

ORIGINAL ARTICLE

Analysis of the order-implantation relationship for musculoskeletal tissue transplantation[☆]



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KEYWORDS

Order;
Implant;
Quality;
Return

Abstract

Objective: To analyze orders requested from a musculoskeletal tissue bank and to evaluate the percentage of tissue implantation.

Material and methods: Two hundred and sixty-five orders for musculoskeletal tissue were analyzed over the course of a year. Exclusions: 5 duplications and 5 orders for which there was no availability to cover the need. We analyzed the number of surgeries in which the graft was finally used.

Results: Of a total of 255 orders, the graft was used in 178 (70%), and the graft was not used in 77 (30%). Of the 178 used, there was a partial refund in 23 (10%). Of the 77 orders not used, surgery was performed in 32 (13%) without the use of bank tissue, while surgery was discontinued in the remaining 45 (17%).

Discussion: A non-utilization rate of 30% was identified, of which 17% was from surgery that was not performed and 13% from surgery that was performed, but the tissue was returned to the tissue bank, because it was not required. In a further 10% there was partial return of the tissue. Based on this analysis, we consider that it is important to have direct confirmation of the surgery to avoid sending tissue for discontinued surgeries, since in addition to the economic impact, the bank must ensure adequate temperature maintenance during transportation and storage in the transplantation centre, to avoid discarding said tissue if it is returned.

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PALABRAS CLAVE

Solicitud;
Implante;
Calidad;
Devolución

Análisis de la relación solicitud-implante de injerto para trasplante osteomuscular**Resumen**

Objetivo: Analizar los pedidos solicitados a un banco musculoesquelético y evaluar el porcentaje de utilización de los tejidos.

Material y métodos: Se analizaron 265 pedidos de tejido osteomuscular en el transcurso de un año. Exclusiones: 5 duplicaciones y 5 pedidos en los cuales no hubo disponibilidad para cubrir la necesidad. Se analizó la cantidad de cirugías en las que finalmente se utilizó el injerto.

Resultados: De 255 pedidos solicitados, en 178 (70%) el injerto fue utilizado, mientras que en 77 (30%) el injerto no fue utilizado. De los 178 utilizados, en 23 (10%) hubo una devolución parcial. De los 77 pedidos de injerto no utilizado, en 32 (13%) la cirugía fue realizada sin necesidad de utilizar tejido de banco, mientras que en los 45 (17%) restantes la cirugía fue suspendida.

Discusión: Un 30% de los injertos solicitados no fueron utilizados; un 17% debido a que la cirugía fue suspendida y un 13% porque el tejido fue devuelto, ya que la cirugía no lo requirió. En otro 10% hubo una devolución parcial del tejido. Con base en este análisis, consideramos que es importante tener una confirmación directa de la realización de la cirugía para evitar enviar tejido a cirugías suspendidas, ya que además del impacto económico, el banco debe asegurar un adecuado mantenimiento de la temperatura durante el transporte y almacenamiento en el centro trasplantológico, para evitar el descarte de dicho tejido, en caso de ser devuelto.

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Introduction

Musculoskeletal tissue banks are responsible for procuring, processing and distributing the needs of replacement material of the musculoskeletal system obtained from a donor. One of their fundamental missions is to guarantee maximum possible quality of the allograft to the surgeon and patient. Nowadays the great majority of tissue banks aim to adopt a quality management system for the purpose of providing safe, high quality tissues to the recipients. Due to the advance of these quality controls there is a progressive increase in the number of therapeutic uses and especially in the field of orthopaedics.^{1–9} The most important causes to condition the rejection of preserved tissue in clinical use are related to serological events and contamination and infection of the bony pieces.^{10–15} The percentage of graft rejection is directly related to the material and human resources each bank has and the preliminary donor selection. However, another occasional source of rejection is erroneous distribution due to the wrong order request or potential discontinuation of the surgical procedure. The aim of this study was to analyse the orders made to a musculoskeletal bank and to evaluate the percentage of usage made of the tissues.

Material and methods

265 musculoskeletal tissue orders received from a musculoskeletal bank were analysed over the course of a year. The orders were made through the SINTRA computer system—the National System of Information of Procurement and Transplant of the Argentinean Republic—regulated by the INCUCAI—National Institute Single Centre Coordinator for excision and implants. Any orthopaedic specialist or

odontologist who has been authorised by INCUCAI may request a graft. Analysis of the data base led to the exclusion of 5 duplications and 5 orders for which there was no availability at the time of order to cover the need. The duplications were made because the professional mistakenly put in the same order twice for the same patient. This left 255 orders to be analysed, of which 24 were massive bone grafts, 23 were tendons, 151 fragmented bone tissue (15,640 cc), 41 structural grafts and 16 combined. The number of operations in which the graft was finally used were analysed, as was the time between order request and surgery.

Results

The musculoskeletal specimens distributed by the bank are obtained from both live donors (head of the femur) and cadaveric donors (mainly femurs and tibias, as well as anterior and posterior tibial tendons). All grafts are stored in sterile bags and preserved at -80°C until their distribution. All grafts are stored and distributed as fresh and frozen.

Out of the 255 orders, the graft was used in 178 patients (70%) whilst in 77 patients (30%), it was not. Of the 178 patients in which the graft was used, in 23 (10%) there was a partial return of the initially requested tissue (3 structural [one femoral condyle + 3 diaphyses], 12 fragmented [1,500 cc] and 8 combined [3 tendons + 5 diaphyses + one extensor apparatus + 300 cc]), whilst in 155 patients (60%) the graft was used entirely (26 structural [12 wedges + 3 femoral condyles + 9 diaphyses + 2 tibial shafts], 18 massive [5 distal femurs + 3 proximal tibias + 5 distal tibias + one humerus + one distal humerus + one radius + one talus bone + one tibia], 97 fragmented (8,850 cc), 9 tendons and 5 combinations [400 cc + 4 diaphyses]). Partial returns were in no cases linked to aspects regarding graft distribution, e.g.

delayed delivery, rupture of the cold chain supply, changes to packaging, etc.), but they were due to medical matters relating to difficulties in the amount of bone required to use for the type of surgery performed (structural and ground bone graft), or changes to the surgical strategy (wedges, tendons). Out of the 77 patients for whom no graft was used, in 32 patients (13%) surgery was performed without the need for the use of a tissue bank (8 structural [2 wedges + 5 diaphyses + tibial shaft], one massive [one distal humerus], 17 fragmented [2.010 cc], 4 tendons and 2 combinations [400 cc + 2 diaphyses]), whilst in the remaining 45 patients (17%) surgery was suspended (4 structural [4 wedges], 5 massive [5 proximal tibias], 25 fragmented [2.180 cc], 10 tendons and one combined [200 cc + one diaphysis]). With regard to the 32 patients for whom the graft was not used, 4 orders corresponded to tendons. In all of them multiligament knee reconstruction surgery had been programmed and during the operation the surgeon decided to reconstruct the anterior cruciate ligament with an autogenous graft. Of the 28 remaining patients, in 2 cases an articular reconstruction had been programmed with alloprosthesis and during surgery this was replaced with a modular joint (tibial shaft + a distal humerus), in 2 cases an additive osteotomy of proximal tibia had been programmed and the surgeon chose to perform a subtractive osteotomy (2 wedges); The other patients (28) were programmed to have complex prosthetic replacements of the hip and knee, and it was difficult to quantify the remnant bone defect and the spongy and structural implant which would be required for reconstruction. Moreover, of the 45 patients for whom surgery was suspended, in all cases the reason for suspension was related to administrative matters not to the quality of the graft nor medical reasons of the patient. For example, lack of authorisation from the National Health Service, lack of availability of hospital beds, etc. It is noteworthy that in all informed consents there is a special section which clarifies that the possibility of receiving an allograft during surgery exists and in no cases was there any record of this being rejected. The average time between an order request and surgery was 18.4 days (0–94).

Discussion

Due to the great development of products derived from human tissue for clinical and research use, tissue banks are starting to adopt standardised safety and quality principles. The tissue banks have much in common with the pharmaceutical industry and the manufacture of medical devices, particularly with regard to aspects involving the safety and quality of the distributed products. In 2014, in Spain, Royal Decree law 9 and order SSI/2057 of 29th October, which modified appendices III, IV and V of Royal Decree law 9/2014, established regulations governing safety and quality for donation, obtainment, assessment, processing, preservation, storage and distribution of cells and human tissues and regulations on coordination and functioning for their use in humans were approved. Moreover, Von Versen et al.¹⁶ proposed regulations ISO 9000 as a very good standard for the quality management system, which once implemented contributed to achieving authorisation by external regulatory bodies, if required by local regulations and standards.

However, it is known that the implementation of these systems is still complex and much work still needs to be carried out in this regard.¹⁷

In our tissue bank, according to our quality management system, we have defined different critical stages throughout the donor process up to tissue distribution. In this study we decided to focus on the stage which included the ‘‘request, delivery, distribution, use, and up to the return’’ when the tissue was not used. Based on this study, a 30% non use of tissue was identified, with 17% relating to surgery which was discontinued and 13% to surgery which was terminated but in which the tissue was returned to the tissue bank. To conclude, in our tissue bank we have a moderate rate of non usage of the grafts which were ordered. The correct request and delivery process is a major cause for rejection in our environment. We believe it is essential to have direct confirmation of the performing of surgery to avoid sending tissue to discontinued operations. Furthermore, the bank must ensure that proper maintenance of temperature during transport and storage in the transplantology centre is adhered to prevent disposal of this tissue once it has been returned.

Level of evidence

Level of evidence V.

Conflict of interests

The authors have no conflict of interests to declare with regard to this study.

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