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ORIGINAL STUDY

Bone banking in a community hospital

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Major orthopaedic operations are now also performed in community hospitals. Because allografts are sometimes used during these procedures, local bone banking could become an essential tool.
We evaluated the indications and results of the allografts from the local bone bank used in our institution. The financial aspect was also examined. Of the 131 allografts stored in our bone bank, only 20 were discarded. Postoperative follow-up showed good ingrowth of the grafts except for one graft failure. There were no superficial or deep postoperative infections. All cultures taken during implantation remained negative.
These data suggest that bone banking in a community hospital is a safe and practical alternative to address the ongoing demand of bone grafts in a small orthopaedic practice. Financial costs are reasonable. In our experience, bone banking also broadens the spectrum of orthopaedic operations that can be performed in an orthopaedic unit.

Keywords : bone bank ; community hospital.

INTRODUCTION

Although allograft bone has less satisfactory results compared to autografts, its favourable biologic characteristics are well known (*2*). It can be used either as a strut, a buttress, to fill up cavities or as augmentation in combination with autografts. Due to the increase in revision and major orthopaedic surgery, there is an increasing demand for bone grafts. Autografts alone cannot supply the required amount and allografts therefore need to be used. Nowadays more and more major orthopaedic operations, including revision arthroplasty, are also performed in community hospitals. These factors highlight the value of a bone bank in the armamentarium of the orthopaedic surgeon.

The advantages of a local bone bank are obvious (*9,12-14,17,18,28,29*). Bone allografts of different size, shape and quantity can be ordered to suit the clinical setting. Bone specimens are easily procured during primary hip replacement and can be stored easily. A community bone bank does not require many staff to operate. This in contrast with institutional bone banks which contain an insufficient supply of allografts, usually offer limited access and are relatively expensive compared to local bone banks (*3,5,8*).

The goal of our study was to assess if bone banking in a community hospital is safe and cost-effective. To investigate this we performed an audit of the first five years of the bone bank in our

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hospital. We looked at the indications and results of the implants including cultures, infection and ingrowth of the grafts. The administrative and financial aspects were also investigated.

MATERIALS AND METHODS

Our hospital is a 300-bed medical centre serving as a primary care and secondary referral centre. In the department of orthopaedic surgery an average of 200 primary and 20 revision total hip arthroplasties are performed annually by three orthopaedic surgeons. Our bone bank is a non-profit hospital based tissue bank, established in 1998 to provide human allograft material for orthopaedic surgical procedures. Its methods are based on the principles of the American Association of Tissue Banks (AATB) *(1)* and the European Association of Musculo Skeletal Transplantation (EAMST) *(6)*. An audit of the first five years of working practice was undertaken to help in deciding future policies.

We only use femoral head grafts which are retrieved during primary total hip arthroplasty under sterile operating theatre conditions as described by Tomford *et al* *(23-26)*. The femoral heads we use are procured in relatively young and healthy patients who undergo primary total hip arthroplasty for osteoarthritis. Femoral heads of patients with a hip fracture or patients with avascular necrosis are excluded. All our hip replacements are performed in laminar air flow conditions, using protective helmets.

A detailed medical history is obtained and all potential donors are tested for hepatitis B and C, cytomegagalovirus (CMV), syphilis, human immunodeficiency (HIV). C-reactive protein levels and erythrocyte sedimentation rate at the time of the primary hip arthroplasty are routinely checked. We always provide Rh-compatible grafts to Rh-negative patients to prevent immunisation which has been previously described *(11)*.

After procurement the graft is swabbed for cultures and soft tissues are removed. The graft is put into a sterile screw-topped jar and amikacin is added. This jar is put in a second, labelled one and stored in a freezer (Advantage QLT 1385) at -86°Celsius (C) or -86°C. The label is attached by the circulating nurse and contains the name of the donor, name of the hospital, name of the surgeon, a unique ID number, the date of procurement and the type of graft.

All our grafts are stored at -86°C by means of a deep freezing system. The freezer is located in the area of the operating theatre for temporary storage of the bone allografts. It has alarms to detect a rise in temperature and has a carbon dioxide back-up system in case of a power cut-off. There is a 24 hour registration system and a 24 hour supervision system with both a visual and an auditory alarm.

Table I. — Contraindications for the procurement of femoral head allografts

Infections
septicaemia
systemic infections
meningitis or encephalitis
leprosy
active or chronic viral disease
active tuberculosis or history
history of hepatitis or unexplained jaundice
history of malaria
history of syphilis
recent immunisation with live vaccine
Malignancy
Auto-immune disease
Severe trauma
major burns
contaminated wounds
Miscellaneous
tracheostomy or respirator > 72 hours
chronic (parenteral) drug use
toxic substance exposure
chronic or high dose steroids
metabolic bone disease
> 5 days hospital stay
age less than 18 years
long standing insulin-dependent diabetes
treatment with growth hormone
dementia
chronic neurological disease

Our criterion for donation is good general health with absence of any transmittable disease. Table I lists the contraindications that are used by our bank. A written informed consent from the potential donor is obtained prior to the surgical procedure. All patients are screened for disease using standard investigations (table II). The serological results for HIV and hepatitis C are checked at time of procurement and after three to six months. If any of the contraindications is present or if the cultures obtained at the time of procurement are positive, the graft is discarded. If results at review are satisfactory the implant is labelled "suitable for implantation" and moved to another drawer of the same freezer to prevent mix-up of grafts.

Table II. — Investigations used for the screening of transmittable diseases

Studies	*Tests performed*	*Specimen obtained*
Blood sample	C-reactive protein Erythrocyte sedimentation rate blood type	serum at time of surgery
Serology	Hepatitis HBsAG and HBcAB HBC CMV HIV Syphilis VDRL	serum at time of surgery*
Microbiology	Aerobic Blood agar Chocolate agar Anaerobic Thioglycolate broth	swab at harvesting and implantation

Hepatitis B surface antigene (HBsAG), Hepatitis B core antigene (HBcAG), Hepatitis C (HBC), Cytomegalovirus (CMV), Human immunodeficiency virus (HIV), Venereal disease reaction laboratory (VDRL).

* tests for HIV and hepatits C are repeated after 3-6 months.

At the time of reimplantation the graft is given to the scrub nurse after removal of the outer jar and thorough check-up of the data regarding the graft is done. A culture swab is taken and the graft is washed in saline prior to implantation.

The exact protocols for the procedure are readily available in the operating room and near the freezer to prevent procedural mistakes. All the procedures are done during the operation, without the need for additional personnel.

All these data are filed in our handwritten bone bank inventory. A computerised record of each femoral head is also kept as a back-up system. These logs are regularly updated by our bone bank nurse. It includes the name of the donor, the date of procurement, the surgeon who procured it, the results of the cultures, the blood type and rhesus factor of the donor. When a graft is implanted, the type of surgery, the surgeon who performed the procedure, the date of implantation, results of the cultures and name of the recipient are added. All officially approved bone banks in our country are submitted to regular controls by the Ministry of Health. We also have to make an extensive annual report of our clinical results and financial status. An intermediate audit is done by the hospital's bone bank commission three times a year.

RESULTS

In the five-year period from April 1998 till January 2003, 131 femoral heads were stored in our bone bank. From these 131 femoral heads, 20 were discarded. Figure 1 shows an overview of the amount of procured and discarded femoral head grafts per year. The reason for discarding the grafts (table III) included positive cultures (4), positive Gram staining (6) and problems with containers (4).

In total 94 femoral heads were used at the time of this audit. At first the grafts were used only in revision arthroplasty of the hip and the treatment of nonunion of the humerus. They are now used in a much wider variety of procedures as listed in table IV.

At a minimum of three years follow-up there was good ingrowth of all our grafts except in one case. This was in a patient with an opening wedge osteotomy of the proximal tibia, which had to be revised. The postoperative follow-up of all the other grafts was uneventful. There were no superficial or deep postoperative infections related to the grafts.

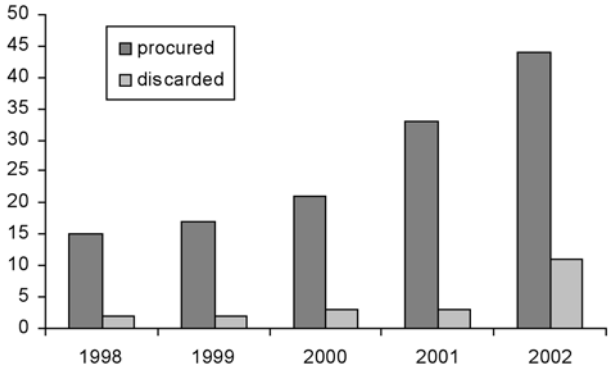

Fig. 1. — Overview of the numbers of allografts that are procured and discarded annually. There has been a marked increase in the absolute number of grafts procured. In 2002, there was a relative increase in the number of grafts that had to be discarded.

Table III. — Different reasons for discarding of allografts

positive culture	4
positive Gram staining	6
positive history	3
procedure fault	5
CMV positive	1
positive lab results	2
total	21

Table IV. — Indications for the use of allografts in our unit

revision total hip arthroplasty
nonunion of the humerus diaphysis
revision total knee arthroplasty
patellar fracture
humeral fracture
tibia plateau fracture
nonunion of the clavicle
opening wedge osteotomy
osteotomy of the tibia
osteotomy of the femur
humeral head fracture
nonunion of an osteotomy
protrusion of the acetabulum
comminuted elbow fracture
tibia fracture
calcaneal fracture
delayed union of the radius
fracture of an enchondroma

Table V. — Cost price and reimbursement of the allografts

annual costs	nurse salary	2,175 €
	freezer	2,675 €
costs per graft	equipment	15.37 €
	laboratory	34.62 €
	amikacin	71.30 €
reimbursement per graft		297.47 €

All cultures taken during implantation remained negative.

The financial aspect was controlled by the financial department of our hospital. There is an annual meeting in which the results are reviewed and problems are discussed. For the overall cost in these first five years of our bone bank, a set salary for a nurse corresponding to 10% of a full-time equivalent is considered. There is also the cost of the freezer which was divided equally over these first five years and a set price for each graft that is procured which includes the use of equipment (jars), laboratory tests and antibiotics (see table V). In our country there is a fixed reimbursement funded by the national health system for each allograft provided by an officially approved bone bank.

DISCUSSION

Femoral heads procured at the time of a primary total hip arthroplasty provide a useful source of bone grafts. Although studies could demonstrate no relationship between the culture of the graft and future failure of joint replacement in case of impaction grafting (*10*), strict precautions are to be taken to minimise the risk of disease transmission and infection (*1,6*).

In our series relatively few femoral heads had to be discarded compared with other bone banks (*4,9, 18*). We believe that this can be attributed to the fact that all our grafts are only procured during primary total hip arthroplasty in relatively young and healthy patients. No femoral heads from femoral neck fractures were used because in these patients there is a greater chance of comorbidity. The donor's history and blood results are checked preoperatively, so unnecessary storage of grafts is avoided.

The use of sterilisation techniques, antibiotics and histopathology are controversial. Attempts to achieve the perfect sterilisation technique continue, but currently the safest method appears to be aseptic harvesting with strict monitoring (*15,16,27*). Antibiotics have not been shown to give an additional benefit in reduction of contamination. Some authors have even been able to demonstrate adverse effects of some antibiotics (*7*) so we currently do not think there is an additional benefit and stopped using them. The use of a histological examination as part of the screening protocol (*19,20,22*) is still controversial. The AATB and the EAMST have not included these tests in their standard screening protocol (*1,6*) and currently we do not use them either.

Removal of blood and blood products from bone allografts may further reduce the possibility of disease transmission (*21*). We therefore use pulsed lavage and afterward soak our graft in an isobetadine solution to further reduce the risk of transmission.

For a small bone bank it is very important to minimise the number of grafts that have to be discarded without compromising the patient's safety. To achieve this a thorough screening of potential candidate allograft donors is very important. Once an allograft is procured, the procedure has to be followed strictly to avoid unnecessary discarding of grafts. This significantly reduces cost. During the five years of our audit we encountered two problems that have caused discarding of grafts that could have been avoided. Firstly, we used Gram staining as a screening tool for possible infection of the graft. Our own experience has shown that a couple of false positive findings have lead to the early discarding of femoral heads which could in fact have been used for reimplantation. We currently wait until the full microbiological rapport is available. Secondly, we changed the type of jars we used. Unfortunately our labels did not adhere on them as well as they used to do and at least 4 grafts were discarded because of this technical error. We now use extra tape to prevent loosening of the label.

Calculation of the financial aspect of our bone bank demonstrates that only 22 grafts a year have to be used to get a break even result. As already stated, the minimum amount of unnecessary discarded allografts is mandatory to prevent extra costs. We do not believe that there is sufficient evidence that amikacin has an additional beneficial effect, so from 2003 on we stopped using it. Since buying a freezer is a once-only cost, new calculations demonstrate that from 2003 onward we only need to use 9 grafts per year for a break even result.

These data show that it is possible for a community hospital to establish a safe and cost-effective bone bank. Donor selection is the single most important step. Clear and practical written policies have to be readily available in the operating room to assure consistent handling. We are convinced that a hospital-based bone bank is an important tool in the armamentarium of the orthopaedic surgeon, because it broadens the spectrum of operations that can be performed. In our personal experience it has proved to be a very valuable tool in the acute setting including treatment of orthopaedic trauma, and in revision surgery. The administrative and financial load is reasonably low.

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