Selective Recertification of Pilots Who Have Undergone a Cardiac Transplant

Ann Norris; Valerie Skaggs; David Kaye; James De Voll; David McGiffin

BACKGROUND: From 2007, the Federal Aviation Administration (FAA) permitted pilots who have had a heart transplant to be considered for recertification under special issuance at the third-class level. The objective of this study was to evaluate certification safety and determine if any adverse outcome occurred in this airman group as a consequence of this policy.

METHODS: Methods involved collecting data from the FAA Document Imaging Workflow System to identify airmen undergoing cardiac transplantation since 2007, and examining medical and safety-related outcomes through the National Transportation Safety Board-related accident database and the Centers for Disease Control and Prevention National Death Index.

RESULTS: Included in the study were 36 airmen, with 16 recertified at the class 3 level and 20 denied certification. No aviation accidents or recorded deaths occurred in the group of 16 airmen undergoing recertification. Of these airmen, 13 underwent a second successful recertification and 6 underwent a third attempt, with 5 being successful. Two airmen have declared their intention to fly under BasicMed. Of the 20 airmen denied recertification, 16 were denied for failure to provide information. There were three deaths in this denied group.

DISCUSSION: The policy allowing third-class heart transplant recipient recertification appears to be safe. Aviation safety is not being compromised by allowing these airmen to resume flying, with the exception that recertification should continue under the special issuance system and not through BasicMed.

KEYWORDS: cardiac transplantation, aviation, medical certification.

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Despite advances in all aspects of cardiac transplantation, recipients still face an increased risk of mortality compared to the general population. Until 2006, airmen with a history of having undergone cardiac transplantation were not considered eligible by the Federal Aviation Administration (FAA) for special issuance of any class of medical certificate. One of the major concerns regarding medical certification of a pilot/heart transplant recipient is the risk for the development of cardiac allograft vasculopathy (CAV) because of its prevalence, significant risk of progression, and its association with sudden death.[1–3,6] The Federal Air Surgeon (FAS) made the decision to review this policy based largely on the results of a specific study to investigate the probability of death following cardiac transplantation. This study by McGiffin and colleagues[4] included a multivariable risk factor analysis for death from any cause and sudden onset death (a composite of causes of death that could conceivably result in a pilot's sudden incapacitation). Based on results of this multivariable equation, absence of certain risk factors predicted a particularly low risk of death during the subsequent 12 mo following an evaluation, a risk no higher than that of the U.S. life table age and gender matched population. Criteria for recertification were established based on the multivariable equation risk factors—no CAV, normal left ventricular systolic function, no history of hemodynamically compromising rejection (at any time since transplant) or treated rejection in the previous 2 yr, no life threatening infection in the previous 6 mo, no nonskin malignancy, and no insulin dependent diabetes. As a result of this study and with the approval of the FAS and FAA consultant

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cardiologists, the FAS adopted a policy that allowed pilots who had a heart transplant and fulfilled these criteria to be medically certified under special issuance at the third-class level only.

The outcome of this policy has implications for aviation safety and, therefore, follow-up of recertified pilots and validation of the policy is mandatory. The objective of this study was to evaluate the safety of certification of heart transplant recipients and to determine overall health status and the occurrence of adverse outcomes.

METHODS

Using the FAA medical pathology code for heart transplant, a pilot was included in the study if: 1) the airman had proper documentation of a history of heart transplantation before their most recent examination; and 2) if the airman had applied for a medical examination after January 1, 2007. Pilots were excluded if their records were too incomplete to ascertain when their transplant occurred. Pilot data was collected from the FAA's Document Imaging Workflow System (DIWS), which includes medical certification data for all pilots who have applied for a medical certificate to fly. Institutional review board approval was obtained from the FAA.

Each eligible case was followed through April 2019 or until their last medical examination in the system, and their records were reviewed by one of the investigators. The variables collected included gender, age at transplant, certification status of examinations post-transplantation, and post-transplant-related variables, including comorbidity and complications. For recipients who were bridged to transplantation with a ventricular assist device (VAD), information was collected on device type and post-VAD complications since these could have impacted the likelihood of recertification.

Finally, BasicMed status was assessed. New federal aviation regulations incorporating BasicMed took effect as a Flight Standards program on May 1, 2017.[5] These regulations allowed private pilots to continue flying after their medical certificate had expired, given that the pilot met new policy criteria and maintained good general health status. Since having a heart transplant is one of the specifically disqualifying conditions while flying under the BasicMed rules, airmen with this condition are required to have held a one-time special issuance medical certificate from the FAA anytime since July 14, 2006, before becoming eligible to fly under the new BasicMed rules.

Safety-related outcomes were defined as a National Transportation Safety Board (NTSB) related accident or incident, or death recorded in the Centers for Disease Control and Prevention (CDC) National Death Index. Accidents and incidents were obtained by matching the pilot's information from DIWS to the NTSB database, which provides information about all aviation accident investigations. The death data were obtained by matching airmen records from DIWS with records from the National Death Index. BasicMed status was determined by obtaining a list of all BasicMed pilots from the FAA's Airmen Registry and matching it with DIWS.

It was not possible to accurately determine the number of flying hours following recertification. This is due to the fact that total flight time and flight time in the last 6 mo recorded on each application for medical certification is based solely on self-report at the time of application and is highly variable and inconsistent across applications by the same airman.

RESULTS

There were 59 airmen who were identified in DIWS as ever having had a heart transplant. Of these, 36 airmen met the eligibility criteria to be included in the analyses. There were 22 who were excluded because their transplant and follow-up was prior to 2007 when the current recertification criteria were introduced. One airman was excluded because of incomplete records. The dataset then included 36 airmen, of whom 16 were certified at least once and 20 who were denied certification.

The mean age at the time of transplantation of the 16 airmen who were certified at the time of initial certification was 59.3 yr, with a minimum and maximum age of 13.8 and 71.7 yr, respectively. All airmen were men. In the certified group, the mean time from transplantation to application for medical certification was 5.4 yr.

The pathology of end stage heart disease was ischemic cardiomyopathy (seven airmen), nonischemic cardiomyopathy (five airmen), end stage valvular disease (two airmen), adriamycin cardiomyopathy (one airman), and cardiac amyloidosis (one airman). Five airmen were bridged to transplantation with a VAD: one with a Jarvik 2000, two with a HeartMate XVE, and two with a HeartMate II. The only VAD complication disclosed was a VAD pocket infection. The only comorbidity reported prior to transplantation was Factor V Leiden associated with a pulmonary embolus (one airman), moderate restrictive lung disease (one airman), and a carotid endarterectomy (one airman).

Early post-transplant complications in the recertified airmen were, not surprisingly, few: cryptococcal meningitis (one airman) and implantation of a permanent pacing system for intermittent third-degree heart block (one airman). No airman had renal failure severe enough to require dialysis either following VAD implantation or transplantation. Long-term complications following transplantation were also, not surprisingly, few: excision of multiple cutaneous squamous cell carcinomas (two airmen); endovascular repair of an abdominal aortic aneurysm (one airman); and a deep venous thrombosis and pulmonary embolus (one airman).

During the recertification evaluation, 3 airmen were found to have CAV—mild nonobstructive disease in the right coronary artery (two airmen) and mild intimal thickening on an intracoronary ultrasound (one airman), and, although it contravened the CAV original certification criteria, the decision was made to allow recertification.

The subsequent certification history of the 16 airmen who were initially recertified was examined. Of those 16, 1 had his medical certificate withdrawn a year later. Of the 16 airmen, 13 underwent a second recertification attempt and were

successfully certificated after their initial one, and 6 of these airmen underwent a third recertification attempt. Of these six airmen who attempted a third reissuance, five were reissued and one was ultimately denied because of failure to provide information. The mean time these 16 airmen were in the DIWS based on time from first successful recertification after transplantation to time until their last medical examination in the system was 2.5 yr, with a maximum time after first recertification of 11.8 yr in the system. Two of the airmen have declared their intention to fly under BasicMed (Part 68).

The mean age at the time of transplantation of the airmen who were denied recertification was 57 yr, with a minimum and maximum age of 21.3 and 73.7 yr, respectively. All these airmen were men. In the group denied certification, the mean time from transplantation to denied application for certification was 5.3 yr.

The pathology of end stage heart disease was ischemic cardiomyopathy (10 airmen), nonischemic cardiomyopathy (5 airmen), CAV (1 airman—previous heart transplant for doxorubicin cardiomyopathy), adriamycin cardiomyopathy (1 airman), cardiomyopathy associated with Becker's muscular dystrophy (1 airman), and unknown (2 airmen). Two airmen were bridged to transplantation with a VAD: one with a HeartMate II and one with a Heartware.

The long-term complications following transplantation were implantation of a permanent pacing system (one airman), hemorrhagic stroke (one airman), and one airman underwent a renal transplant. The reasons for denial of certification were failure to provide information (16 airmen), CAV (one airman), failure to provide neurology information (one airman), muscular dystrophy (one airman), and insulin dependent diabetes (one airman).

Aviation Accidents

No aviation accidents occurred for any of the 59 airmen following heart transplantation, either those with successful recertification or denial.

Deaths Following Recertification or Denial

There were no deaths during the follow-up of the 16 airmen who were recertified, but there were 3 deaths in the group of 20 who were denied recertification. The ages and causes of death based on the National Death Index ICD-10 codes were: 1) one death, malignant neoplasms of independent (primary) multiple sites (age 58.8 yr); 2) one death, chronic obstructive pulmonary disease, unspecified chronic obstructive: airway disease not otherwise specified (NOS), lung disease (NOS) (age 74.4 yr); and 3) one death, perforation of intestine or rectum (nontraumatic) (age 73.1 yr).

Airmen Pre-2007

Although not the cohort considered in this study, it is worth noting that 12 of the 23 heart transplant recipients who attempted certification and were denied prior to the 2007 policy have died of a variety of causes associated with the complications of transplantation (such as malignancy) as well as those of the transplanted heart. These 12 deceased airmen had a mean age at transplant of 52 yr compared with a mean age at transplant of 60 yr for the 3 deceased airmen who were denied post-2007. Moreover, the mean age of death for these 12 airmen was 64 yr compared with 69 yr for the 3 denied post-2007. **Table I** lists the individual age and cause of death for these 12 airmen. While these comparisons are based on low numbers, the differences may indicate the health status of those denied pre-2007 were even worse than the airmen denied post-2007. This could be the product of more thoughtful selection of airmen who applied for a medical certificate after the policy change. On the other hand, given the fact that the group of airmen applying pre-2007 are going to currently be older than the group applying post-2007 and have a case-fatality ratio of approximately 50% as of 2018, this difference could be arbitrary and may indicate that while the current policy is successful and safe, the FAA is nevertheless dealing with airmen with serious disease and potential mortality that demands constant medical oversight to fly.

DISCUSSION

Medical recertification under special issuance of pilots who have received a heart transplant has been a contentious issue in the United States. In the early 1980s, a number of pilots were reissued their medical certificates following cardiac transplantation. However, further special issuance certification was suspended in 1989 when CAV became apparent in one pilot. This incident prompted very reasonable concerns regarding the risk of sudden death, posing a legitimate aviation risk. Following the decision in 2007 to allow recertification of pilots who had undergone cardiac transplantation after satisfying strict criteria, it is now an appropriate time to examine the outcome of this policy and determine any potential impact on aviation safety.

There are inherent limitations to the study[4] that underpinned the decision to allow application for recertification after a heart transplant. This study was based on a large number of

Table I. Age and Cause of Death for the 12 Heart Transplant Recipients Who Were Denied Certification Prior to the 2007 Policy.

AGE AT DEATH (YR)	CAUSE OF DEATH
69.3	Cardiomyopathy, unspecified
80.5	Atherosclerotic coronary artery disease
59.3	Ischemic cardiomyopathy
72.3	Malignant neoplasm of prostate
61.6	Malignant neoplasm of unspecified part of bronchus or lung
48.7	Pulmonary hypertension, unspecified
69.6	Malignant neoplasm of unspecified part of bronchus or lung
61.8	Unspecified diabetes mellitus: With renal complications
68.5	Hypertensive heart disease without (congestive) heart failure
44.4	Malignant neoplasm of unspecified part of bronchus or lung
67.2	Malignant neoplasm of pancreas, unspecified
66.2	Chronic viral hepatitis C

heart transplant recipients in the Cardiac Transplant Research Database (CTRD) and the end point of interest (sudden onset death) could not be precisely defined, but nevertheless was applied inclusively and probably overestimated the risk of sudden unexpected death, but was an appropriate decision in the interest of aviation safety. This current follow-up study also has its limitations because of lack of follow-up of pilots who were not recertified because of failure to provide information and also the lack of a reliable estimate of the number of hours flown by certified airmen.

The principal finding of this study is that although there were a limited number of airmen who were recertified, there were no aviation incidents, accidents, or known deaths of certified airmen and that this policy of recertification of airmen who have satisfied recertification criteria has not breached aviation safety. Not surprisingly for pilots who were medically recertified following a VAD and then a heart transplant, comorbidity and complications were infrequent since recertification was a marker for a post-transplant course that was sufficiently uncomplicated to exceed the high bar set by the recertification criteria.

Despite the optimistic findings of the study affirming the statistical model and the subsequent recertification FAA policy, it is important that the potential for the emergence of life-threatening disease in these patients not be underestimated. It is sobering to note that 12 of the 23 heart transplant recipients recertified prior to 2007 have died. Also, 3 of the 16 airmen denied certification (in the current study) have died. Furthermore, sudden cardiac death accounts for at least 10% of deaths after cardiac transplantation[7] and a meta-analysis[1] of post-transplant sudden cardiac death found that the risk, although difficult to quantify, was higher than that of the general population. However, it should be noted that the presence of risk factors identified in the meta-analysis for sudden cardiac death, such as CAV and acute cardiac rejection, would have specifically excluded airmen for recertification.[1]

It is possible that the recertification process may be unduly conservative given the results of this study. However, patients after cardiac transplantation, despite what would appear to be a relatively benign post-transplant course in terms of acute cardiac rejection, may unpredictably develop CAV, which is the main concern for allowing airmen to resume flying. Due to denervation of the transplanted heart, typical symptoms associated with coronary artery disease may not be present in patients with CAV and one of the principal manifestations of CAV is sudden death. Therefore, it is entirely appropriate that the recertification process in heart transplant recipients is mindful of the unpredictable emergence of CAV and regular imaging of the coronary arteries as specified in the current special issuance protocol is undertaken. With newer methods of imaging of the coronary arteries such as intracoronary ultrasound and CT coronary angiography, changing the protocol so that coronary angiography is not mandated but allowing other modalities of imaging would seem appropriate. Furthermore, there may need to be some recalibration of the recertification protocol to account for the fact that many transplant centers are no longer performing routine protocol endomyocardial biopsy where a patient's rejection history is benign.

We are concerned that two airmen from this study have notified the FAA of their intention to fly under BasicMed (14 CFR 68).[5] BasicMed was enacted to comply with the Federal Aviation Administration Extension, Safety, and Security Act (2016) and provides for the operation of certain small aircraft without a medical certificate. These airmen may operate aircraft authorized to carry no more than six occupants and a maximum takeoff weight of 6000 lb for noncommercial purposes. Airmen must possess a valid U.S driver's license, complete an online medical self-assessment course biennially, and complete a physical exam with any state-licensed physician using a Comprehensive Medical Examination Checklist (CMEC) every 4 yr. Airmen with listed medical conditions, including heart transplant, must complete a one-time special issuance before exercising these privileges. It appears these two airmen are fully compliant with these provisions.

The heart transplant community would certainly not endorse a 4-yr window between evaluations by transplant physicians because of the possible development of exclusionary conditions such as CAV or nonspecific graft failure, both of which may not present with symptoms. During the extended interval allowed by BasicMed, both the personal health and flight safety of these airmen is dependent upon their continuation of care with their heart transplant physician. It seems unlikely that a heart transplant recipient would reduce the frequency of their transplant physician visits, noting that the recipient's ongoing requirements for monitoring of immunosuppression and graft function does require follow-up with their treating transplant physician. Heart transplant patient transition to BasicMed may represent an elevated risk to the National Airspace System and raises the question of whether the provisions of BasicMed are sufficient to adequately mitigate the risks.

With the exception of the potential concern regarding the timeliness and rigor of follow-up for airmen who have had a heart transplant flying under BasicMed, the policy of recertifying airmen at the class 3 level under special issuance following a heart transplant appears to be safe. Apart from allowing changes to the recertification protocol to reflect contemporary cardiac transplantation medicine, the policy should continue, allowing appropriately certified airmen to resume flying.

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