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Coimbra University Hospitals' Bone and Tissue Bank: Twenty-two Years of Experience

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ABSTRACT

We report the microbiological contamination rate of sterilely procured 3953 tissue allografts obtained during 22 years of activity for musculoskeletal reconstruction from 1982 to 2003. From 1987 to 2000, allograft retrievals were performed in 191 cadaveric donors and in 323 living donors. In the former group 30 retrievals (15.7%) were excluded based on laboratory criteria. Among living donors 108 femoral heads (33.4%) were also excluded by the same criteria. The microbiological contamination rate of sterilely procured allografts in the operating room was 8.3% for cadaveric donors and 18.2% for living donors. A questionable positive serology for HIV antigen was registered in two non–heart-beating donors. Hepatitis C virus antibodies were positive in two other non–heart-beating donors. Hepatitis B virus serological markers were positive or questionable in more than 11 non–heart-beating donors. In living donors 20 femoral heads were excluded (6.1%) due a positive or questionable hepatitis B virus serology. One femoral head donor showed a positive HTLV-I antibody and another one a positive syphilis serology. No positive serology cases for the HIV antibodies were found. No cases were registered of transmission of viral diseases from the donor to the recipient. Our extremely rigorous criteria led to the exclusion of a considerable number of both donors and allografts.

ALLOGRAFTS ARE frequently used by orthopedic surgeons both for bone tumor surgery and for revision of failed joint replacements. The most common source is cadaveric donors; these types of donors should increase over the next few years.[1] Preservation and availability of bone allografts harvested from cadaveric human donors are only possible in tissue banks, which offer adequate structural, human, technical, and managerial conditions for the storage of large quantities of allografts for clinical application.

In 1982, we were established and in March 1994, remodeled to provide the necessary conditions to extend services to the whole country.

A major disadvantage of using allografts is the possibility of disease transmission. Bone banks have made significant progresses in the past few years to develop a plentiful supply of safe and efficacious grafts.[2–4] We have undergone an organizational evolution throughout 22 years of activity to meet all these developments.[5,6] The aim of this work was to present the microbiological contamination rate of allografts sterilely procured in the operating room.

MATERIALS AND METHODS

From 1982 to 2003, we provided a total of 3953 tissue allografts for musculoskeletal reconstruction in orthopedic, neuro-, and maxillofacial surgery (Fig 1). Most allografts were used to revise hip arthoplasties.

Four types of allografts were provided: (1) sterilely procured and cryopreserved bone and osteochondral allografts; (2) sterilely procured and cryopreserved tendinous, fascial, or ligamentous allografts; (3) gamma-irradiated and freeze-dried small cancellous or corticocancellous bones; and (4) demineralized cortical bone allografts.

Allografts were harvested from living donors (the bone was procured during hip arthroplasty), from brain-dead donors (multiorgan retrievals), and from non–heart-beating donors. The donor selection criteria (medical history, physical examination, autopsy, biological screening), allograft procurement, processing, and storage were performed in accordance with the international standards concerning the activity of tissue banks.[2,3]

Allografts were treated in an ethanol (70°) and hydrogen peroxide solution. The cortical bone was demineralized in a 2.4 N HCl solution and preserved in a 0.5% formaldehyde solution at 4°C.[6]

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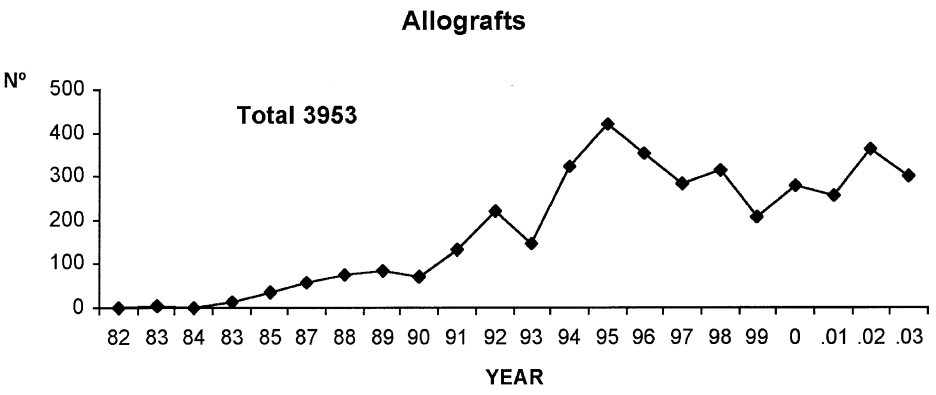

Fig 1. From 1982 to 2003, the Columbia University Hospitals' Bone and Tissue Bank provided 3953 tissue allografts for musculoskeletal reconstruction.

The quarantine period was respected. Autopsy constituted another safety element.

Tissues were removed under aseptic conditions and stored in liquid nitrogen, after the processing. In the case of freeze-dried allografts, clean nonsterile techniques were used, because the grafts were submitted to a complementary sterilization with gamma rays (25-kGy dose). Massive contamination was, however, avoided.[5]

RESULTS

From our experience morselized cancellous allografts are the most popular ones (85% of the cases), particularly for revision of total hip joint arthroplasties, for treatment of upper and lower extremity fractures/nonunions, and for spinal fusions.

Our general data analysis showed that between 1987 and 2000, allograft retrieval was performed in 191 cadaveric donors and 323 living donors. In cadaveric donors 30 retrievals (15.7%) were excluded on the basis of laboratory criteria. In living donors 108 femoral heads (33.4%) were excluded by the same criteria.

The overall microbiological contamination rate of sterilely procured allografts in the operating room was 8.3% of cadaveric donors (50% of the cases were due to multiple microorganisms) and 18.2% in living donors. *Staphylococcus epidermidis* was the most frequent organism in tissues culture (45.3%).

A questionable positive serology to HIV antigen was reported in two non–heart-beating donors who were reported to be false-positives, thus these donors were excluded. In two non–heart-beating donors, hepatitis C virus antibody was positive. The serological markers for hepatitis B virus were positive or questionable in more than 11 non–heart-beating donors. In living donors 20 femoral heads were excluded (6.1%) due to a positive or questionable serology to hepatitis B virus. One femoral head donor indicated a positive HTLV-I antibody and other one a positive VDRL. No positive serology cases for HIV antibodies were found.

A non–heart-beating donor, who experienced meningococcus meningitis not detected by clinical and laboratory examinations, was only excluded with the autopsy finding results.

DISCUSSION

The basic purpose of bone banking is to provide orthopedic, neurological, and other musculoskeletal surgeons with safe and adequate allografts for the reconstructive surgery. From 1982 to 2003, 3953 tissue allografts were provided with no risk of viral transmission, the control of microbiological sterility of allografts is one of the most important steps in bone banking.[7] Processing provided the opportunity for the bank to remove blood and bone marrow in which the viral agents reside.

At the moment, no transmitted viral diseases from the donors (hepatitis, HIV) were observed, possibly due to our extremely rigorous criteria when selecting potential donors and quality control of the harvested allografs, resulting in the exclusion of a considerable number of both donors and allografts. Allograft retrieval is always excluded when any questionable factor is present.

It is absolutely necessary for the orthopedic surgeon to be well informed about the methodology used by the bone bank to prepare the allograft and about the influence of these procedures on biological, mechanical, and immunogenic properties in order to to select the most appropriate type of allograft for each clinical situation.

In recent years, many factors have led to important changes concerning the structure of tissue banks, which seek to procure allografts with the best integrity and biological safety in large quantity.[1–4] The legislation changes concerning retrieval of organs and tissues of human origin for transplantation were important.

In Portugal, a favorable legal framework concerns the retrieval and transplantation of organs and tissues, allowing the development and the increase in the number of allogeneic human transplantations.[5,8] However, as we have seen in other countries, there is still a scarcity of clinical allografts.

Bone transplantation is not an urgent intervention, being only part of an elective surgical procedure. It must therefore only be carried out when all the conditions of maximum biological safety are met. The osteochondral and tendon allografts should be retrieved from brain-dead donors. In non–heart-beating donors only bone allografts should be retrieved, since quarantine is not possible. There-

fore, a validated tissue processing is required. The surgeon must cooperate with the tissue bank by participating in the quarantine period or by verifying the suitability of the transplanted graft.

In conclusion, the main aim of bone and tissue banking is to provide safe and appropriate allograft tissues. The risk of disease transmission will be remote if the international protocols of donor selection criteria, blood testing, and allografts quality assurance are followed and the quarantine period is respected. Our extremely rigorous criteria have led to the exclusion of a considerable number of both donors and allografts.

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