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Mycobacteria and allograft heart valve banking: an international survey

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Summary Since the 1970s many tissue banks have been testing allograft heart valves (HVs) for *Mycobacterium tuberculosis* (MTB). Donor selection for low risk of tuberculosis (TB) was introduced in the 1980s and appears to have reduced the risk of TB transmission. Regulatory guidance does not specify testing for TB, but does exclude donors with a recent history of TB. This survey of HV international bank practices revealed variations in donor selection, testing and processing of valves. Participant banks (from Europe and the USA) reported that over a period of 15 years, HV tissues from 38 413 donors were banked and 32 289 donors were tested for TB, none being positive. HV-associated tissue from 27 840 donors was stained and underwent microscopy; none of these were positive for acid-fast bacilli (AFB). Non-tuberculosis mycobacteria (NTBM) were detected by culture on 24 HVs. It is recommended that HV banks employ donor selection to exclude donors at risk of TB, to culture material for mycobacteria,

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and to investigate potential sources when clusters of NTBM are found to facilitate corrective and preventative actions.

Introduction

A survey of heart valve (HV) banks was undertaken to investigate current practices aimed at prevention of transmission of *Mycobacterium tuberculosis* (MTB) and other mycobacteria by allografts to HV recipients. The survey examined variation in practice and whether current practices provide useful information about MTB as well as non-tuberculosis mycobacteria (NTBM).

Methods

In 2006, questionnaires plus supplementary questions were sent to 39 banks; eight in Britain, one in Ireland, 22 in Europe and eight in the USA. The survey period lasted from 1990 to 2004. Some banks gave information over shorter or longer periods. The results were collated and discussed with bacteriologists providing services to British and Irish HV banks. The returned data were shared with participant banks. Data sources were anonymised with banks identified by assigned letters. The banks, whose data was provided for publication, are listed in alphabetical order in the Acknowledgements.

Results

Partial or complete responses were received from 24 banks (61.5%). Data from one bank were incomplete, and from another were provided without permission for publication and so both were excluded. Responses for 1990—2004 including supplementary data for 2005 and 2006 are detailed in Table I with information from 22 banks (56.4%). Some banks did not have access to all relevant records or had not been banking for the entire period.

There were 38 413 HV donors included in the survey. Ten banks specified analytes (myocardium, HV-associated tissue and saphenous vein) for mycobacteria testing and the remainder either did not specify or did not test for mycobacteria. AFB staining was employed by 15 banks (68%) and covered 27 840 donors (72%). Four of 22 (18%) banks did not employ liquid or solid mycobacteria culture techniques, representing 6124 of 38 413 donors (16%). Eighteen banks used a variety of manual and automated culture systems to test 32 289 donors (84%). One moderate-sized bank and one small bank (Banks M and K) respectively did not use microscopy or culture to detect mycobacteria. A pathologist for Bank M inspects every HV morphologically and microscopically to exclude active mycobacterial infection. No bank reported transmission of mycobacteria from donor to recipients.

No donors were found to be positive for MTB by acid-fast bacilli (AFB) testing or culture. There were two clinical diagnoses of donor tuberculosis (TB): a 27-year-old Algerian-born male multi-organ donor (MOD) with a history of pulmonary illness suggestive of TB and another case diagnosed macroscopically at organ explantation and autopsy. Both cases were rejected as donors.

Donor selection was introduced from 1983 with a variety of criteria for donor acceptance such as medical history of infectious disease, history of past or treated TB, travel history and behavioural risk such as homelessness. Examination was also undertaken at organ explantation for MODs or post-mortem examination for some donors with results sought as part of the medical record.

Twenty-four donors had NTBM culture-positive HV representative tissue and were from seven HV banks which between them processed 24 279 donors (0.099% NTBM culture positive) and represented 0.073% of donors (32 289) from all banks which cultured HV representative tissue samples for mycobacteria. The percentage of NTBM culture-positive donors in the seven banks ranged from 0.027% to 1.005%, except one small bank which had three cases of NTBM over three years from 37 donors (Bank T). Bank G identified eight NTBM from 796 donors (1.005%), one-third of the 24 cases of NTBM identified from all banks between 1996 and 2006.

A number of potentially relevant variables in Bank G were investigated further. All NTBM-positive donations were from MODs, although such donors provided only half the donated material. All positive NTBM species cultures were from 2003 or later, although HV processing commenced in 1996. The contaminated valves were from several hospitals with no apparent geographical link. No changes in banking or testing procedures or suppliers were made