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Comunicación breve

Living donor bone bank: Costa Rican experience

(Banco de huesos a partir de donantes vivos: experiencia costarricense)

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Abstract

Aim: The use of bone grafts is a common practice in orthopedic surgeries. However, the daily problem in traumatology is the limited access to adequate bone grafts. These grafts provide mechanical stability in the affected area of the bone, as well as repair and regeneration of weaknesses through osteoinductive, osteogenic and osteoconductive properties. The main objective of this report is to provide information about the experiences and the importance of establishing a Bone Bank in Costa Rica.

Method: all relevant information was gathered to provide a brief overview of the establishment of a Bone Bank in Costa Rica. First, legal issues were taken into consideration; followed by the definition of the donor exclusion criteria according to international standards. Potential donors were defined as all patients undergoing hip or knee replacement surgeries. In order to select the right donors, blood samples from all potential donors were tested for transmittable diseases. Bone tissues were obtained in the operating room to be processed later, under strict standardized conditions. Once the tissues were processed, allografts were stored at -80°C until the transplantat procedures were carried out.

Results: Between 2016 and 2019, the bone bank had a total of 69 donors and 258 bone allograft recipients, all of them were patients at the Trauma Hospital.

Conclusion: The establishment of the bone bank in Costa Rica has been a challenge for the National Insurance Institute (INS). The goal is to make the Bone Bank available to the medical community in general, in order to strengthen the tissue donation and transplant network in Costa Rica.

Keywords: Allografts, tissue banking, tissue donation, bone.

Resumen

Objetivo: el uso de injertos óseos es una práctica común en cirugías ortopédicas. Sin embargo, el problema diario en traumatología es el acceso limitado a injertos óseos adecuados. Estos injertos permiten proporcionar estabilidad mecánica en el área del defecto óseo, así como reparar y regenerar los defectos a través de sus propiedades osteoinductivas, osteogénicas y osteoconductivas. El objetivo principal de este trabajo fue proporcionar información a la población sobre las experiencias y la importancia de establecer un Banco de Huesos en Costa Rica.

Metodología: se recopiló toda la información relevante para proporcionar un breve resumen del establecimiento de un banco de huesos en Costa Rica. En primer lugar, se tomó en cuenta consideraciones legales, seguido por la definición de los criterios de exclusión de donantes de acuerdo a los estándares internacionales. Los potenciales donantes se definieron como los pacientes sometidos a reemplazo de cadera y de rodilla. Con el fin de elegir los donantes adecuados, a todos los

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potenciales donantes se les realizaron pruebas de sangre para detectar enfermedades transmisibles. Los tejidos óseos se obtuvieron en sala de operaciones para, posteriormente, ser procesados bajo condiciones estrictas estandarizadas. Una vez que se procesaron los tejidos, los aloinjertos se almacenaron a -80 °C hasta que se llevó a cabo el procedimiento de trasplante.

Resultados: entre los años 2016 y 2019, el Banco de Huesos tuvo un total de 69 donantes y 258 receptores de aloinjertos óseos, todos ellos pacientes del Hospital Trauma.

Conclusión: el establecimiento del banco de huesos en Costa Rica ha sido un gran desafío para el Instituto Nacional de Seguros (INS). El objetivo es hacer que el mismo esté disponible para la comunidad médica en general, a fin de fortalecer la red de donación y trasplantes de tejidos en Costa Rica.

Descriptores: aloinjertos, banco de tejidos, donación de tejidos, huesos.

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The use of bone grafts is a common practice in orthopedic surgeries. Many surgical procedures, such as tumor resections, prosthetic replacements, spinal fusions, and osteosynthesis, use bone grafts as bone substitute material.[1-4] Bone grafts provide mechanical stability to the area of the bone defect. At the same time, they help to repair and to regenerate defects through osteoinductive, osteogenic and osteoconductive properties.[2,5,6]

Autologous bone graft, which means a bone graft harvested and transferred from one site to another on the same individual, has been the material most commonly used by orthopedic surgeons in the treatment of bone defects.[5] Its effectiveness has been well demonstrated; however, it presents disadvantages related to the morbidity of the donor site. Furthermore, additional drawbacks are related to increased postoperative pain, bleeding, and risk of infection. These characteristics, along with the limited availability of bone tissue, restrict autograft applications.[1,2]

On the other hand, the use of bone allograft, which means a bone graft harvested and transplanted from one person to another, has many advantages: immediate availability, the absence of morbidity of the donor site, and the possibility of reconstructing much larger defects. However, the principal disadvantage is the decrease in osteoconductive and osteoinductive capacity, compared to autografts.[7] Furthermore, transmitted diseases from the donor tissue to the recipient are a potential risk, which can be mitigated or eliminated with an adequate selection of donors, microbiological tests and appropriate tissue sterilization and preservation.[8-10]

The Trauma Hospital in San José, Costa Rica, owned and operated by the National Insurance Institute of Costa Rica *(Instituto Nacional de Seguros, INS)*, is specialized in traumatic injuries. In Costa Rica, there is limited access to adequate bone grafts, not only in quantity but also in aspects of quality. Due to the rapid increase in the number and variety of pathologies managed in the hospital as a result of the traumatic injuries, in 2014 INS approved the establishment of a bone bank at the Trauma Hospital.

The bank is responsible for harvesting, processing, storage and distribution of the bone allografts that could be used for the treatment of patients insured by INS. However, the goal for the near future is to offer services to the general population of Costa Rica through the entire hospital system. The development of tissue banking procedures contributes to reducing costs in the health system, thereby providing viable alternatives for the treatment of many health problems.[8,11,12]

The main objective of this report was to provide information about the experience and value of establishing a bone bank in Costa Rica according to strict international standards, in order to increase the safety, quantity and the quality of transplanted tissues.

Methodology

In order to provide an overview of the process carried out for establishing a bone bank in Costa Rica, all information related to legal and technical considerations was gathered. Since in Costa Rica technical standards for bone banking do not exist, international standard guides were taken into consideration to launch this project, based on the Guide to the quality and safety of tissues and cells for human application, Europe Council, 2017; and Guidance for industry current good tissue practices, Federal Drug Administration of the USA, 2011.

The bone bank of the Trauma Hospital was licensed by the *Secretaría Ejecutiva Técnica de Donación y Trasplante de Órganos y Tejidos of the Ministry of Health of Costa Rica*, in accordance with the Costa Rican law No.9222 for Donation and Transplantation of Human Organs and Tissues.

Donors: Potential donors for providing bone were all patients from hip and knee replacements treated at the Trauma Hospital, between the ages of 18 and 85, who accepted and signed an informed consent release for the bone donation process. During the trial period, from 2016 to 2019, donors

answered a questionnaire in order to detect potential risks of any transmittable diseases. Medical records were also analyzed to detect exclusion criteria for bone donation (Table 1).

Laboratory tests: serology and NAT blood tests were performed on samples from all of the initially screened donor candidates to detect antibodies to human immunodeficiency virus (HIV), Hepatitis B and C Virus, Chagas´s disease, Human T-cell lymphotropic virus (HTLV type I and II) and syphilis. All these test were performed according to Costa Rican policy No. 30697-S "Norms for the habilitation of immunohematology divisions and blood bank" and following the guidelines of "Standards for Blood Banks and Transfusion Services", 31st Ed of AABB.

Bone specimens: approximately 50g of bone tissues from femoral heads and tibial plateaus were aseptically obtained from living donors. Tissues were collected in the operating room and placed in two sterile bags that were identified with the patient´s name, age, surgeon´s name, and the date of the surgery. The bags containing the tissues were immediately transported in a cooler to the bone bank where they were stored at -80°C in an isolated area until processed. [13,14]

Table 1. Main criteria for the exclusion of bone donors[15]

Under 18 years of age
Active or recent systemic infection
Active or recent coxitis and / or osteomyelitis.
Active infection of '' slow virus '' or anamnesis in the past
Recent vaccination (< 4 weeks) against attenuated viruses such as measles, yellow fever, mumps, polio, oral typhoid fever or rubella.
Rheumatoid arthritis
Autoimmune diseases
Metabolic disorders
Growth hormone treatments
Chronic medication (especially corticosteroids)
Recent exposure to toxic substances
Malignant neoplasms
Recent exposure to radiation
Dementia
Barrier of language, or when the patient does not understand the information for some reason (for example psychiatric patients).
Recent tattoo or piercings (last 6 months)
Medical history of diseases such as syphilis, tuberculosis, brucellosis, Chagas, HBV, HCV, HIV / AIDS and HTLV
Use of intravenous drugs
People who work in prostitution or their sexual partner does, in the last 6 months.
Hemophiliac patients managed with coagulation factors
Hospitalization time longer than 8 days

Bone tissue processing: all procedures were performed under sterile conditions following aseptic and antiseptic techniques. The Bone Bank is located in an area of the Trauma Hospital with restricted access. Tissues were processed in a class II biosafety cabinet. Cartilage and muscle tissue were removed manually from the bone by using sterile scalpels and tweezers. Bone tissue was cut using an orthopedic saw, into small pieces of approximately 5cm^2, followed by a milling procedure. The tissue was placed into a bottle containing sterile water at 60°C; it was incubated for 40 minutes in order to remove fat, bone marrow, and blood remains. Disinfection procedures were also carried out with several alcohol and hydrogen peroxide washes. At the end of the process, a sample tissue was collected and transported to an external microbiology laboratory where aerobic and anaerobic bacteria and fungal cultures were performed following the 4th edition of Clinical Microbiology Procedures Handbook of American Society for Microbiology standards. Any bone allograft with a positive bacteria culture result would be discarded.

Bone allografts were dispensed into 1, 5 and 10 cc vials and packed within two sterile polyethylene bags using vacuum sealing. Finally, the bagged allografts were stored in a freezer at -80°C, until receiving the results of the sample specimen's cultures. Due to high demand in the Hospital, bone allografts are rapidly being used in patients and do not last more than 2 months in storage; although, bone allografts can be stored for up to five years. [16]

Data control: All the information, including lab tests, informed consent, questionnaire, and clinical information, was coded and archived under controlled access at the Bone Bank administrative office, and will be kept for 10 years, in accordance with the Costa Rican regulation for donation and transplant of organs and tissues. All relevant information about the donors was both physically and digitally stored in order to have easy access to the data.

Results

Sixty nine (69) donated bones were received during the first three years of operation, (2016-2019). Sixty two percent (62%) of these tissues were femoral heads and the other 38% corresponded to femoral condyle and tibial plateau segments. Of all donated bones, only 70% were adequate to be processed and used as a final product. The remaining 30% of the bones were discarded. Principal causes for rejection were positive serology test results or history of contraindicated diseases for bone donation, being the most frequent Hepatitis B.

Two hundred fifty eight (258) patients at the Trauma Hospital were implanted with these bone allografts, mainly in joint fusion, open reduction and osteosynthesis surgical procedures, without presenting any complications related to the use of the bone allograft (Table 2). According to Nosocomial

Infection Department at Trauma Hospital, no infection related to the allograft was detected during that period, verifying the safety of the tissue allograft in these patients

Discussion

Most of the patients treated at the Trauma Hospital have suffered severe physical trauma, the bone bank plays an important role as it helps people regain mobility to return to their normal lives as soon as possible.

Currently, the high rejection rate for donors is a significant issue to be considered in the process of tissue banking, but in order to provide safe tissues, it is critical to screen the donor at the beginning of the process. The cost-benefit analysis carried out should consider benefits to patients and the quality of the local production, as well as reduction of the time and costs related to imported allografts. Currently, the Trauma Hospital has patients waiting for a specific allograft, such as tendons, for more than 9 months due to the long process of tissue importation according to local and international regulations. This delay means the patient is deprived of mobility, affecting the quality of life and increasing the costs in the social health system.

Costa Rica did not have a bone bank to provide bone allografts for the treatment of patients until the INS took the first steps to develop one. The initial efforts were based on collecting tissues from living donors; these bones would otherwise be discarded after the operation procedure. Additionally, the hospital and the personnel are being trained to harvest and process other types of musculoskeletal tissues, such as soft tissue allografts, cortical bone and bone block allografts. The bone bank is working on a deceased donation program in order to be able to provide other tissues such as tendons and long bones, which Costa Rica currently imports, paying a high price compared to the cost of processing these locally.

Table 2. Frequent surgeries in which bone allografts from the Bone Bank were used between 2016 and 2019

Type of Surgery	% of implanted patients with bone allograft
Arthrosis	0.39
Fracture	12.40
Graft	5.04
Hip replacement	0.78
Joint fusion	34.88
Limb Lengthening Surgery	0.39
Lumbar discectomy	0.39
Maxillofacial	0.78
Osteosynthesis and open reduction	38.76
Osteotomy	1.16
Patella cerclaje	0.39
Pseudoarthrosis	3.10
Reconstruction	1.55
Total	100

The establishment of the first bone bank in Costa Rica was a challenge that the National Insurance Institute accepted. At the same time, its goal is to provide quality tissue for all patients in the country. The INS has embarked on a mission to establish agreements with public and private hospitals, in order to harvest usable tissues currently discarded after operations. Likewise, the goal for the near future is to harvest viable tissue from deceased donors, not only at Trauma Hospital but also at others hospitals in order to strengthen the tissue donation and transplant network in Costa Rica.

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