Journal of Orthopedic Research and Therapy
Kale AB, et al. J Orthop Res Ther 7: 1217.
www.doi.org/10.29011/2575-8241.001217
www.gavinpublishers.com

Research Article

Bone Retrieval from Deceased Donors in Western India: The Current Scenario

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Citation: Kale AB, Gajiwala AL, Banerjee S, Samant U, Jadhav P, et al. (2022) Bone Retrieval from Deceased Donors in Western India: The Current Scenario. J Orthop Res Ther 7: 1217 DOI: 10.29011/2575-8241.001217

Received Date: 26 January, 2022; **Accepted Date:** 02 February, 2022; **Published Date:** 07 February, 2022

Abstract

Introduction: With the increased demand for bone graft in reconstruction surgeries and limb salvage surgery, bone retrieval from deceased donors has attracted much attention. This study was conducted to throw light on the current scenario in a few cities in western India, with regard to bone retrieval from deceased donors, and to suggest a way forward. **Methods**: The study assessed the bone donations from deceased donors that occurred from January 2016 to March 2020, to the Tata Memorial Hospital Tissue Bank, Mumbai. The bones were donated by hospitals in Mumbai, Pune and Surat. They were transported in insulated containers with ice packs, after wrapping them in a sterile plastic sheet. The inclusion and exclusion criteria for the bone donors were as per the APASTB Standards of Tissue Banking. The bones received in the tissue bank were checked for donor consent, and evaluated for time between procurement and banking, conditions of transport and storage, and quality of the bone. **Results**: 12 donations were received, with iliac crest and ribs being the most common bones procured. Four donations were rejected due to improper documentation and storage. The majority of the bones were procured in the operation theatre. **Conclusion**: Bone donation after death is not popular in India. A more vigorous promotion of bone donation is required, involving government and non-government organizations, and the recruitment of celebrities as brand ambassadors. Concerns of family members regarding disfigurement of the body must be addressed. Trained retrieval teams and coordination between the donor hospital, retrieval team and tissue bank are necessary to avoid the rejection of tissues.

Keywords: Allograft; Bone retrieval; Deceased donor; Western India

Introduction

With advances in the treatment of musculoskeletal tumors, limb salvage surgery, with its concomitant demand for bone graft, has increased significantly [1,2]. Additionally, bone graft is used in revision arthroplasty [3] spinal fusions [4], reconstructive procedures [5-8] and treatment of periodontal disease [9]. Autogenous bone graft is the gold standard, but since this is available only in limited quantities, allograft bone becomes a necessity. Currently, in Western India, bone allograft is mainly produced at the Tata Memorial Hospital Tissue Bank, Mumbai, from surgical residues from patients undergoing joint replacement surgery (femoral head in hip arthroplasty, and distal femur and proximal tibial slices in knee replacement), or limb amputations. With the increased demand for allograft bone, however, these sources are inadequate to meet the requirement, and the use of bone from deceased donors has become one of the most effective ways to increase the pool of available bone allograft [10,11].

Deceased donors from whom tissues are recovered include those who may have died due to cardiac arrest, or who may have been declared brain-stem dead. In India, brain-stem death has been defined by the Transplantation of Human Organs And

Tissues Act (THOTA), 1994 as the stage at which all functions of the brain-stem have permanently and irreversibly ceased (Section 2(d)) [12]. It has to be certified by a Board of medical experts, which includes the registered medical practitioner in charge of the hospital in which brain-stem death has occurred, an independent specialist approved by the Appropriate Authority, a neurologist or neurosurgeon approved by the Appropriate Authority, and the registered medical practitioner treating the person whose brain-stem death has occurred. In the absence of a neurologist or neurosurgeon, a surgeon, physician, anesthetist, or intensivist nominated by the Medical Administrator in charge of the hospital can be appointed on the team (Section 3 (6) (i)-(iv)) [12]. The conditions and requirements for certification of brain-stem death are described in Form 10 of the Transplantation of Human Organs and Tissue Rules, 2014. Certification occurs after a set of tests conducted twice after an interval of at least 6 hours, are positive [13].

One of the key considerations when retrieving bone from deceased donors is transmission of disease [14]. Tissues may get contaminated either by the donor, the environment, the instruments and equipment used at every stage of recovery, storage, transport and processing, as well as by the personnel handling the tissues. Careful donor screening for infectious disease risks based on medical and social (behavioral) history and physical examination, is imperative [15,16]. If applicable, autopsy reports must be evaluated. Serology tests for communicable diseases including human immunodeficiency virus-1 and -2, hepatitis B and C viruses must be conducted [17].

Microbial contamination of bone during the recovery process is usually assessed by taking swabs of the retrieved bone and later inoculating them into aerobic and anaerobic culture media [14]. Culture results can determine the interventions necessary to reduce the risk of disease transmission via the allograft and these may include rejection, disinfection or secondary sterilization of the retrieved bone [18]. A single donor may provide bone for many recipients, as bone can be cut into different shapes and sizes, morsellised or demineralized, and used in a variety of conditions. Measures to prevent microbial contamination and its monitoring, are consequently critical, as many recipients can be affected in case of an adverse event. This study is conducted to throw some light on the current scenario in Western India with regard to bone retrieval from deceased donors.

Methods

The study was conducted in the Tata Memorial Hospital (TMH) Tissue Bank located in the city of Mumbai, in the State of Maharashtra. It is India's first and largest tissue bank and uses gamma radiation for the sterilization of biological tissue [19]. It is registered by the Appropriate Authority of the State of Maharashtra, under the Transplantation of Human Organs and Tissues Act (THOTA), 1994.

The study was performed between January 2016, when the first bone graft was donated to the TMH tissue bank from a deceased donor, to March 2020. Inclusion and exclusion criteria of bone donors were followed as per the APASTB Standards of Tissue Banking [17]. The donors were within 15-75 years of age. Exclusion criteria were as follows:

1. Acute and chronic infection/sepsis, patients positive for HIV, HBsAg, Anti-HCV, VDRL (syphilis), acute hepatitis or unexplained jaundice, slow viral infection such as Cytomegalovirus (CMV) etc., and history of tuberculosis;
2. Malignancy;
3. Neurodegenerative disorders such as Alzheimer's and Parkinsonism;
4. Connective tissue disorders such as rheumatoid arthritis;
5. Death due to disease of unknown etiology;
6. History of tattoo and blood transfusion in the last 6 months;
7. Known intravenous drug abuser;
8. Received organ or tissue or pituitary growth hormones in his/her lifetime.

The bone was retrieved from cardiac death donors and Brain-Stem Dead (BSD) organ donors. The donated bone was retrieved after taking written consent from the next-of-kin of the deceased. Bone accompanied by incomplete consent or screening reports, were rejected. Donated bone was received from Mumbai and Pune in the State of Maharashtra, and Surat from the State of Gujarat. The bone was retrieved using aseptic techniques, and precautions were taken to minimize the risk of contamination. (Figure 1).

Figure 1: Pic of bone retrieval from multi-organ donor being carried out in the operation theatre with aseptic precautions. From Clockwise direction i. painting of the body part after skin graft procurement. ii. Instruments used for bone retrieval iii. Retrieval of Fibula. iv. Retrieval of Patella.

The iliac wing grafts were retrieved by making incisions over both iliac crests from the Anterior Superior Iliac Spine (ASIS) to The Posterior Superior Iliac Spine (PSIS) (Figure 1). A longitudinal incision along the anterior axillary line was made to retrieve alternative ribs. Another incision was made anteriorly over the knee joints to retrieve both patella (Figure 1). Incisions on the lateral aspects of the lower limbs enabled retrieval of the fibula (Figure 1). In case the femur was also retrieved along with fibula, then a single incision was made on the lateral aspect of the lower limb and the fibula and femur disarticulated. Bamboo sticks were cut to size and screwed in position to maintain the shape of the lower limb after removal of the femur. All the incisions were surgically sutured. The retrieved bone was wrapped in sterile plastic sheets, surrounded with ice packs, placed in an insulated container, and transported from the donation site to the tissue bank (Figure 2). After reaching the tissue bank the written consent was checked, and the conditions of packing and storage during transport were evaluated. These included maintenance of the cold chain and proper labeling of the tissues. To help assess their effects on the donated bone, the time intervals between the death of the donor and bone procurement, and between procurement and receipt of the bone in the tissue bank were also recorded. Blood samples of the deceased donors were subjected to serological testing for human immunodeficiency virus-1 and -2, hepatitis B and C viruses.

Figure 2: Packing and transport of retrieved bone. Allografts placed on sterile plastic sheet.

Results

Between January 2016 and March 2020, bone was retrieved from 12 deceased donors. 42% of these donors were multi-organ brain stem dead donors and the remaining were cardiac death donors (Figure 3). 75% of the donors were male and the mean age was 52 years with a range between 21 to 72 years. The average time interval between death and procurement of bone graft was 8 hours, and all procurement was done within 12 hours of death. The bones retrieved were both iliac crests, alternate ribs, patella, fibula and femur. In a single donor, bone was retrieved from more than one site. Iliac crest and ribs were the most common bones retrieved, while the femur was the least (Figure 4). 33% of the donors were rejected. 3 out of the 4 rejections were due to improper history, records or consent. 1 rejection was due to storage of the bones in formalin during transport. The average period between procurement of bone and its receipt in the tissue bank was 40.5 hours, and the range was between 6 hours to 7 days. When the bone could not be immediately transported to the tissue bank it was stored in a -20˚C freezer. Of the 8 donors that were accepted, in 6 the bones were procured in the operation theatre and in 2 they were procured in the morgue. Among the 4 rejected, details of procurement of 3 were not available and one was procured in the morgue.

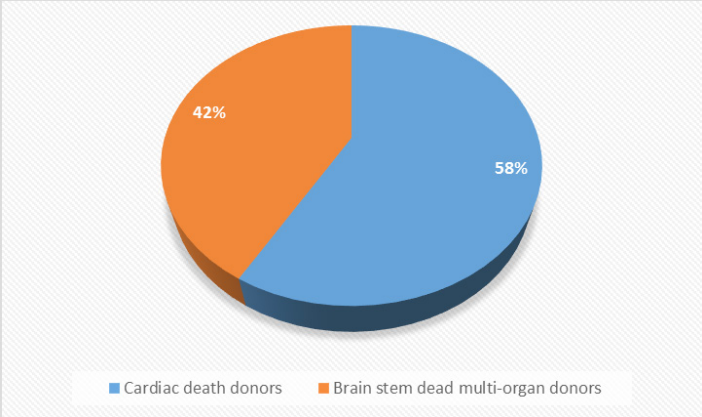

Figure 3: Distribution of type of donors.

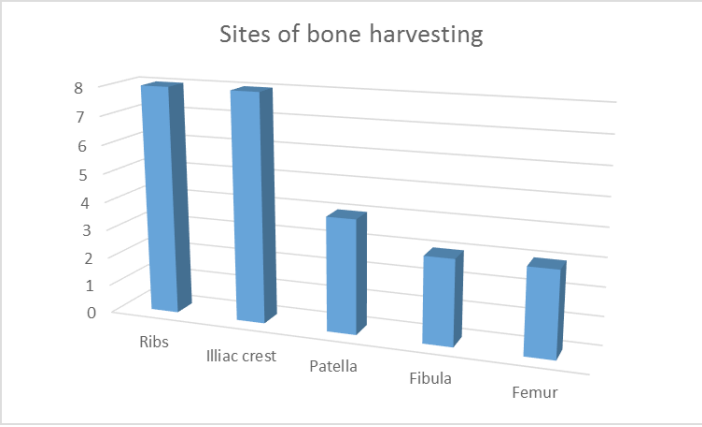

Figure 4: Bar Diagram showing types of bone retrieved from deceased donors.

Discussion

Bone retrieval from deceased donors occurs from brain stem dead multi-organ donors or individuals who have undergone cardiac death. The quality of bone is better when procured from brain stem dead donors. However, procurement of bone soon after cardiac arrest improves the quality of donated bone [20,21]. Bone should

preferably be procured under aseptic conditions, as contaminated allografts have an increased risk of postoperative infection in the recipient [18]. Studies have shown that contamination rates are high if procurement is done in morgues as compared to operation theatres [16]. Bone retrieval should therefore, ideally be done in the Operation Theatre (OT). While this may be convenient in multi-organ brain stem dead donors where organ retrieval takes place in the OT, it is not possible for cardiac death donors. Operation theatres may not be available for this purpose, and if available, will increase the cost of procurement due to OT charges. A robust bone donation program would therefore require tissue banks or hospitals with retrieval teams to have designated tissue retrieval rooms to ensure that retrieval is done under optimum conditions to reduce contamination of the tissues during retrieval.

For best results, bone should be procured within 12 hours but at least within 24 hours of death [17]. Bones procured after 24 hours of death are contaminated with multiple microorganisms from the surrounding environment and the donor's abdominal cavity and respiratory tract [16,22]. Further, the osteoinductive property is maximum in bone procured within 24 hours of cardiac arrest [23]. In European countries the bones retrieved are deep frozen to -70˚C in 60 to 90 minutes and then transferred in dry ice to the tissue bank within 7 days [21]. Cold conservation with temperatures between -4˚C to -10˚C is sufficient for conservation for few days (up to 7 days). If a longer period is required, then the temperature should be kept between -30˚C to -40˚C. Bone can be stored in this way up to 6 months [24]. In our study the bones were transferred in insulated containers with ice packs. For smaller bones, vaccine carriers which maintain an average temperature of below -8˚C in India [25] may be used, which are convenient, and cost effective, important considerations for the Indian context. Bacteriological screening is recommended for all allografts, and tissues with pathogenic organisms or mixed bacterial contamination should be discarded [17]. However, tissues contaminated with skin commensals such as coagulase negative staphylococci, may be banked after secondary sterilization [26]. In the TMH Tissue Bank all the bones were terminally sterilized using 25 kGy of gamma radiation from a Cobalt-60 source. This is sufficient to kill bacteria, provided the initial bioburden was less than 1000 cfu/graft [17,27]. This dose, however, does not kill viruses, necessitating proper donor screening. In Poland, bone allografts are irradiated with 35 kGy to eliminate viruses, and no infectious disease transmission has been reported [28].

The limitation of our study was the lack of a proper storage and transportation chain. Dry ice was not easily available, and faster modes of transport from distance cities, such as air travel, were not always accessible or cost effective. Lack of proper training of personnel involved with the transport of retrieved bone was also lacking, resulting in loss of valuable bone which had to be rejected because of improper storage, labeling and/or documentation. The availability of donated bone is also affected by the type of deceased donor. In registered transplant hospitals and Non-Transplant Organ Retrieval Centers (NTORCs) the next-of-kin of the deceased, in instances of cardiac arrest and brain-stem death, are approached by the hospital transplant coordinator for tissue donation as these hospitals are geared for organ and tissue donation [12]. In hospitals not registered under THOTA, 1994, tissues may be donated after cardiac arrest, but frequently the infrastructure and training for taking consent are absent, and the opportunity is lost. When a death occurs at home too, bone donation only occurs if the deceased had previously pledged her/his tissues, or if the family makes a decision on their own. There is no transplant coordinator available. Much therefore depends on public awareness of bone donation. However, even if there is willingness to donate bone, since bone donation cannot take place in the home and involves the transport of the body to a retrieval center, many relatives see this as an unnecessary delay to the funeral service and ultimately refuse donation.

When tissue donation takes place along with organ donation, the process is easier, as the next-of kin are already counseled for organ donation. Tissue donation however, does not take place as often as organ donation for a number of reasons. Not being lifesaving (except in the case of skin and heart valve donation), it may not have the same appeal as organ donation for relatives who are already struggling with the grief of losing a loved one. Further, many transplant coordinators do not have the same enthusiasm for tissue donation as they do for organ donation. A major obstacle is that tissue retrieval teams, unlike organ retrieval teams, are often not available round the clock. The lack of acceptance of bone procurement, by the potential donor's family can also be a hindrance to bone donation. There are a number of myths about organ and tissue donation. Many believe that their religion does not permit it, or if they believe in rebirth, they are worried that they will be reborn without the donated organs and tissues. Some are anxious about possible costs. The biggest concern, however, is that the body will be disfigured after procurement of bone, and that a public funeral procession or viewing of the body, will not be possible. To allay this fear, it is important to maintain the aesthetics of the body. In our study incisions for the removal of iliac crest, fibula and patella were therefore kept to a minimum, and all incisions were neatly sutured. Alternate ribs were retrieved to maintain the shape of the thorax. When the femurs were procured, the limbs were reconstructed using bamboo sticks. Bamboo has the advantage of being easily available. It can be cut to size, and is cost effective. It is also biodegradable, so poses no problem to either cremation or burial, which are the routine modes of disposing of the dead in India. The body was treated with utmost respect at all stages of tissue recovery. It is to be noted from our preliminary observations that retrieving the bones of the extremities is usually avoided (Figure 4), as many retrieval teams are unprepared for reconstruction of the limbs. Training in this area is therefore required if long bones, which are critical for limb salvage surgery, are to be retrieved.

A recent development that has helped boost the bone donation programme in Maharashtra is the establishment in February 2017, of the Regional cum State Organ and Tissue Transplant Organization (ROTTO-SOTTO) by the Ministry of

Health and Family Welfare, Government of India, as stipulated by THOTA, 1994, at the King Edward Memorial Hospital and G.S. Medical College, Mumbai, Maharashtra [29]. One of the functions of ROTTO-SOTTO is to promote tissue donation from deceased donors. It does this through supporting the establishment of tissue banks and strengthening existing ones, and conducting public awareness programmes on organ and tissue donation from deceased donors. ROTTO-SOTTO works closely with Non-Governmental Organization (NGOs), institutes of learning, social associations, corporate companies, housing societies, government employees etc. to provide information and to clear misconceptions about the donation process. However, much more needs to be done through mass media and the recruitment of public figures and celebrities as brand ambassadors, as is being done for cornea and skin donation.

Another obstacle to bone donation from deceased donors is the availability of trained retrieval teams. According to the Transplantation of Human Organs and Tissue Rules, 2014, the procurement of tissue must be carried out by registered health care professionals or technicians having necessary experience or specialized training (Rule 28 D (10)) [13]. However, THOTA, 1994, gives authority for the removal of tissues other than cornea, only to a registered medical practitioner [Section 3, Subsection (4)]. Thus, for the procurement of bone, trained registered medical practitioners must be available and responsible for the procedure, as well as for preservation of the tissue removed (Section 7, THOTA, 1994). State approved training for bone procurement is the first necessary step. In addition, hospitals must designate tissue retrieval teams that will be available when an organ donation takes. Each team must consist of at least 3 members, two to retrieve the bone and reconstruct the limbs, and one to simultaneously take swabs for microbial culture, and package and label the bones and other musculoskeletal tissue retrieved. One study showed that an increased number of people in the operating room during tissue recovery increased the contamination of the tissue [30]. An extensive review of recovery practices in studies published between 1992 and 2013 suggested that minimizing recovery times (<24 h) and the number of personnel performing tissue recovery are the greatest factors affecting the rate of tissue contamination at or following recovery. The experience of the recovery team may also affect the level of contamination observed. The study also indicated that the use of povidone iodine to decontaminate skin, multiple sets of sterile instruments, and double gloving do not appear to result in a great reduction of the contamination rate [31].

Our experience with bone retrieval indicates that in order to function efficiently, each team must be provided with a kit containing sterile instruments for retrieval, material for reconstruction of the limbs, equipment for collecting blood samples of the donor, material for taking swabs for microbial culture, and a checklist for the same. An insulated container with ice packs or dry ice should be provided for transporting the retrieved bone. In case there is a delay in transporting the bone to the tissue bank, appropriate arrangements must be made for storing the bone in the cold. Coordination should be established between the tissue banks, donor hospitals, and tissue retrieval hospitals and their teams, to minimize delays and reduce rejection of donated tissue due to non-compliance with the tissue bank's standard operating procedures.

Conclusion

The demand for allograft bone far exceeds the supply, but the gap can be reduced by retrieving bone from deceased donors. A more vigorous public awareness program with the recruitment of celebrities as brand ambassadors to promote bone donation, is necessary. Concerns of family members regarding disfigurement of the body and misconceptions about the donation process must be addressed. To reduce contamination of the retrieved bone, members of the retrieval team should be well trained and their numbers limited. An approved protocol for bone retrieval should be followed, and coordination between the donor hospital, retrieval team and tissue bank must be established.

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