

Case Series

Current scenario and challenges for bone retrieval for allograft use in North India

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ABSTRACT

Bone grafts are the second most common tissue transplanted. With advances in the treatment of musculoskeletal tumors, limb salvage surgery, with its concomitant demand for bone graft, has increased significantly. This study aims to evaluate current scenario for bone donation in north India. This study was done in bone bank, Government Medical College, Kota, Rajasthan. Inclusion and exclusion criteria of bone donors were followed as per the APASTB standards of tissue banking. Bone was retrieved from deceased donor and live donors after proper consent and counselling in this institute during period 01 January 2021 to 31 January 2022. During the period of study bones were retrieved from 26 donors – 24 live donors and 2 cadavers. Out of 24 live donors 20 were femoral head, 2 tibia and fibula and 2 hemi-radius and hemi-ulna. All donors were between 28-71-year age group and mean age was 56 years. 18 males and 8 females participated in study. There is huge difference between demand and supply of bone allograft in this region of country. There is lack of initiative from government for encouraging people to donate bone along with other organ and tissue donations. Lack of infrastructure for to and fro transport of bone retrieval from deceased and live donors to storage unit results in loss of bone samples. Less trained personnel and sufficiently low coordination between various institutes. Concerns of family members and misconceptions to be addressed properly to reduce morbidity burden in society.

Keywords: Bone bank, Allograft, Organ and tissue transplant

INTRODUCTION

Bone grafts are the second most common tissue transplanted and they are an essential treatment tool in the field of acute and reconstructive traumatic and planned orthopaedic surgery. 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 spinal fusions, reconstructive procedures and treatment of periodontal disease.^{3,4,5-9} Available in cancellous, cortical, or bone marrow aspirate form, autogenous bone graft is regarded as the gold standard in the treatment of post-traumatic conditions such as fracture, delayed union, and non-union. However, drawbacks

including donor-site morbidity and limited quantity of graft available for harvest. Bone bank in our institute Government Medical College, Kota was established in December 2021, which is first in Rajasthan and seventh in India. With this advancement next comes the availability of donors (both live and deceased donors) for increased demand of allograft in various procedures in orthopaedics. Use of bone substitutes is very attractive for orthopaedic surgeons, but they have different indications for use.¹⁰⁻¹²

Worldwide, approximately 2.2 million bone grafting procedures are done annually. One of the key considerations when retrieving bone from donors is transmission of disease.¹³ 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.^{14,15} 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.¹⁶ In bone allograft transplantation, the function of the transplant (mechanical integrity and the continuous stress-related remodelling of the graft) is restored only after a long-lasting incorporation process of the graft to the host bone. After surgery, the recovery and rehabilitation of the patients must be carefully followed and supervised using the modern non-invasive imaging techniques not only for months but for years.

CASE SERIES

This study was done in bone bank, Government Medical College, Kota, Rajasthan during year 2021-2022. This bone bank was established in 2021 and is certified by appropriate authority Directorate of Medical Education, office of transplantation of human organ and tissue, Government of Rajasthan under the transplantation of human organs and tissues act (THOTA), 1994.

Government Medical College Kota, has its own bone bank where the allograft is stored in deep freezer at around -80°C. It's the first and the only bone bank in the whole Rajasthan state, thus helping this study. Inclusion and exclusion criteria of bone donors were followed as per the APASTB standards of tissue banking.¹⁶

Table 1: Legal frame work governed by transplant of human organ act.

Parameter	THOA 194	THOTA 2011	THOTA 2014
Nature of guideline	Act	Amendment of act	Rules
Organs of retrieval	Yes	Included tissues	Tissues and organs
Setup of tissue bank	No	Yes	Defined the rules of tissue bank setup
Swap donation	No	Swap donations	Swap donations should be approved by authorized committee
Near relative	Only first degree relatives	Definition of near relative: inclusion of grandchildren, grandparents	
Brain death declaration	Neurologist, neurosurgeon	Physician and anesthetists added	Physician and anesthetists added. Signature of doctor on duty in Form 10
Forms	No mention	No. of forms: 11	No. of forms: 21
Quality of labs	No mention	NABL accredited	NABL accredited
Offence and punishments		Mentioned	Increased
Transplant coordinator	No mention	Mandatory	Mandatory
Infrastructure and equipment in transplanting hospitals	No mention	Defined	Defined
Regulatory bodies	No mention	Yes	Yes
National registry	No	Yes	Yes
Organ allocation priority	No	No	Mentioned



Figure 1: Bone procured from living donor after hemiarthroplasty.



Figure 2: Deep freezers for ready to use samples and quarantine bone samples in our institute.

Bone bank procures bone grafts from either living or deceased donors after proper consent as per the transplantation of human organ act 1994 (amended 2011, 2014) serving as the legal framework in India. We accepted bone from deceased donor within 12 hours (if body is restored at room temperature) or 24 hours (if body is refrigerated at 4° C).

The specimen obtained is subjected to processing that have been validated to ensure tissue quality, safety and efficacy for safe transplantation into recipients. End sterilisation of the procured bones is usually done by gamma irradiation at a dosage of 25 kGy.

Donor exclusion criteria

Person with hemophilia or related clotting disorders; acute or chronic infection or sepsis; malignancy, autoimmune disease, e.g. rheumatoid arthritis; significant history of connective tissue disorders (e.g. systemic lupus erythematosus); prolonged corticosteroid therapy; hepatitis, syphilis, AIDS related complex, slow virus infection; bone disease (osteoporosis, osteopenia, steroid induced osteonecrosis); inflammatory diseases; debilitating, degenerative, neurological diseases; suspicion of central degenerative neurological diseases including Alzheimer's disease, crutzfeldt-Jakob disease or family history of cruetzfeldt-jakob disease, multiple sclerosis; history of chronic viral hepatitis; history, clinical evidence, suspicion or laboratory evidence of HIV; high risk factors of AIDS and/ or hepatitis; acute viral hepatitis or jaundice of unknown aetiology; intravenous drug abuse; history of chronic hemodialysis; septicemia and systemic viral disease or mycosis or tuberculosis at the time of death; exposure to toxic substance; serious illness of unknown aetiology; treatment with human pituitary-derived growth hormone; and unknown cause of death.

Minimum testing requirement

Laboratory testings done were – syphilis-VDRL (rapid, spot test); hepatitis B- HBsAG (ELISA); hepatitis C- anti-HCV (ELISA); HIV-anti-HIV1, anti-HIV2 (ELISA); and microbiological (culture sensitivity) testing for anaerobes, aerobes and fungi.

Traumatic bone loss

Raju, 32-year-old male presented to emergency OPD at New Medical College with compound grade III fracture distal femur with bone loss. Fracture was initially fixed with external fixator and wound was allowed to heal. Once wound healed completely, external fixator was removed and patient was prepped for definitive surgery with prophylactic antibiotics and skin traction for 6 weeks to tend to any pin tract infection.

Irradiated fresh frozen allograft of desired length and desired bone is obtained from bone bank, preferably matching the size of the host bone, as judged

radiologically, stored at -80°. At the time of surgery, allografts were thawed in normal saline solution mixed with antibiotic (gentamicin) for 30 minutes. An extra 2 cm more than the desired length of allograft was taken, and the allograft was washed twice with 10% betadine followed by hydrogen peroxide, and finally washed with gentamicin 240 gm/3 litres of normal saline) irrigation solution.

Procured allograft after processing from bone bank and treated with antibiotic solution and cut into the desired length

Fracture site is opened. Opening of the canal is done using reamer and the host bone is fashioned to accommodate the allograft. Step cut osteotomy of both host and allograft made for better stability. After placing the allograft in proper position it is internally fixed using plates. Autogenous cancellous remainings can be used at the allograft-host junction. The wound is closed in layers over a suction drain, which is removed on the second postoperative day. The patient is kept immobilised for a week in a splint or slab and is mobilised after a week. Partial weight-bearing can be started after 4-6 week. Between three and six months, the patients are allowed to gradually increase weight-bearing. Full weight-bearing is allowed after six-eight months depending on the radiological findings.

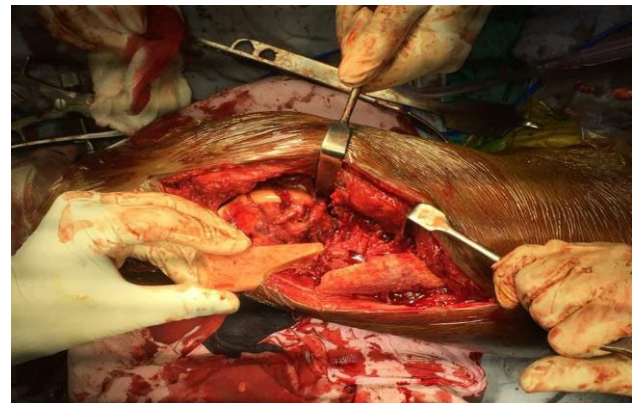


Figure 3: Allograft which is cut in a step cut fashion and of adequate length to fit into the host bone.



Figure 4: Allograft secured to the host bone using plate.

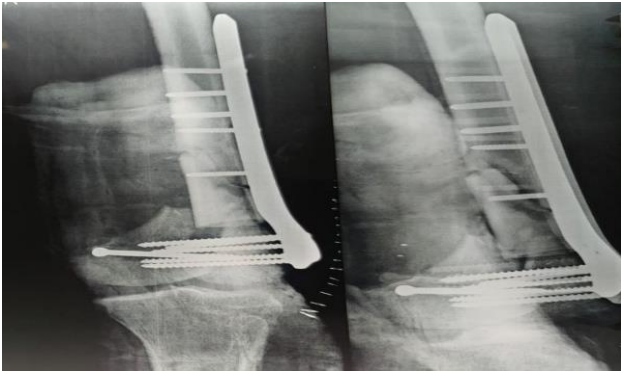


Figure 5: Immediate post op X-ray.



Figure 6: Follow up X-ray showing callus formation.

Allograft done in a case of cyst in lateral end of clavicle

26-year-old male presented to OPD of New Medical College with complaint of painful swelling over right shoulder. There was a lytic lesion in clavicle which needed excision. And based on this requisition form is given to the bone bank for the required bone and length.

Around 1/3rd of lateral end of clavicle was excised using anterior approach to clavicle. Opening of the canal is done using a drill bit or tap and the host bone is fashioned to accommodate the allograft. Allograft of proper size is prefixed to a plate. Step cut osteotomy of both host and allograft can be made for better stability. Allograft is then fixed to the host bone using this plate and k wire.

Lesion of proximal femur and use of proximal femur allograft prosthetic composite

A 44-year-old male came to NMCH OPD with a discharging sinus in proximal thigh since 4 months and inability to bear weight since 2 days. A pathological closed fracture of proximal one third of shaft femur was diagnosed clinically followed by radiological confirmation. Proximal femur along with significant part of neck was osteolysed due to infection. Resection of proximal one third of femur was done with proper antibiotics started based on tissue and pus culture sensitivity. Once patient got rid of all signs of infection, after a period of 6 months' further procedure was planned.

The femoral neck is divided using a guide and the canal reamed; the allograft is then re-washed with antibiotic and saline solution. After rescrubbing and redraping, the primary surgeon marks the planned level for the osteotomy after confirming rotation, anteversion and the length of the graft. A step-cut osteotomy is performed in the allograft to match the osteotomy in the host bone in order to obtain additional stability and enhance union at the graft-host junction. The host bone is prepared to accept a cementless coated 'solution' femoral stem (Depuy, Johnson & Johnson, Warsaw, Indiana). Antibiotic powder (2 g vancomycin, can be used as it increases the antibacterial spectrum) is placed into the canal. The stem is introduced into the allograft using gentamicin-impregnated bone cement. Care is taken to prevent the cement sticking to the distal part of the stem while introducing it into the allograft. The APC is then press-fitted into the host femur. Additional fine tuning of the length of the graft and version of the osteotomy may be necessary, depending on the final trial reductions of the hip joint. Autogenous cancellous reamings can be used at the allograft-host junction. The femoral stem acting as a major stabilising factor at the osteotomy site and the step-cut osteotomy provided rotational stability. A cerclage wire at the site of the step-cut, with or without an additional strut allograft can be used if felt that rotational stability is still not complete. Acetabulum can be replaced using an uncemented component, a pinnacle cup or a delta motion cup based on the requirements of patient. Ceramic-on-ceramic bearings is preferred and the largest possible size of femoral head should be used, especially when the abductors has been sacrificed. The abductor muscles, when conserved with a periosteal sleeve, has to be re-attached to the greater trochanter using ethibond sutures. The wound is closed in layers over a suction drain, which is removed on the second postoperative day.



Figure 7: Allograft prosthetic composite of proximal femur.

The patients can be mobilised immediately after operation and partial weight-bearing continued for three months. Patients are instructed not to sit cross-legged on the floor. Between three and six months, the patients are allowed to gradually increase weight-bearing. Full weight-bearing is allowed after six months.

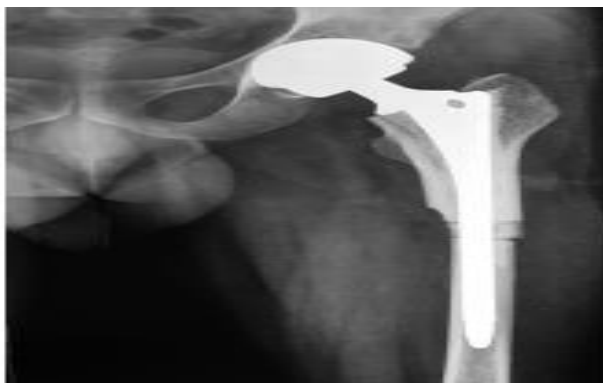


Figure 8: Post-operative AP radiograph.

Results

During the period of study bones were retrieved from 26 donors – 24 live donors and 2 cadavers. Out of 24 live donors 20 were femoral head from patients who underwent hemiarthroplasty after fracture neck of femur, 4 were from patients who undergone amputation and bones retrieved from them were – 2 tibia and fibula and 2 hemi-radius and hemi-ulna. Both deceased donors died from cardiac arrest and The average time interval between death and procurement of bone graft was 3 hours. All donors were between 28-71-year age group and mean age was 56 years. 18 males and 8 females participated in study. Out of these 26, 1 was rejected due to positive culture and sensitivity report.

DISCUSSION

Bone is the most commonly transplanted tissue in the body than any other tissue or organ except blood. For every 100 kidney transplantations, 400 bone transplantations occur every year. In our country we are in primitive stage of using allograft in orthopaedic conditions.

Allografts are preferred over synthetic implants by value of their desirable features of natural resources. Bone is often destroyed by infection, tumor, trauma and implanted materials and has to be replaced to restore structure and function.

For best results, bone should be procured within 12 hours but at least within 24 hours of death.¹⁶ 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.^{15,17} Further, the osteoinductive property is maximum in bone procured within 24 hours of cardiac arrest.¹⁸ 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.¹³ 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.¹⁹ In our study each bone after retrieval was packed

by sterile triple wrap technique (inner two surface sterile and outer one unsterile) and were properly labelled. All samples were stored in deep freeze at -80 degrees in deep freeze after sending laboratory samples for testings. After this sample was quarantined for a period of 180 days till repeat donor serology is negative. Terminal sterilization was done before the use of allograft using 25 KGy gamma radiation using Cobalt 60 source. This is sufficient to kill bacteria, provided the initial bioburden was less than 1000 cfu/graft.²⁰ 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.²¹

The limitation of this study was limited number of donors, limited knowledge of bone bank and bone donation among population, lack of trained staff, no transplant coordinator. 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. 5 kin of deceased refused donation and many did not know bone donation do occur. The availability of bone is also influenced 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. 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. When tissue donation takes place along with organ donation, the process is easier, as the next-of kin are already counselled 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, 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.

Biggest concern in transplanting bone was control of infection. One study showed that an increased number of people in the operating room during tissue recovery increased the contamination of the tissue.²² An extensive review of recovery practices in studies published between 1992 and 2013 suggested that minimizing recovery times (<24 hours) and the number of personnel performing tissue recovery and the greatest factors affecting the rate of tissue contamination at or following recovery. The study also indicated that the use of povidine 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.²³

Lack of infrastructure and propaganda from government is one of the major factor responsible for less number of allograft available. Official sites and government schemes do not include or create awareness for bone donation. There is need to include and counsel people about donating bone along with other tissue and organ donations.

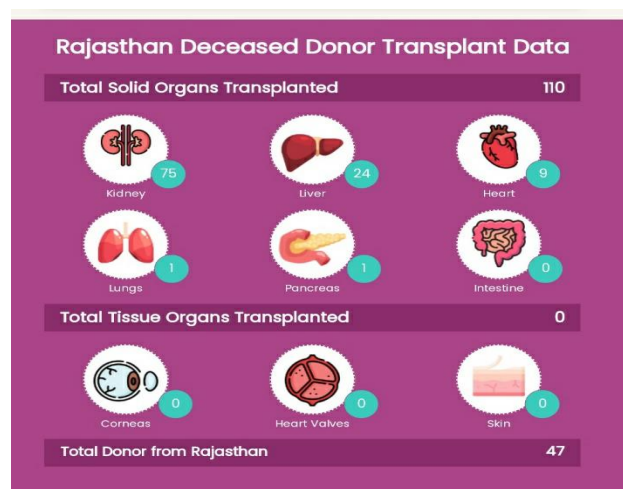


Figure 9: State organ and tissue transplant organisation (SOTTO)- Rajasthan official website which have no mention about bone donation.

CONCLUSION

Our experience with bone retrieval and transplantation concluded. There is huge difference between demand and supply of bone allograft in this region of country. There is lack of initiative from government for encouraging people to donate bone along with other organ and tissue donations. Lack of infrastructure for to and fro transport of bone retrieval from deceased and live donors to storage unit results in loss of bone samples. Less trained personnel and sufficiently low coordination between various institutes. Concerns of family members and misconceptions to be addressed properly to reduce morbidity burden in society.

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