Banking cryopreserved heart valves in Europe: assessment of a 5-year operation in an international tissue bank in Brussels

Abstract  Objective. The heart valve bank of the European Homograft Bank has been set up in 1988 to meet the growing demand of cardiac surgeons for various sized and quality controlled cryopreserved homografts.

Methods. Heart valve donors less than 60 years of age were classified in 3 categories: multiple organ donors with non transplantable hearts, recipients of cardiac transplantation and non beating heart cadavers with a warm ischemic time of less than 6 hours. Past history and biology were checked for transmissible diseases. Preparation, progressive freezing and storage in liquid nitrogen vapors, and quality control were according to the standards of the Belgian Ministry of Health.

Results. From end January 1989 to end May 1994, 989 homograft valves were cryopreserved (514 pulmonary, 475 aortic and 3 mitral) whereas 962 valves were discarded. The first cause of rejection being a major macroscopic lesion (41.48%). 138 hearts accepted at inspection were contaminated and 43 cases remained so after antibiotics. 38 cases were positive for hepatitis B or C. Complication at distribution and thawing included 10 instances of bag rupture and 15 of transversal fracture through the wall of the conduit. 477 aortic, 474 pulmonary valves as well as one mitral were implanted between May 1989 and May 1994, either for left or right ventricular outflow tract reconstruction. In the left ventricular outflow tract series 111 aortic and 23 pulmonary homograft valves were used in cases of native endocarditis, prosthetic endocarditis or recurrent endocarditis after homograft implantation. 9.6% of the requests could not be satisfied. Regular follow up information was available from 382 implants – 40.1% only. 

Conclusions. The assessment of 5 years operation of the heart valve bank indicates: 1) the efficiency of selecting, cryopreserving and allocating quality controlled homograft valves from a large pool of donor hearts provided by a network of hospitals; 2) the difficulty of obtaining regular follow up information on the implants. [Eur J Cardio-thorac Surg (1996) 10:505-512]

Key words  Pulmonary valve - Aortic valve - Homograft bank - Cryopreservation
cases of aortic valve endocarditis [11]. Right ventricular outflow tract reconstruction with a aortic pulmonary homograft is performed in various forms of congenital heart disease [4, 7], whereas a pulmonary valve monocusp graft can be implanted in cases of Fallot’s tetralogy [19].

The growing demand for homograft valves in cardiac surgery together with the recent opportunity to use beating-heart donors and the progress of cryobiology have favored the creation of heart valve banks. The heart valve bank of EHB was set up in 1989 in order to respond to the growing demand of cardiac surgeons for quality-controlled cryopreserved heart valve homografts. It is located in the Military Hospital in Brussels, where it benefits from the excellent facilities of the Skin Bank. The European Homograft has been conceived as an open non-profit-making organization in accordance with the Belgian legislation on Tissue Banks [15]. Its activity is based on the cooperation of an international network of procurement and implantation centers. The aim is to store and offer to surgeons a fair number of various sized aortic and pulmonary valves. Distribution of these valves is not exclusive but depends, in priority, on the clinical indications. On the other hand, implanting surgeons are invited to contribute to the procurement of donor hearts according to the EHB selection criteria. Other aims of EHB are interbank cooperation, clinical research and data collection about implanted homograft valves.

In this paper we report our experience in heart valve banking and the indications as well as the early clinical data of the implantations.

Material and methods

Procurement

Only non-transplantable hearts are selected and classified in three categories:

- hearts from recipients of cardiac transplantation, without valvular alteration and
- hearts from brain death cases with bad contractility, rhythm disturbances etc.

Hearts from these two categories constitute beating heart donors. They are removed under sterile conditions.

- Hearts from cadavers, the vast majority from forensic cases, are removed under sterile conditions.

The procurement is based on well defined selection criteria of heart valve donors:

1. Categories and delays

- beating hearts: (brain death, transplantation cases); delay: 18 h maximum
- non-beating hearts: (hospital and forensic cases); post mortem delay: * 24 h or less (in no case more than 36 h). Warm ischemic time less than 6 h.

* This means the time between death and the beginning of the sterilization in EHB in Brussels. The body temperature should ideally be reduced to and maintained at 4°C as soon as possible after death.

2. Age

From birth to 60 years.

3. Medical status of the patient

- no transmissible disease (AIDS, hepatitis B or C, syphilis, tuberculosis, Creutzfeldt-Jacob dementia). Patients at risk for AIDS should also be rejected as donors
- no active infection, septicemia etc.
- no generalized cancer (cases with primary tumors of the CNS are not included in this category).
- no patient with altered immune competence or patients with corticosteroids on a long-term basis (4 years for a daily dosis of less than 10 mg, or 1 year for a dosis of more than 20 mg).
- no dilatation of the arterial roots and/or obvious lesions of valves and proximal segment of coronary arteries. (Valves with large round fenestrations in the commissural area are discarded).
- All potential donors whose cause of death is unknown should be rejected.

In the case of a non-beating heart donor, it is extremely important to respect a limited post mortem delay and to keep the warm ischemic time (time between death and refrigeration at 2-4°C) as short as possible (less than 6 h).

All hearts or excised arterial roots are transported to EHB in Cold ice sterile transport medium. So far the transport medium has not been standardized and varies according to the procurement centers: Saline, Ringer, Eurocollins, etc. as well as Tissue Culture Medium 199 HEPES (TCM 199) (Gibco N° 041-02350 M) have been used.

Preparation

Dissection of the aortic and pulmonary root and/or arteries as well as all the steps of the protocol are performed inside a first grade laminar flow room. Tissue are constantly rinsed with cold TCM 199. A first selection is operated, based on the macroscopic examination of the leaflets; atheroma, synechia and large fenestration are not tolerated. Small alterations are accepted but categorize the homograft valve as 2nd grade on the basis of morphology.

Competence test

A test of leaflet coaptation is applied. It consists simply of filling the conduit with TCM 199 and observing the degree of leakage: none, trivial, slight or moderate leak (i.e. drop by drop).

Measurements

The internal diameters of the aortic and pulmonary homografts are measured at the annulus by using calibrated Hegar dilators. In cases of important dilated infundibulum muscle (e.g.: dilated cardiomyopathy) a valve obturator is used. The internal diameter at the annulus is measured twice: before and after antibiotic decontamination. In certain cases, the diameter of the distal arterial section is also measured when the aortic tube reaches the arch and for the pulmonary conduits with intact bifurcation. The length of the aortic and pulmonary stumps is measured from the valvular annulus whereas the length of right and left pulmonary arteries is taken from the bifurcation.

Decontamination

This is achieved by means of a low concentrated antibiotic cocktail recommended by A. Strickett et al.: cefoxitin 240 µg, lincomycin
120 µg, polymyxin B 100 µg & vancomycin 50 µg per ml (Tissue Culture Medium 199) [18]. The homografts are kept in the solution at 4°C for 24 h, when the heart has been procured under sterile conditions. However, nystatin is added at the concentration of 2,500 IU/ml and the antibiotic incubation is prolonged up to 48 h when the heart has been procured under clean conditions and/or the donor has been kept on respirator for more than 24 h.

Cryopreservation

Following decontamination, the tissues are rinsed with TCM 199 and transferred to an ice-cold cryoprotective solution consisting of 10% dimethylsulfoxide (DMSO) in TCM. No serum is added to the solution. A total volume of 100 ml is sealed in a double bag and kept at 4°C for 40–60 min, in order to allow the DMSO to penetrate completely into the tissues.

The pouches are frozen in liquid nitrogen vapors according to an electronic monitored program, together with a pouch containing a control valve of approximately the same type and size, and the temperature probe. The freezing is achieved at the rate of 1°C/min until the temperature of the control valve reaches -40°C, and at -5°C/min down to -100°C. Additional frigorifies are released when the system reaches the freezing point of the solution in order to compensate the release of warmth (Fig. 1).

Storage

Frozen homografts are stored in liquid nitrogen vapors at -150°C until they are transported to the operating theater.

Quality control

Microbiology

Microbiological tests are performed before and after decontamination of various tissue samples and working solutions. Culture media for aerobic and anaerobic bacteria as well as for fungi are used for all donors, a culture medium for mycobacteria is used for donors with incomplete clinical data.

Serology

The following tests are performed: HIV1 & HIV2 antibodies (Elisa, and when positive, immunofluorescence & Western blot); HIV1-DNA by polymerase chain reaction (PCR); HTLV1; HBsAg and anti-HBe (when anti-HBe is positive, anti-HBc is also carried out); anti-HCV; VDRL (syphilis test); Q fever antibodies.

Undiluted frozen serum is kept in the freezer up to 1 year after implantation of the homograft.

Fibroblast culture

A fibroblast culture from two samples of the posterior leaflet of the mitral valve is performed after decontamination and the results are graded 1–3, on the basis of the delay of cellular proliferation.

Histology

Samples are routinely taken from the posterior leaflet of the mitral valve, interventricular septum, right and left ventricular wall and from pulmonary and aortic wall margins, and formalin-fixed; paraffin sections are stained with hematoxylin-eosin. Additional samples are collected from macroscopic lesion of unknown nature.

Grading of homografts

Aortic and pulmonary homograft valves are categorized as sleeves or conduits (AS, AC, PS, PC) (Fig. 2) and classified in three grades according to quality. This classification depends on several criteria: morphology, post mortem delay (ischemic time), freezing curve. Grade 1 valves are perfect or above average; Grade 2 are lesser quality but still acceptable; Grade 3 are below average and discarded. Other criteria of rejection are positive serology and persistent positive microbiology after decontamination.

Distribution of homograft valves

Homografts are ordered by telephone and/or fax and allocated on the basis of clinical diagnosis and patient age, generally after a dialogue between the surgeon and the physician on call at the heart valve bank. Priority indications are prosthetic and native endocarditis with often severe lesions of the annulus (abscess etc.), congenital heart disease and aortic valve replacement in young adults and/or when anticoagulation is counterindicated. For 2nd grade quality valves, the dissection and description sheet is generally sent to the surgeon by fax. In most instances, the cryopreserved valves are transported in liquid nitrogen vapors at -150°C in a cryogenic dry shipper, which allows the homograft to stay at this low temperature for 6–7 days.
Moreover the dry shipper allows homografts which are not implanted to be sent back to EHB without any significant temperature fluctuation. Homografts have also been sent by air in dry ice at -80 °C, but this mode of transport is seldom used. According to a recent cooperative study with the Cryobiology Group of the Medical Research Council - Cambridge UK, this implies that the homograft may not be restored at -150 °C and must be implanted within 2–3 months [10]. All homografts are sent together with their records (donor information, description sheet of the valves, laboratory results and instruction for thawing and dilution).

Follow-up of implanted homografts

Surgeons are requested to provide operative and postoperative information on the implanted valve by filling in special forms provided by EHB. Follow-up forms are usually sent to the cardiologist every 6 months with specific questions concerning echocardiography results, complication, death (valve- or not valve-related) and homograft explanation.

The explanted homografts recovered by EHB are submitted to a histopathologic examination and in some cases, ultrastructural studies. Recently, DNA fingerprinting and fibroblast culture of selected samples of the specimens are performed in order to discriminate between donor and recipient cells. The results of these pathologic studies will be reported elsewhere.

Results

Procurement, preparation and storage

The first heart was received in January 1989. Up to 31st May 1994, 981 hearts, 137 arterial conduits (aorta descendens, aortic bifurcation and femoralis arteries) have been procured in 36 institutions (Fig. 3). During the same period, 992 usable homografts valves were cryopreserved and stored in liquid nitrogen vapours (except for six which were refrigerated). Of the 989 cryopreserved valves, 514 pulmonary, 475 aortic and 3 mitral valves have been prepared, either as conduits or sleeves; the internal diameter of the stored homograft valves ranges from 9 to 30 mm.

On the other hand, 962 valves out of 1949 were discarded at different stages of the protocol, the main causes of rejection being: macroscopic lesion of the valvular leaflets (41.48%), dilated pulmonary valves with an internal diameter over 30 mm (28.20%) and cuts through the leaflets, the annulus or the commissures (22.50%).

Grading of homografts

Of 992 homograft valves accepted between May 1st 1989 and May 31st 1994, 674 were considered as 1st grade (67.94%) and 318 as 2nd or 3rd grade (32.06%). The proportion of 1st grade homografts was higher in the pulmonary group (84%) than in the aortic one (73%). The four most frequent criteria of 2nd grade determination were the same in both groups: pathologic lesions, 2nd rate freezing process, moderate leak at competence test and prolonged post mortem delay, in that order (Table 1). Some 2nd grade aortic homografts were accepted for the right position only, either because of medium-sized fenestrations or when the leaflets were considered as somewhat weakened, for instance as a result of a 2nd rate freezing process. A small proportion of abnormal pulmonary valves with at least one normal cusp were processed and saved for the monocusp reconstruction techniques.

Quality control

Microbiology

Of 974 hearts accepted at inspection, 155 (15.91%) were contaminated. The origins of contaminated hearts were as follows: non-beating hearts: 98 (63.22%), beating hearts from multi-organ donors: 46 (29.67%), and heart transplantation 11 (7.11%). Of these 155 hearts, 43 remained contaminated after antibiotics (27.74%). The fibroblast culture performed after decontamination was positive in 388 cases out of 455 (85.27%). Table 2 details the microbiology analysis in 974 cases of hearts before and after antibiotic decontamination.

Serology

The results of serologic screening of 959 donors are presented in Table 3. The only single cause of valve rejection on the basis of serology was the presence of positive markers for either hepatitis B or hepatitis C.
Table 2  Microbiology analysis in 974 cases of hearts before and after antibiotic decontamination

<table>
<thead>
<tr>
<th></th>
<th>Cocci Gram +</th>
<th>Rods Gram +</th>
<th>Gram -</th>
<th>Anaerobics</th>
<th>Yeast and fungi</th>
</tr>
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<tbody>
<tr>
<td><strong>Before antibiotics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recipient of heart transplantation</td>
<td>24</td>
<td>-</td>
<td>4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Multi-organ donors</td>
<td>50</td>
<td>-</td>
<td>13</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Non-beating hearts</td>
<td>30</td>
<td>3</td>
<td>19</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total hearts</strong></td>
<td>104</td>
<td>3</td>
<td>36</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td><strong>After antibiotics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>31</td>
<td>-</td>
<td>11</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Efficiency of antibiotics: % of decontamination</td>
<td>29.8%</td>
<td>30.5%</td>
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</tr>
</tbody>
</table>

Table 3  Cases of valve rejection on the basis of positive serology, according to the test and the donor category

<table>
<thead>
<tr>
<th>Category of donors/ number</th>
<th>Non-beating hearts: 12</th>
<th>Recipient’s heart transplant: 18</th>
<th>Multi-organ donors: 18</th>
<th>Total: 48</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV 1 &amp; 2</td>
<td>(1 *)</td>
<td>-</td>
<td>-</td>
<td>(1 *)</td>
</tr>
<tr>
<td>HBV (HBsAg+ or antiHBc+ anti-HBs-)</td>
<td>7</td>
<td>9</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>1</td>
<td>7</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Syphilis (VDRL)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Anti-Q fever</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Anti-HTLV 1 &amp; 2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

3 HIV, not confirmed: loss of material

Fibroblast culture

Fibroblast culture has been routinely performed from mid-1990 in 497 cases. Of the 497 cultures, 287 presented early growth (grade 1) and in 64 cases the growth was somewhat delayed (grade 2) whereas it was mediocre or did not occur in 146 cases (29.37%).

Distribution and implantation

The first EHB homograft valve, a 15 mm aortic conduit, was implanted in a 2-year-old boy with transposition of the great arteries in May 1989. Nine hundred fifty-two homograft valves have been distributed to institutions in 10 countries. The sizes ranged from 9 to 27 mm for the aortic and from 10 to 30 mm for the pulmonary valves. On the other hand, not every demand for a specific valve was satisfied, as 9.6% of the 720 requests addressed to EHB between January 1st 1992 and May 31st 1994 could not be met.

All homografts were transported in a dry shipper at −150°C, except nine that were sent by air in dry ice. In 12.86% (n=121) of the shipments, the homografts was not removed from the dry shipper but sent back to EHB.

Of those 952, 926 have been implanted, whereas 26 were temporarily stored in the institutions to be available for suitable recipients.

Complications during distribution and thawing

Rupture or puncture of the bag was reported in ten instances, of which eight occurred during transportation and two during storage in the institution. Thawing fractures (i.e., transversal tears) were recorded infrequently and occurred always through the wall of the conduit (15 cases). Inquiry showed that these fractures occurred generally when the wall of the cryopreserved valves was palpated before the ice had melted inside the tube. In one other case a thawing fracture was suspected when two leaflets of a pulmonary valve ruptured shortly after the operation and the patient had to be reoperated 2 h later because of massive transvalvular regurgitation.

Surgical indications and techniques

Four hundred seventy-seven aortic, 474 pulmonary and 1 mitral valves have been implanted between May 1989 and May 1994. The indications, the surgical techniques and the number of implants per operative technique are presented in Table 4.

In the series of LVOT reconstruction there were 134 cases of native or prosthetic aortic endocarditis. In these instances, 79 subcoronary aortic valve replacements were performed versus 55 simple or extended aortic root replacements; this last procedure being more frequently uti-
Table 4  Number and type of implanted valve and implantation procedures (LVOT left ventricular outflow tract, RVOT right ventricular outflow tract, AVR aortic valve replacement, ARR aortic root replacement, MVR mitral valve replacement)

<table>
<thead>
<tr>
<th></th>
<th>LVOT reconstruction</th>
<th>RVOT reconstruction as part of a Ross procedure</th>
<th>(Hemi-)Fontan operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>→ aortic: 285</td>
<td>Aortic: 121</td>
<td>111</td>
</tr>
<tr>
<td></td>
<td>→ pulmonary: 53</td>
<td>Pulmonary: 299</td>
<td>3</td>
</tr>
<tr>
<td>ARR</td>
<td>→ aortic: 66</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ pulmonary: 13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVR</td>
<td>→ mitral: 1</td>
<td></td>
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</table>

lized because of better results in terms of regurgitation and stenosis.

Further analysis led to interesting observations about pulmonary valves: a) nowadays pulmonary valves are more frequently used for RVOT reconstruction than aortic valves because of a rate lower degeneration; b) pulmonary valves are also more frequently used in the Ross procedure.

Postoperative results

The European Homograft Bank has access only to the information reported on a voluntary basis by the implanting surgeons. According to this source of information 69 patients died early (30 days) between May 1989 and May 1994. The large majority of these were children.

Eight early explants were sent to EHB. Seven homografts were explanted as a result of technical problems: two with transvalvular insufficiency, one geometrical mismatch, one with left coronary ostium obstruction resulting in acute myocardial ischemia, one instance of patch-loosening in a case of RVOT reconstruction for correction of double outlet right ventricle, one cusp prolapse soon after implantation and one case of paravalvular leak. The eighth case concerned an explantation performed 2 h post-operatively as a result of massive regurgitation after implantation of a pulmonary valve in the aortic subcoronary position: the explanted valve showed two hemorrhagic leaflet tears. No explanation for this acute tissue failure could be given, but a faulty thawing procedure was suspected.

Regular follow-up information was reported to EHB on only 382 patients (40.1%) of whom 30 died and 3 had their homograft explanted — two cases of delayed surgical technical failure, one case of endocarditis. The three explants were sent to EHB for pathologic evaluation. The pathology study will be reported elsewhere.

Discussion

The balance of EHB's first 5 years of heart valve banking may be considered as satisfactory considering the large number of medical institutions participating in the procurement of donor hearts and, generally, also in the implantation of valvular homografts. However, the availability of grafts is far from being guaranteed, as the bank does not always have a valve presenting the specific measurements requested by a surgeon for his patient. This situation is mainly due to a relative shortage of good quality aortic valves.

The categorization of homograft valves in 1st grade (good) and 2nd grade (fair quality) has proved to be useful in our experience. But it is demanding for the one who examines and dissects the donor roots to describe thoroughly the small abnormalities of the valves. We also have to consider all aspects of quality: warm ischemic time, morphology, competence test, cooling curve etc., before deciding on the category of the homograft: 1st or 2nd grade.

In doing so, we are able to explain to the surgeon the reason for this decision and discuss the possibility of implanting a 2nd grade homograft. Lifenet in Virginia Beach uses a more elaborate classification at inspection, grading the valves from 1 to 6 [13]. We consider that this system makes the choice between subcategories more difficult, and content ourselves with a three grade system.

Several methods are available for evaluating the viability of valvular fibroblasts: metabolic (marked aminocoids) [8], enzymatic using a tetrazolium salt [10] and cell culture [13] methods. We have chosen the latter for routine quality control after having conducted a preliminary multivariant analytic study involving 65 cases. This study has shown that, when three grades of fibroblast vitality are defined, the fibroblast from a double sample of the mitral valve is highly dependent on the warm ischemic time of the donor heart at the time of procurement and the total ischemic time of the homograft [6]. Thus, the reason for choosing this method rather than others is that it is simple and reliable. The diagnostic usefulness of routine histology of donor hearts turns out to be minimal: not a single case of malignancy has been discovered and the only case with septic lesions (micro abscesses in the interventricular septum) concerned a multi-organ donor with suspected sepsis. However, microscopic examination as a routine method for quality control of donor tissues has been maintained since it was considered as useful, firstly in estimat-
ing the three degrees of preservation of the ground substance and the endothelial cover of the mitral valve, and secondary in screening degenerative lesions in the media of the great arteries, in other words in the wall of the homograft conduits. This method has also allowed us to communicate some interesting and often unexpected findings either to the clinician of the emergency/intensive care department, or to the forensic pathologist: amyloid infiltration of the heart, catecholamine effect on the myocardium, obstructive lesions of the coronary arteries, etc.

In contrast to hepatitis B and C, HIV1 and HIV2 do not seem to challenge the constitution of a sufficient stock of implantable valves. No valve was discarded because of a positive HIV1 DNA or confirmed anti-HIV1&2, whereas the identification of a relatively large number of HBAg or anti-HCV+ donors has resulted in the elimination of 35 homografts. The same experience has recently been reported at the 1992 Congress of the Association of American Tissue Banks [20]. With regard to hepatitis C, it is likely that the introduction, in the future, of supplementary and more elaborated laboratory tests such as those existing for the hepatitis B will prevent the elimination of valves from donors presenting serologic markers of hepatitis C immunity.

The microbiology of the specimens taken at the beginning of the preparation shows clearly that all valves have to be treated with antibiotics, including those prepared from the recipients heart in the transplantation cases. Indeed, we feel that the relative shortage of available homografts obliges us also to save slightly contaminated valves through a low concentrated antibiotics cocktail in spite of the likelihood of its moderately deleterious effect on the viability of the donor fibroblasts.

It is important to stress that the distribution of the homografts follows the requirements of the Belgian legislation on tissue banks [15]. The request of the surgeon for a specific valve is adressed to the bank (usually by phone) and the decision to allocate an appropriate homograft is taken most often after a discussion between the director of the bank or his delegate and the cardiac surgeon. We think that this dialogue is essential, since the homograft bank is responsible for the distribution of human tissues of good quality, especially at a time when the demand is increasing and often exceeds the supply. The transportation of the cryopreserved valves to the implanting centers in a dry shipper at –150 °C has proved to be very advantageous. Indeed, in an unexpectedly high proportion of cases (24% of the shipments) the homograft was not implanted but sent back to EHB. It has also happened in a few instances that two or even three valves of different diameters were shipped to the surgeon, allowing him to choose the appropriate diameter during the operation. In those instances homografts could be saved for other patients.

The reason for not keeping cryopreserved valves at –80 °C for more than a few months is that at this temperature the ice crystals have a tendency to grow and might become harmful to the structural integrity of the tissues [10]. On the other hand, one disadvantage of transportation at very low temperatures seems to be the great fragility of the conduits, which can break like glass. This is the probable reason why thawing fractures have only been reported in valves cryopreserved at either –196 °C or –150 °C [1]. This hazard can be avoided by handling the homografts with great care and abstaining from palpating the wall of the conduit during the final phase of the thawing process. Such careless thawing procedure can become hazardous not only for the homograft but also for the patient (one patient died postoperatively as a result of a massive hemorrhage from a torn pulmonary homograft rendered fragile by intense overheating).

Regarding the problem of the limited supply of good quality aortic valve homografts, it is interesting to note the current trend among surgeons to use pulmonary valves, particularly in two instances: 1) in the reconstruction of the RVOT, where they are thought to function as well as aortic valves, and 2) as part of a switch procedure, where they replace the patient’s own valve transplanted in the aortic root as an autograft.

Finally, after 5 years of operation the only disappointing aspect of EHB’s work is the low figure of regular follow-up information on the implants, transmitted by the clinicians: 40.1% after several reminders.

In conclusion, the assessment of 5 years’ operation of the EHB heart valve bank demonstrates: 1) the efficiency of selecting, cryopreserving and allocating quality-controlled cryopreserved homograft valves from an important pool of donor hearts provided by a large network of hospitals and 2) the difficulty of obtaining regular follow-up information on the implants.
References