Ensuring the safety of allograft tissues (Iranian Tissue Bank & Research Center experience)

Mitra Mahdavi-Mazdeh
Tehran University of Medical Sciences, Iran

We witness over 2 million human tissue transplantation annually worldwide. These tissues are used in different surgeries from lifesaving orthopedic or early excision grafts for severe burns to reconstructive or ophthalmologic ones. These are shared between countries with different protocols and regulatory systems to look for different viral or microbial agents which may be a real concern for infection transmission. It seems necessary to have not only a national legislative framework with mandatory requirements and a regulatory system to authorize cell &tissue establishments but also a reporting system for allograft-associated complications by clinicians to prevent errors or donation from the same donor or same batch. (1, 2) The US Navy Tissue Bank, launched in 1949, was the first standard setter for the world community of tissue banks and established many of the standards that are still followed. Processing, immunological principles of tissue transplantation and sterilization by irradiation were developed in half a century by Navy scientists. (3) There are reports of transmission of infections or malignancies to recipients of not only solid organs but tissues and eye grafts.(2, 4) Infectious pathogens can include viruses, bacteria, parasites and prions. The risk may amplify due to the high number of tissues which can be recovered from a single donor. However, the overall risk of infectious disease transmission in tissue and cell recipients thanks to more than 50 years of experience in the field is much less than solid organ recipients which is less than 1%. (1) Furthermore, bone banking procedures have improved significantly during the last three decades. The balance between safety and availability and cost has long been a concern but cannot be an excuse to jeopardize the patient to the risk of disease transmission. We need to follow strict evidence- based algorithm to prevent even the very limited risk and allograft safety is dependent seriously on effective sterilization. In a retrospective review of allograft recall data from January 1994 to June 30, 2007 it was found that 59,476 (96.5%) of recalled allograft tissues by FDA were musculoskeletal. However, interestingly the percentage of different errors has been changed through years. From 1994to 1998, insufficient or improper donor evaluation plus positive serology accounted for 96.4% of musculoskeletal recalls which decreased to 67.2% in the period of 1999 to 2007.(5) So the importance of retrieval phase is evident. Any biologic-based products is expected to carry such a risk due to intrinsic characteristics. It should be claimed that the risk of transmission can be eliminated. All the efforts are taking place to achieve the lowest possible risk of disease transmission. There are three stages from donor tissue retrieval, tissue processing in clean room and sterilization before storage and packaging to provide safe tissues appropriate for patient transplantation. Each needs supervision of quality control and assurance protocols.

Speaker Biography

Mitra Mahdavi-Mazdeh is working as a Professor in the Division of Nephrology at Tehran University of Medical Sciences. She was the Director of Management Center of Transplantation and Special Diseases in Moh for two years (2005-2007). She has been the Director of Iranian Tissue Bank Research Center since 2007. Her major research interests lie in the epidemiologic features of RRT especially transplantation in developing countries.

e: mmahdavi@tums.ac.ir

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