OR Manager Inc

OR Manager
Vol. 20 No. 8
August 2004

CDC gives advice on tissue safety

When a healthy 23-year-old Minnesota man died of an infection in December 2001 after routine surgery to receive a knee allograft, alarm bells went off across the country.

The question on everyone's mind—did the relatively rare type of infection caused by *Clostridium sordellii* come from the graft?

The Centers for Disease Control and Prevention (CDC) started an investigation and asked surgeons and public health officials to report any other allograft-related clostridium infections.

As of March 2003, 14 such patients had been identified, according to the CDC's report published in the June 17 *New England Journal of Medicine.* All 14 patients had received allografts from the same tissue bank, identified in the report as Tissue Bank A and in press reports as CryoLife.

What caused infections?

The infections were probably caused by microbes present in the cadaver tissue when it was recovered, according to an accompanying editorial by physicians from the Mayo Clinic College of Medi-cine. As a person is dying, microorganisms can pass through the intestinal wall and seed blood or tissue with normal intestinal flora, such as clostridium. Even with refrigeration, the body cools slowly enough for the organisms to proliferate. Clostridium has spores that can persist for years, and implanting a contaminated allograft in a closed wound sets up an ideal setting for a clostridium infection, they note.

The CDC reports that the 14 patients received allografts from 9 donors. Tissues from 3 donors were processed by Tissue Bank A. Tissues from 5 donors were processed and distributed by Tissue Bank A as well as other tissue banks. The other tissue banks used either gamma sterilization or a low-temperature chemical sterilization method (BioCleanse by Regeneration Technolo-gies Inc, or RTI). No infections were reported from the grafts processed by these tissue banks. Tissues at Tissue Bank A were not sterilized but were processed using a solution of antibiotics and other chemicals. Tissue Bank A did not validate this method for killing spore-forming organisms, according to the CDC's report.

The report includes the CDC's recommendations for reducing the risk of allograft-associated infections (sidebar). The Food and Drug Administration is expected to issue final regulations for good tissue practices shortly.

Though guidelines can help improve tissue safety, the CDC says, the best way to reduce the risk of infection is to develop sterilization methods that don't affect the function of the tissue after it is transplanted. ❖

Reference

Kainer M A, Linden J V, Whaley D N, et al. Clostridium infections associated with musculoskeletal-tissue allografts. *N Engl J Med.* June 17, 2004;350:2564-2571.

Recommendations to reduce risk of allograft-associated infections

- Tissue banks should process tissue using a method that can kill bacterial spores. Existing sterilization techniques used for tissue allografts, such as gamma irradiation, or new techniques effective against bacterial spores can be used.
- Unless a sporicidal method is used, tissue should not be considered sterile. Health care providers and patients should be informed of the possible risk of bacterial infection from these tissues.
- If no sporicidal method is available (eg, for fresh femoral condyles), tissue banks should minimize the potential for release of contaminated tissue.
  —Allograft tissues should be cultured before suspension in antimicrobial solutions, and if clostridium or other bowel flora are isolated (ie, if the presence of enteric pathogens suggests that clostridium spores may be present), all donor tissue that cannot be sterilized should be discarded.
  —Tissue banks should consider performing both destructive testing and swab cultures of tissue to increase sensitivity for detecting bacterial contamination.
  —Recommended time limits for recovery of tissue, from the time of donor death or asystole to the time of tissue recovery, should be followed [American Association of Tissue Banks, 2001]. Research should be performed on the effect of such restrictions on tissue procurement and tissue safety.
- Tissue banks should validate all quality assurance methods used for tissue culture to ensure that carryover of residual antimicrobial agents does not result in false-negative culture results.
- After a tissue bank receives a report of potential allograft-associated infection, any remaining tissue from the implicated donor should not be released until it is determined that the allograft is not the source of infection. In the event of a reported allograft-associated infection, tissue-bank personnel should notify health care providers of other recipients of tissue from the same donor. A sample of nonimplanted tissues that was processed in the same way as the tissue from an allograft-associated infection should be cultured by an independent laboratory using a validated method.
- Tissue banks with identified tissue-processing problems that resulted in a contaminated end product should perform a one-time audit of their unreleased tissue inventory to estimate the proportion of unreleased tissue that may be contaminated with microorganisms or spores.

Source: Kainer M A, Linden J V, Whaley D N, et al. N Engl J Med. *June 17, 2004; 350:2564-2571. Copyright © 2004 Massachusetts Medical Society. All rights reserved.*