendency towards the decline of hospital and late mortality. However some problems remain unsolved until now. Among them one can mention: (1) the technique of coronary arteries implantation (direct-indirect); (2) the tactics of aortic valve insufficiency treatment (reconstruction-replacement); (3) surgical tactics in type I dissection; (4) the choice of material for conduit formation. Our investigation deals with the last problem.

According to classical technique of Bentall–DeBono the coronary ostia are sutured into the graft wall in situ. The graft is wrapped by the remnants of the aneurysmatic aortic wall. The main disadvantage of use synthetic conduit with this technique consists in the development of false aneurysms at coronary ostia [2]. Cabrol [9], trying to prevent this complication has suggested an original technique with the use of additional inter-coronary vascular prosthesis, graft wrapping and creation of paraprosthetic-right atrial appendage anastomosis. This technique has its own disadvantages, in particular, kinking development or intercoronary prosthesis, compression and persisting aortic-right atrial shunt [9,10]. Most authors use Dacron conduit for aortic replacement. Formerly, due to the risk of transgraft bleeding the graft was necessarily preclotted with albumin and autoclaved. With those synthetic tissue often becomes too dense which makes the sutureing more difficult and increases the risk of suture cutting in frail aortic tissues. During the last decade major companies have created a new generation of synthetic grafts, impregnated with gelatin and absolutely hemostatic [4,5]. We have also a small experience with the use of Carbo-seal® prostheses; to our opinion, they are easy to sew and prevent bleeding.

The work of Ardito et al. [6] published in 1987 led us to the creation of an original pericardial conduit. We used the treatment by glutaraldehyde with additional anti-calciﬁcation treatment tested experimentally and in clinical practice with xenopericardial valvular prostheses and monocusp patches [11]. The ﬁrst surgical results were impressive, and we started to use this device widely for surgery of the ascending aorta [12]. Thus, in the period 1990–1999 we have used Dacron prostheses for ascending aorta replacement in only 57 patients (28%). Just as our Brazilian colleagues, we have noticed the facility of coronary ostia implantation and good hemostasis [12]. The possibility of modeling conduit’s diameter when creating distal anastomosis also facilitates its adaptation to the aorta. In two cases the use of separate xenopericardium sutting with subsequent implantation of valvular prosthesis allowed us to solve the problem of creating the anastomoses with low-positioned coronary arteries. The conduit wrapping is always accompanied by the creation of anastomosis with the right atrium. In one case with hermetic sutures the anastomosis was not created. However during the first postoperative day the patient suddenly developed hypotension with cardiac arrest. EchoCG revealed conduit compression

### Table 2

<table>
<thead>
<tr>
<th>Causes of late death (n = 12)</th>
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<tbody>
<tr>
<td>Late prosthetic endocarditis</td>
<td>2</td>
</tr>
<tr>
<td>Distal dissection</td>
<td>3</td>
</tr>
<tr>
<td>Thromboembolia</td>
<td>2</td>
</tr>
<tr>
<td>Thoraco-abdominal aneurysm</td>
<td>1</td>
</tr>
<tr>
<td>Car accident</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig. 2. Late survival after ascending aorta replacement with composite xenopericardial conduit. Dashed lines represent 95% confidence limits.
with a haematoma. Urgent revision was successful in revealing bleeding from the distal anastomosis. This bleeding was stopped, but the patient died. It was the sole lethal conduit-related complication. Four cases of non-fatal bleeding were connected with disturbances of blood clotting or non-cardiac origin of the bleeding. According to different authors the rate of such complications reaches 8–14.5% [10]. The source of bleeding after ‘open’ operations is often found in conduit suture lines. In our series the bleeding occurred only in five patients (3.4%) and was not connected with conduit site. We consider it to be connected with conduit wrapping. The wrapping and the creation of anastomoses with the right atrium are performed at the stage of patient rewarming, it does not increase the time of operation and does not create problems with hemostasis awaiting. The shunt stops to function in the nearest days. One of the arguments for conduit wrapping consists in the decrease of the risk of erosive bleeding if mediastinitis develops.

Total hospital mortality in ascending aorta replacement is 4–26% [2,10,14], the highest level is seen in the group with acute dissection. In our series hospital mortality in the whole group was 8.1%, with the lowest level in patients with true aneurysms (4.9%) and the highest in acute dissection (19%). The presence of type I acute dissection is an independent predictor of hospital death. Our data are in conformity with those of the authors using synthetic conduits.

According to different authors, late survival after ascending aorta replacement in those last years is about 61–70% by the 10th postoperative year [2,10,14]. Our data agree with those from the literature. The authors point out that the development of pseudo aneurysms after using inclusion technique with synthetic conduits contribute to the deterioration of the late results. The ‘open’ technique allows to avoid this complication. At the same time the use of xenopericardial conduit with wrapping [13] also allows to prevent pseudoaneurysms formation. We did not see false aneurysms formation on the anastomoses in any of the patients after the implantation of biological conduit. We cannot correlate late lethal outcomes with the type of the conduit used. However it is necessary to mention that 18 patients were lost from the follow-up and their fate is unknown. The second important factor is a relatively small duration of the follow-up. The technique of biological tissue treatment, used in our center and including anti-calcium defense (dodecyl-sulphate) will, probably, slow the process of tissue degeneration and calcification. While we did not assist at such processes in terms up to 9 years, it is necessary to study operations results in more prolonged follow-up.

References


Appendix A. Conference discussion

Dr B. Messmer (Aachen, Germany): I have a question with regard to the valve bioprosthesis you use and which is implanted as I have seen in one of your pictures into the pericardial conduit with a running suture. Are you not afraid of degeneration of the bioprosthesis which in case of reoperation may force you to exchange the whole basis of your reconstruction?

Dr Malashenkov: We use only separate pledgedated sutures, not continuous sutures, for implantation of the prosthesis, and second, xenopericardial valve, which is produced in our center, we used only in the patients over 50 years old, and we did not see any valve-related complications such as degeneration or calcification of this bioprosthesis.

Dr Messmer: Probably not so far, but it will come.

Dr Malashenkov: Maybe.

Dr J. Pirk (Prague, Czech Republic): I would like to ask you, do you use any kind of glue?

Dr Malashenkov: In cases with acute dissection we use our homemade glue, cyanacrilate, and in some cases with a fibrin glue.

Dr Messmer: I think one of the major advantages to use biological material is (1) less postoperative bleeding, a complication we know from the Dacron grafts, and (2) prevention of false aneurysm at the suture lines.
Dr Malashenkov: Yes.

Dr Messmer: One thing we have seen with xenopericardium, when we used it for coarctation repair in infants there was an immunologic reaction in spite of glutaraldehyde treatment of these grafts. Did you see anything like that?

Dr Malashenkov: Sometimes we see nonspecific inflammatory reaction after operation with fever without any signs of infection, and we believe that it is pericardium-related problems.

Dr Messmer: I think this is indeed a problem primarily in children. When we have to use bigger patches of xenopericardium, we use early postoperative immunosuppression with cortisone and azathioprin.

Dr Malashenkov: Yes, yes.