Analysis of Potential Bone Donors and Deferral Rates for Bone Bank in a Tertiary Care Hospital

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Abstract

Background: Bone grafts are widely used in various orthopaedic procedures. Problems of limited availability of autograft and donor site complications can be overcome by use of allograft procured from the bone bank. The banks are underutilized due to high donor deferral rate. Hence this study is done to analyse the donor profile and donor deferral rate of our bone bank.

Material & Methods: Donor deferral rate in pre-harvesting phase, intraoperative phase and post harvesting phase in 67 patients of fracture neck of femur undergoing hemi-replacement / total hip replacement (THR), osteoarthritis hip undergoing THR and osteoarthritis knee undergoing total knee replacement, who donated the bone was analysed.

Results: Overall donor deferral rate was 69% as 46 donors out of the total 67 were rejected and only 21 (31%) donors were eligible for use. 24 (35%) donors were rejected during the pre-harvesting stage; 1 (1.4%) donor was rejected intraoperatively, whereas 21 (31 %) donors were rejected during the post harvesting period.

Conclusion: High rate of donor deferral rate has led to donation losses and burden on limited resources. Awareness, effective trained staff, proper counselling and consent, improved serological testing and equipped bone banks can reduce donor rejection and meet the increasing demand for bone grafts.

Keywords: Bone bank, Allograft, Donor selection.

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Introduction

Bone grafts, bone substitutes and bioactive factors are now commonly used in various orthopaedic surgical procedures. Bone grafts augment natural healing via osteoinductive, osteoconductive and/or osteogenic mechanisms [1]. Use of bone substitutes as alternative for bone grafts is limited because of its limited role in osteosynthesis, its cost and availability [2-3]. Bioactive factors, although have better osteogenetic potential, but they lack in providing structural support and are costly and not readily available. Hence bone graft still remains the gold standard especially autologous bone graft.

Allograft although can be used as a strut, a buttress, to fill up cavities or as an augmentation in combination with autografts but its osteoconduction and osteoinduction properties are limited in comparison to autografts [4]. Further, autografts are advantageous in terms of immunology, storage, transmission of infectious diseases and vitality, which are of concern with allograft use [5]. Autologous bone grafts can be procured from iliac crest, fibula, tibia, rib etc. But the use of autologous bone grafts is limited due to the fact that only small amount can be harvested as its availability is limited and it can lead to donor`s surgical site complications such as hematoma, increased

surgical time, peritoneal perforation and herniation of the contents, sacroiliac joint instability, dysesthesia, fatigue fractures, growth impairment, growth disturbances and osteomyelitis [3].

These problems of limited availability of autograft and donor site complications can be overcome by use of allograft stored from the bone bank. The head of femur of patients undergoing hemi-arthroplasty or total hip replacement, femoral and tibial condyles of patients undergoing total knee replacements and bones from traumatic amputation of limb are generally discarded. These bones if processed and stored properly can provide a steady supply of allogenic bone graft which can meet the increased demand of bone grafts. Various methods can be adopted in bone bank to increase the osteoconduction and osteoinduction of bone grafts and reduce their immunogenicity like freezing, chemosterilisation, demineralization, lyophilisation and antigen extracted autodigested allograft [1,2].

Thus bone banks which are centers for acquiring, characterizing, and storing bones or bone tissue for future use, can ensure availability of bone in large quantities of different size and shape and decreases donor site morbidity. Thus availability of a hospital based bone bank, can broaden the spectrum of operations that can be performed [6,7].

But performance of bone bank depends on strict control at all the stages [6,7]. The majority of bone bank adheres to the guidelines formulated by American Association of Tissue Banks and also endorsed by the European Association of Tissue Banks. It consists of five components- organization of well-trained harvesting team, donor selection, documentation, storage, processing and testing of tissues obtained and implementation [8]. Combination of these factors enables a greater scope of use and number of recipient's patients, reducing the incidence of tissue contamination.

Donor screening or selection is an important step in the maintenance of bone banks as it aids in selecting the donor and reduces the risk of disease transmission, thus improving results of allografting [9]. Donors can be deferred in any phase from pre-operative phase, intraoperative phase to post-operative phase. This present study is done to analyze the donor profile for a bone bank and the donor deferral rate of a bone bank in a tertiary care hospital at different levels.

Material and Method

This observational study was conducted in Department of Orthopaedics and Microbiology at tertiary care center, Delhi from October 2017 to September 2018. Patients of fracture neck of femur undergoing hemi-replacement / total hip replacement (THR), osteoarthritis hip undergoing THR and osteoarthritis knee undergoing total knee replacement were included in the study. Patients with history of malignancy, history/clinically active infection, history of autoimmune disorder, vaccination (live vaccine within four weeks), serology positive for HIV, HBV or HCV, history of diabetes mellitus or any hormonal imbalance or narcotics use were excluded from the study. In addition to surgical consent the donors were also consented for both donation of bone for harvesting and to be a part of the study. Patients who denied consent for donation of harvested bone or to be part of study were also excluded from the study.

A head to toe clinical examination was carried out of all the patients to rule out any active infection. Surgical site examination was performed. All eligible donors were listed and were given a unique identification number and a database was maintained. The patients who had consented to be a part of the study were asked to fill a pre designed questionnaire. This step led to the deferral or acceptance of the donor in the pre-operative stage itself. The selected donor's blood samples were sent for blood grouping and cross matching, erythrocyte sedimentation rate, total leukocyte count and serology for viruses - HIV, Hepatitis C and Hepatitis B.

The number of donors excluded after this step and the reason for exclusion was recorded. During harvesting the bone specimens were sent for aerobic culture, anaerobic culture and fungal culture to the department of microbiology. Bone was processed and

preserved in the bone bank as per the standard protocol. Repeat serology of patients (HIV, HBV, HCV) and culture sensitivity was sent again after 6 months. The grafts of donors whose repeat serology could not be taken as they were lost to follow up were also coined deferred. A complete record of all the donors and the reason for their exclusion was recorded. The donor data was analyzed using excel work sheets and the percentage of donors/grafts accepted or deferred due to various reasons out of the total donors was calculated.

Results

A total of 67 patients were included in the study for the purpose of donor analysis and bone harvesting. 35 were male patients and 32 were female patients. The average age of the patients was 62 years.

46 (68%) patients underwent hemi-arthroplasty for fracture neck of femur and 14 (20%) patients underwent THR. Out of 14 THRs, 8 patients were cases of secondary osteoarthritis of hip, 2 patients were case of ankylosing spondylosis and 4 patients were cases of avascular necrosis of femoral head. 6 (12%) patients underwent total knee replacement for osteoarthritis knee of which one patient underwent bilateral total knee replacement.

The donor deferral rate was 69% as 46 donors out of the total 67 were rejected and only 21 (31%) donors were eligible for use. 24 (35%) donors were rejected during the pre-harvesting stage; 1 (1.4%) donor was rejected intraoperatively as bone was used as autograft, whereas 21 (31 %) donors were rejected during the post harvesting period.

The causes of donor rejection during pre-harvesting period were no consent for bone donation (2 donor), history of tuberculosis (7 donor), avascular necrosis of femur head (5 donors), osteoarthritis of the knee (2 donors), ankylosing spondylosis (2 donors), secondary osteoarthritis of hip (1 donor) with previous surgical intervention, positive serology testing for viral markers 5 donors (3 for Hepatitis B and 2 for Hepatitis C). Only one donor was rejected during intra-operative period as the bone harvested was used as autograft.

A total of 21 (31%) donors were rejected during the post-operative period. 16 donors were rejected as their bone cultures came out to be positive. Yeast was in culture of 6 patients, Staphylococcus epidermidis in 5 donors, Pseudomonas species in 2 donors, Streptococcus species in 1 donor and Micrococcus species in 2 donors. 5 donors were rejected as they were lost to follow up. 2 donors died during the post harvesting period and 3 donors despite repeated attempts could not be contacted. No donor was rejected after follow up serology done 6 months post harvesting.

Discussion

There is an unmet need for bone grafts in the field of orthopaedics. Bone grafts are widely used in various orthopaedic procedures for reconstruction of bone skeletal defects, non-union, arthroplasty, revision arthroplasty, malignant bone tumor resection, and spinal surgery for segmental fusion or deformity correction [1,2].

Autogenous bone grafts are the gold standard, as they provide all necessary factors to promote bone repair, osteoconductive collagenous scaffold matrix, osteoinductive growth factors, and osteogenic stem cells and does not carry the risk of disease transmission or immunogenicity [10,11]. Graft can be obtained from iliac crest, fibula, tibia, ribs etc. But autograft harvesting increases the surgical time and is associated with complications related to donor site morbidity in up to 25% of patients including pain, hematoma, herniation of soft tissue, perforation, infection, nerve or arterial injury and cosmetic defects [12]. Further the amount of autograft which can be harvested is also limited.

Donor site morbidity and limited availability of autograft can be prevented by use of allograft obtained from cadaveric donors or discarded bones during surgery as in hemi-arthroplasy, THR or TKR etc. In the bone bank, before these bones are ready to be used are required to be prepared, processed and stored properly so that they can retain their properties. Allografts are prepared as fresh, fresh frozen, freeze dried, decalcified or lyophilized bone. Allografts are processed by freezing,

chemosterilisation, demineralisation, lyophilisation, antigen extracted autodigested allografts to reduce the immunogenecity and risk of disease transmission [13].

Donor selection is of paramount importance in the bone banking to reduce disease transmission, in addition to other steps like organization of trained harvesting team, documentation, storage, processing and testing of tissues obtained and implementation. Pre-operatively this includes an informed consent to be taken both verbally and orally along with thorough history, clinical examination and investigation to determine the serological status for HIV, HBV and HCV of the patient. Intra-operative selection requires bone specimen to be sent during surgery for aerobic, anaerobic and fungal culture. Following which the harvested bone is processed and preserved in the bone bank. A repeat serology for HIV, HBV and HCV is sent after six months, after which bone is ready for clinical use.

This study was performed to analyze the donor profile of 67 bone donors from our bone bank and to record the deferral rate as per the stage of rejection as pre-harvesting rejection, intraoperative rejection and post-operative rejection. In our series, 24 (35%) donors were rejected during the pre-harvesting stage, 1 (1.4%) in intra-operative stage as procured allograft was consumed as autograft in the same patient and 21 (31 %) donors in post harvesting period.

2(3%) donors were rejected as they didn't give consent for bone donation, this can be due to the fact there is still lack of awareness and religious obligations which prevents people from bone donation. There is a need to create awareness about the importance of bone donation from both, living as well as cadavers and about the fact that bone harvested from living donors does not cause any harm to the donor.

A positive history of tuberculosis, despite having taken complete treatment led to the rejection of 7(10%) donors in the pre harvesting stage itself, to prevent the risk of disease transmission and there are case reports to support this [14, 15]. Donors suffering from ankylosing spondylosis (2 cases), avascular necrosis of femoral head (5 cases) and secondary osteoarthritis (3 cases) were rejected because bones from such donors cannot be used as grafts due to the ongoing disease activity and poor bone quality which is not suitable for grafting and may lead to increased chances of graft failure and graft rejection [16].

The risk of HIV transmission has been estimated to be around one in 1.6 million, in properly screened and processed allografts and two cases of HIV transmission as a result of musculoskeletal allografting have been reported [17, 18]. Hepatitis B and C transmission occurs in less than 1% of solid organ recipients and is believed to be at a lower rate for tissue and cell recipient [19]. We rejected 5 donors who tested serology positive preoperatively for HBV (3 cases) and HCV (2 cases) to prevent viral disease transmission. The risk of disease transmission can be eliminated by-correct allograft processing, removal of blood, blood products and soft tissues and by gamma radiation [20].

16 (23%) donors were rejected as their cultures for aerobic, anaerobic and fungal came out to be positive post-operatively. The percentage of culture positive allograft in our series is comparable with other centers [21]. Most common organisms in our series were skin contaminants Staphlycoccus epidermidis (5 cases) and Micrococcus (2 cases). Some studies used culture positive allograft also for transplantation, as authors could not link this post-operative infection to a positive bone graft culture and this has even led to discontinuation of practice of performing intraoperative allograft bone culture on a routine basis [22-24]. But in contrast to this, we rejected such culture positive allografts [22]. We suspect, inadequate decontamination of the patient's skin pre-operatively, subsequent manipulation during operative procedures or resource limited setting like ours with the possibility of bio-burden exceeding the maximum acceptable limited value could also be a reason for culture positive allografts [24]. The possibility of low grade bacteraemia/ fungaemia pre-operatively leading to hematogenous spread of the microorganism to the operative site can also

be attributed to culture positive bone allografts. Donors who were lost to follow up (5 cases), died (2 cases) and who could not be contacted (3 cases) were also rejected since their post harvesting serology status could not be ascertained. This rejection can be reduced by formation of proper integrated database with all contact details, patient's complete medical and surgical history.

Overall, only 1/3 of the bone from donors was available for transplantation and the rest 2/3 was rejected, which is a huge amount of donor rejection and subsequent donation losses. Hence we need measures to reduce donor rejection and look for more sources to harvest bones in order to meet the ever increasing demand for bone grafts. Effective training of staff, proper counseling and consent of potential donors, rapid screening, and improved serological testing by nucleic acid amplification test can lower the donor deferral rate. Allograft obtained from femoral head, tibial and femoral condyles from live donors is not sufficient and bones from traumatic amputation and cadavers can contribute to a large amount of allografts. There is a need to create awareness about the need and utilities of bone donation and requirement to set up bone banks where bones are harvested, processed and stored for further clinical use. These bone banks should also be equipped with various tools such a gamma radiation, deep freezing, lyophilisation to reduce the immunogenicity and chances of graft failure.

Conclusion

Bone grafts are widely used in various orthopaedic procedures. Donor site morbidity and limited availability of autograft, has increased the potential for use of allograft obtained from cadaveric donors or discarded bones. In the bone bank, these allografts are prepared, processed and stored properly so that they can retain their properties. High donor deferral rate has led to donation losses and burden on limited resources. Awareness, effective trained staff, proper counseling and consent, improved serological testing and equipped bone banks can reduce donor rejection and meet the increasing demand for bone grafts.

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