

CARDIAC TRANSPLANT

Case Report, by N.V.T. Tran, MD, MPH

Cardiac disease is the leading cause of mortality in the United States. Every minute, one American dies due to cardiac disease (1,2). Technological advances in cardiac transplants have saved many lives. As of December 2013, more than 56,000 cardiac transplants have been performed in the U.S. since 1988 (3). An airman with a cardiac disease obviously raises safety concerns. The Federal Aviation Administration strives to support airmen in their pursuit for flying, while keeping the airspace safe. This is sometimes a delicate balance, especially if the disease process is very complex. To fly after a cardiac transplant is such an example in which we have to carefully explore the boundaries between risk acceptance and safety.

History

A 69-YEAR-OLD AIRMAN WITH 900 flying hours applied for a third-class medical recertification in April 2010 after an orthotopic heart transplant in November 2006. His medical history consisted of non-Hodgkin's lymphoma (1996), which was treated with doxorubicin hydrochloride (Adriamycin) and stem cell transplant. Subsequently, he suffered from a drug-induced cardiomyopathy, which led to his cardiac transplantation. He was treated for depression after his surgery; the treatment was discontinued in 2010. Additionally, he underwent radiation therapy in 2008 for prostate cancer (adenocarcinoma) that was confined within the prostate capsule. No recurrence of the malignancies has been noted upon regular medical evaluations.

His surgery and recovery after the heart transplant was uneventful. Multiple biopsies of the allograft over the years showed no signs of rejection. The coronary angiography of his new heart in April 2010 showed no abnormalities. Additionally, a Holter monitor was performed in May 2010, and no malignant arrhythmias or pauses were present. His stress echocardiography on dobutamine over a period of 8:31 minutes recorded an ejection fraction of 55%, with 98% of the maximum predicted heart rate; maximum blood pressure 186/92; and no ST changes or arrhythmias were seen. His current medications: cyclosporine, sirolimus, aspirin, simvastatin, and olmesartan.

Aeromedical Issues

Separately, each medical issue in this airman's history might be disqualifying. His malignancies showed no recurrence, and his psychiatric and psychological evaluation was normal. Let us focus on the more challenging medical condition, namely his cardiac transplant. As you can imagine, this raises many aeromedical concerns. Until the present day, only eight airmen with cardiac transplants have been issued a third-class medical certificate. The major concern is the sudden incapacitation due to coronary allograft vasculopathy, rejection of the allograft, malfunction of the pacemaker, infections due to the immunosuppressive state, adequate cardiovascular response to high stress, high performance demands, etc.

DISEASE STATISTICS

Common diseases that may lead to cardiac transplantation include coronary heart diseases, cardiomyopathies, congenital/valvular heart diseases, and hypertensive heart diseases. In the United States, heart disease is the number-one leading cause of mortality. According to U.S. Department of Health and Human Services statistics, a total of 56,435 heart transplantations have been performed in the United States since January 1988. More than 4,000 heart transplants have been performed in the last two years (3). The one-year unadjusted patient survival data from 1998 to 2007 ranges from 84-85% (4). McGiffin and colleagues reported a 12-month mortality risk of 1% from any cause and a risk of sudden incapacitation of 0.3% (5).

Federal Aviation Administration Policy

The Federal Aviation Administration (FAA) has only issued third-class medical certificates for airmen with cardiac transplants. The authority level lies with the Federal Air Surgeon (FAS). Applications are only considered after at least one year of uneventful post-surgical recovery. All mandatory studies must be performed within 30 days of application and reviewed by the FAA cardiac surgery consultant for initial authorizations. Criteria for favorable consideration are:

- » No angiographic evidence of coronary allograft vasculopathy
- » Normal left ventricular systolic function (either angiogram, echocardiography, or radionuclide ventriculogram)
- » No treated rejection in the 2 years before the anniversary evaluation
- » No hemodynamically compromising rejection at any time since cardiac transplantation
- » For initial authorization: no significant infection within the previous 6 months
- » For renewal of authorization or certificate: If an infection has occurred less than 6 months before an anniversary evaluation, therapy must be completed, and there must be no residual sequelae
- » No non-skin malignancy since transplantation
- » No lymphoma within 2 years of the anniversary evaluation
- » No pre- or posttransplant insulin-dependent diabetes

Applicants found to be qualified for a Special Issuance will receive a 12-month time-limited certification and are required to have annual follow-up evaluations. Due to the complexity and dynamic nature of a heart transplant, no Aeromedical Examiner Assisted Special Issuance is allowed.

The examiner (AME) must defer the airman and submit all documentations to the FAA for Special Issuance consideration. A list of required documents (performed within 30 days of the 8500-8 application or Authorization renewal) is outlined in

Continued on page 5

the FAA *Guide for Aviation Medical Examiners* (7) under the cardiac transplant disease protocol:

- » A 1 year recovery period shall elapse after the cardiac transplant before consideration
- » A current report from the treating transplant cardiologist regarding the status of the cardiac transplant, including all pre- and post-operative reports. A statement regarding functional capacity, modifiable cardiovascular risk factors, and prognosis for incapacitation
- » Current blood chemistries (fasting blood sugar, hemoglobin A1C concentration, and blood lipid profile to include total cholesterol, HDL, LDL, and triglycerides)
- » Any tests performed or deemed necessary by all treating physicians (e.g., myocardial biopsy)
- » Coronary angiogram
- » Graded exercise stress test and stress echocardiogram
- » A current 24-hour Holter monitor evaluation to include selective representative tracings
- » Complete documentation of all rejection history, whether treated or not; include hospital records and reports of any tests done
- » A complete history regarding any infectious process
- » All complete history regarding any malignancy
- » List of all present medications and dosages, including side effects

Outcome

Our airman met the stringent requirements listed above. He requested a third-class medical 4 years after his cardiac transplant. His cardiac examination showed no signs of rejection, and cardiac functioning was normal. A concern can be raised for his non-skin malignancy (prostate cancer) two years after his surgery, although no recurrence has been found on subsequent medical evaluations. With a favorable advice by the FAA cardiology consultant and normal medical results, the FAA has granted a Special Issuance with a 12-month time limitation.

References

1. Centers for Disease Control and Prevention. *Leading causes of death*. Online at: www.cdc.gov/nchs/fastats/lcod.htm. Accessed 19 Dec. 2013.
2. Roger V, Go A, Lloyd-Jones D, et al. Heart disease and stroke statistics—2011 update. A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation* 2011;123:e1-e192.
3. U.S. Department of Health & Human Services. Organ Procurement and Transplantation Network. Online at: www.optn.transplant.hrsa.gov/latestData/rptData.asp. Accessed 19 Dec. 2013.
4. U.S. Department of Health & Human Services. Organ Transplantation and Procurement Network/SRTR Annual report. Online at: http://optn.transplant.hrsa.gov/ar2009/112b_dh.htm. Accessed 7 Dec. 2011.
5. McGiffin DC, Brown R, Kirklin JK, et al: The case for selective re-issuance of medical certificates to allow pilots who have received a heart transplant to resume flying. *J Heart Lung Transplant* 2005;24:259-69
6. Federal Aviation Administration. 2011 aerospace medical certification statistical handbook. Online at: www.faa.gov/dat_research/med_humanfacs/oamtechreports/2010s/media/201302.pdf. Accessed 19 Dec. 2013.
7. Federal Aviation Administration. *Guide for aviation medical examiners*. Cardiac transplant disease protocol. Online at: www.faa.gov/go/ame/guide/dec_cons/disease_prot/cardiactransplant. Accessed 19 Dec. 2013.



LETTER TO THE EDITOR

Good Information

Dear Editor,

I was actually fortunate to read this issue [Federal Air Surgeon's Medical Bulletin, Vol. 51, No. 4]....This FASMB has got to be one of the better ones I have read in the last several years. It had a great deal of very important medical and administrative information that the AME needs to know about.

Job well done to you, your staff and the authors for a great issue. Keep 'em coming.

Thomas B. Faulkner, MD, MHA
Peachtree City, Ga.

Dear Dr. Faulkner,

We appreciate your kind comments and will continue to provide timely, useful information to aviation medical examiners.

Editor

About the Author

N.V.T. Tran, MD, MPH, was a U.S. Air Force School of Aerospace Medicine Resident in Aerospace Medicine, Class of 2012. He is an Exchange Officer from the Royal Netherlands Air Force. He wrote this article during a rotation at the FAA Civil Aerospace Medical Institute in Oklahoma City, OK.