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Bone allografting: an Indian experience

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Abstract Freeze-drying is considered to be the best technique for allograft preparation and storage. This method is, however, unsuitable for use in developing countries due to high costs. Ethylene oxide sterilization is still controversial because of its effect on osteoinductive capacity. This study involved setting up a bone bank for the first time. Cancellous bone collected from 40 patients was cleaned thoroughly, chemically processed, and sterilized with ethylene oxide gas and stored doubly packed. The grafts were implanted in 11 patients with 14 nonunions. Patients were followed up clinically and radiologically. Thirteen sites were united at the end of 12 months, taking an average of 44.8 weeks to unite. Allograft was also used in 8 benign bone lesions, which showed incorporation of the graft by 29 weeks. This study shows cancellous allograft is suitable for packing cavities in the treatment of benign bone lesions and in treatment of nonunion. There was one deep infection. The low infection rate confirms the efficacy of ethylene oxide as a reliable option for sterilization of bone allograft, and it is also cost effective.

Résumé La congélation sèche est considéré comme la meilleure technique pour la préparation et le stockage des allogreffes. Cependant cette méthode est inapte pour les pays en voie de développement en raison des coûts élevés. La stérilisation à l'oxyde d'éthylène est encore controversée à cause de son effet sur l'osteoinductivité. De l'os spongieux de 40 patients a été collecté, nettoyé entièrement, traité chimiquement et stérilisé avec de l'oxyde d'éthylène gazeux puis entreposé sous double emballage. Les implantations ont été faites à 11 malades avec 14 non-

consolidations. Les malades ont été suivis d'une manière clinique et radiologique. Treize sites étaient consolidés à 12 mois avec une moyenne de délai de 44,8 semaines. Ces allogreffes a aussi été utilisées dans 8 lésions osseuses bénignes qui ont montré une incorporation de la greffe à 29 semaines. Cette étude montre que les allogreffes spongieuses sont convenable pour combler des cavités dans le traitement de lésions bénignes aussi bien que dans le traitement des non-consolidations. Il y avait une infection profonde. Le faible taux de l'infection confirme l'efficacité de l'oxyde d'éthylène pour la stérilisation des allogreffes osseuses ce qui a, de plus, a un coût assez bas.

Introduction

Cancellous bone grafts are commonly used in orthopedic surgery. Autograft is the most convenient way to procure a bone graft. This procedure increases operative time, adds to postoperative pain, and prolongs recovery. Allograft is an alternative, and there are many methods described in the literature for its preparation and clinical use. Among all the techniques, freeze-drying is considered to be the best for allograft preparation and storage. However, this is not usually feasible in developing countries due to the high cost of equipment and its maintenance. Ethylene oxide (EO) sterilization is accepted as a cost-effective method for processing and preserving bone. This study was aimed at comparing the graft incorporation time when used in different surgical procedures and assessing the infection rates associated with this technique. The effect of EO on osteoinductive capacity is controversial, and this has been investigated extensively in the literature. We looked at the difference in time required for radiological healing when cancellous EO sterilized allografts were used for cavity filling after excision or curettage of benign bone lesions and for nonunions.

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Materials and methods

Cancellous bone was collected from 40 patients (28 men and 12 women) who underwent elective orthopedic procedures, such as hip arthroplasty. Donors were healthy living adults. A detailed medical history was taken, and systematic examination was done to exclude coexisting medical conditions. Donors were screened for HIV and hepatitis B infection by serology. Grafts were cleaned thoroughly in running water and treated with various chemical agents, as outlined in Fig. 1. This was based on the technique used by Parthiban and Ramani [8]. Grafts were doubly packed and sterilized with gaseous EO, stored for elective use, and used within a month. They were reconstituted in chloramphenicol solution for 30 min before implantation. The chemicals used in graft preparation contributed significantly to reducing disease transmission and immunogenicity of graft bone. Trisodium phosphate is a useful bone-cleansing agent that removes soft tissue and marrow. Sodium hypochlorite is virucidal and inactivates HIV. Hydrogen peroxide removes organic content, reducing immunogenicity. Absolute alcohol

dehydrates bone and reduces chances of toxic by-product formation during EO sterilization. Both alcohol and EO also inactivate HIV. Antibiotics were given in the postoperative period, depending on the procedure, for at least 72 h. Patients were followed-up radiologically until grafts showed evidence of incorporation.

Results

Fracture nonunion

Eleven patients had nonunions at 14 sites that were grafted (Table 1). Most of those fractures were initially treated conservatively by native bonesetters, and patients presented with either delayed union or frank nonunion. All patients had open reduction and internal fixation of fracture with either an intramedullary or extramedullary device. Graft incorporation took an average of 44.8 weeks.

Fig. 1 Graft preparation

Table 1 Graft incorporation and complications

	Nonunion	Cavity filling	Arthrodesis	Total
No. of patients	11	8	4	23
No. of sites	14	8	8	30
Nonunion (graft failure)	1	0	1	2
Deep infection	0	0	1	1
Average healing time (weeks)	44.8	29	54.8	41.8

Filling cavities

In eight cases, the allografts were used to pack cavities or defects after excision or curettage of benign bone lesions. No patient had any postoperative infection, and grafts incorporated at an average of 29 weeks.

Arthrodesis

The other four cases were primary bone tumors around the knee where allografts were combined with fibular autografts and an intramedullary nail for resection arthrodesis of the knee. One patient developed deep infection postoperatively that did not resolve with regular chemotherapy and after many failed surgical procedures was treated with an above-knee amputation. One out of the eight grafted sites failed to unite. Others healed at an average of 54.8 weeks.

Discussion

In our study, results were better where benign bone lesions were curetted and the cavities packed with crushed cancellous grafts. They showed an early healing at an average of 29 weeks. Spence et al. [9], using freeze-dried crushed cortical bone grafts in solitary bone cysts, observed that complete healing took over a year. Carr and Hyatt [1] had three failures in 13 cavities that were packed with freeze-dried grafts. Goel and Tuli [2], using decalcified bone preserved in ethanol, reported graft incorporation as early as 3–4 months in bone cysts.

In our study, 11 patients with nonunion were treated with internal fixation and allografting at a total of 14 sites. Thirteen were radiologically united at 1 year; one failed to unite, which was a case of nonunion of fracture of both forearm bones where the radius failed to unite. Carr and Hyatt [1] reported similar cases of nonunion of fracture of both forearm bones where allografts failed to achieve union. Mankin et al. [6], and Korkala et al. [5] also reported nonunion when using allografts.

One patient had a deep infection in the postoperative period. This was a giant cell tumour of the proximal tibia with pathological fracture where resection arthrodesis of the knee was carried out using an intramedullary nail and fibular autografts. Allografts were used at proximal and distal junctions to enhance union. The procedure involved additional risk factors that could have contributed to infection, such as lengthy operative time and extensive tissue dissection. Cultures showed MRSA and acinetobacter resistant to all antibiotics, and ultimately, the patient needed an above-knee amputation. Similar findings with

regards to infection involving allografts in tumor surgery were observed by Mnaymneh and Malinin [7], Tomford et al. [11]. Ivory and Thomas [3] reported an infection rate of 3.6%, Korkala et al. [5] reported 6%, and Mankin et al. [6] reported 10%. In our study, infection rate was 4.3%.

EO sterilization is still a controversial issue in bone allograft preparation. The effect of EO on the bone-inducing capacity of graft bone has been studied previously, and the studies seem to contradict [4, 10]. We observed a reasonable rate of graft uptake in our study, with an average healing time of 41.8 weeks, which is comparable to autografts.

Apart from an EO sterilizer, which most hospitals have, and a team of dedicated orthopedic residents, maintenance of a bone bank requires only the chemicals mentioned. This study shows that this technique is a reliable and safe method for bone allograft preparation and that EO is an effective sterilizing agent for bone. Though it may affect osteoinduction, it does not affect the osteoconductive properties of the allograft. It is a cost-effective alternative to other expensive techniques and hence suitable for use in developing countries.

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