Aeromedical Hazard Comparison of FAA Medically Certified Third-Class and Medically Uncertified Pilots

Eduard M. Ricaurte; William D. Mills; Charles A. DeJohn; Maria C. Laverde-Lopez; Daniel F. Porras-Sanchez

BACKGROUND: Since 2004, in the United States, light sport aircraft (LSA) and some aircraft with standard airworthiness certificates can be operated for recreational purposes with a valid state driver's license rather than a Federal Aviation Administration (FAA)-issued aeromedical certificate. There have been recent efforts to allow operation of much larger, heavier, faster, and more complex aircraft without requiring a medical certificate. The primary objective of this research was to compare hazards to flight safety identified in fatally injured pilots required to possess a valid FAA third-class medical certificate to hazards in fatally injured pilots who were not required to possess a valid medical certificate.

METHODS: A search of all fatal U.S. aircraft accidents in the FAA Medical ANalysis and TRAcking (MANTRA) registry between January 1, 2011, and April 30, 2014, identified 1084 individuals. A review of accident pilots' medical, autopsy, and toxicological data was conducted. After applying exclusion criteria, 467 pilots remained, including 403 medically certified and 64 medically uncertified pilots.

RESULTS: A significant difference was found in a surrogate measure for risk between medically certified and uncertified pilots (25% vs. 59%). This difference remained significant after adjustment for age. No significant difference was found in the proportions of hazards identified on toxicological review.

CONCLUSION: The results of this study suggest that the risk of an adverse medical event is reduced in pilots required to possess a valid medical certificate.

KEYWORDS: certified pilots, uncertified pilots, light sport pilots, hazards, autopsy, pathological, toxicological, civilian operations, accident.

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Flight operations that do not require individuals to possess standard aeromedical certification have been growing in popularity and importance worldwide. Since 2004, U.S. aircraft that meet the definition of light sport aircraft (LSA) can be operated for recreational purposes with a valid state driver's license rather than a Federal Aviation Administration (FAA)-issued aeromedical certificate.[10]

The FAA defines an LSA as an aircraft limited to 1320 lb gross weight, maximum occupancy of two persons, with an unpressurized cabin, single reciprocating engine, maximum stall speed of 45 kn, maximum level-flight speed of 120 kn, fixed or ground adjustable propeller, and fixed landing gear.[9] However, there have been efforts by pilot groups to advocate consideration for regulatory change which has led to proposed legislation to extend recreational operation to much larger, heavier, faster, and more complex aircraft of up to 6000 lb, at speeds of up to 250 kn, with the ability to carry a maximum of five passengers without requiring a medical certificate.[1,2,5,7]

It is important to obtain evidence as to whether an alternative approach to aeromedical oversight, coupled with an increase in aircraft size and complexity, would result in increased hazards to aviation safety due to an increase in the probability of medically related accidents. While some authors believe ample operational evidence exists to adequately compare the accident experience of medically certified and uncertified pilots, others have reported that it is too soon to draw conclusions, since the available data is small by aviation standards and calculated rates are subject to change.[1,3,6] We found

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that the data needed to directly calculate accident risk for medically uncertified LSA pilots does not exist because they are not required to report their flight time, and the total number of pilots flying under these rules is unknown; therefore, only surrogate measures of risk could be explored.

The primary goal of this research was to compare hazards to flight safety identified in fatally injured pilots who were required to possess a valid FAA-issued third-class medical certificate to fatally injured pilots who were not. We defined a surrogate measure of aeromedical risk based on hazard level determined from a review of medical records, autopsy reports, and forensic toxicology findings.

METHODS

Subjects

The subjects studied were pilots involved in fatal U.S. aircraft accidents between January 2011 and April 2014. They were divided into two groups: FAA medically certified pilots and noncertified pilots. The certified group included pilots who held a current, valid third-class FAA medical certificate while operating either a general aviation aircraft or LSA. All the subjects were fully qualified pilots in their respective groups. Pilot-passengers with valid third-class medical certificates were also included in the certified group. The noncertified group was pilots flying aircraft meeting LSA criteria who were required to hold a valid U.S. driver's license as evidence of their medical qualification and was comprised of two subgroups: LSA pilots with expired FAA medical certificates that had not been suspended, denied, or revoked, and LSA pilots who had never held an FAA medical certificate. Pilot-passengers flying in LSA who met either of these criteria were also included. Each case was reviewed by one medical officer using a Likert scale based on predefined criteria.

Procedure

The FAA Medical Case Review Program was established at the FAA Civil Aerospace Medical Institute (CAMI) on October 1, 2008, to conduct medical case reviews for all fatal U.S. aircraft accidents. The results of these reviews performed by CAMI aerospace medical physicians are stored in the Medical ANalysis and TRAcking (MANTRA) Access® registry. Data stored in MANTRA include reviews of the accident pilots' aeromedical records contained in the FAA Document Imaging and Workflow System, autopsy reports, and CAMI forensic toxicology reports.

Hazards to aviation safety were identified as any pre-existing medical condition or postmortem pathological or toxicology finding that could degrade a pilot's performance, resulting in sudden or subtle incapacitation or impairment of the pilot's ability to safely operate an aircraft as determined by the reviewing physician's best professional judgment. Hazards were rated on a 0-to-6 Likert scale, with 0 being no hazard and 6 representing a severe hazard. A rating of "undetermined" was assigned when autopsy or toxicology was not performed, was inadequate, or the reviewing physician was unable to determine whether the information available represented a hazard to flight safety. For this study, a hazard level of 0-to-2 was recoded as no significant hazard and a hazard rating of 3-to-6 was recoded as a significant hazard.

A search of all U.S. aircraft accidents involving at least one fatality in the MANTRA registry between January 1, 2011, and April 30, 2014, returned 1084 individuals. This time interval was selected because of improved consistency of case reviews and adoption of the Likert rating scale. We excluded individuals who were either 1) not fatally injured or where autopsy and toxicology were not available; 2) held first- or second-class medical certificates with higher screening standards; 3) were flying illegally and, thus, were likely to be at greater risk due to a general disregard for rules, in particular preventive health care recommendations; 4) were operating ultralights or gliders, which have marked differences between types of operations and require no form of medical certification; or 5) were nonpilot passengers, since they were not in the intended study population. After exclusions, 467 pilots remained, including 403 medically certified pilots and 64 medically uncertified pilots.

Statistical Analysis

This is a retrospective cohort study with medical certificate status as exposure and hazard finding as outcome. Chi-squared testing was used for crude comparison of hazards to flight safety identified from the information contained in autopsy and toxicology reports of medically certified and uncertified pilots. Mantel-Haenszel odds ratio estimates with 95% confidence intervals were calculated. A logistic regression model was used to adjust the odds ratio for confounding due to age since the medically certified group was significantly younger than the uncertified group. A *t*-test was used to compare continuous variables for body mass index (BMI) and age. A statistical significance level of $\alpha = 0.05$ was used for all comparisons. Analyses were performed using SPSS software version 21 (IBM; Armonk, NY). For the toxicology results, GPOWER software (version 3.1.9.2, 2014; Heinrich-Heine-Universitat, Dusseldorf, Germany) was used to carry out a power analysis for sensitivity to estimate the difference in the proportion of hazards in medically certified vs. uncertified pilots that could be detected using our data.[4] This study was approved by the FAA Institutional Review Board.

RESULTS

Table I compares the medically certified and uncertified pilot groups. The MANTRA registry includes an assessment of hazards to flight safety based on the pilots' medical records held in the FAA's aeromedical certification database. However, the presence or absence of a hazard could not be determined for 97% (62/64) of the uncertified pilots due to unavailability of any current medical records, which made meaningful comparisons of medical record findings between the two groups impossible.

Autopsies were performed on 94% (380/403) of medically certified pilots and 94% (60/64) of the uncertified pilots. Presence or absence of a hazard could be determined in 75% (332/440) of these pilots, including 73% (278/380) of the certified pilots and 90% (54/60) of the uncertified pilots.

Table I. Characteristics of Medically Certified and Uncertified Pilots

VARIABLE	MEDICALLY CERTIFIED	UNCERTIFIED
Number of Pilots	**86% (403/467)**	**14% (64/467)**
Autopsies Performed	94% (380/403)	(94%) (60/64)
Presence or Absence of Hazard Determined (Autopsy)	**73% (278/380)**	**90% (54/60)**
Significant Hazard Identified (Autopsy)	**25% (70/278)**	**59% (32/54)**
Toxicology performed	93% (374/403)	89% (57/64)
Presence or Absence of Hazard Determined (Toxicology)	60% (223/374)	70% (40/57)
Significant Hazard Identified (Toxicology)	13% (29/223)	13% (5/40)
Age in years (Mean ± SD)	**56 ± 14**	**63 ± 13**
Gender (Male/Female)	399/4	61/3
BMI (Mean ± SD)	28 ± 4	27 ± 4

Significant differences ($P < 0.05$) are shown in bold.

Significant hazards identified on autopsy were found in 31% (102/332) of the pilots, including 25% (70/278) of medically certified pilots and 59% (32/54) of uncertified pilots with autopsies. This difference was statistically significant with $P < 0.001$ and the odds ratio was 4.3 (95% CI 2.3 to 7.9). The certified pilots were significantly younger (mean 56 yr old) than the uncertified pilots (63 yr old) ($P < 0.001$). Logistic regression was employed to produce an age-adjusted odds ratio, which was still significant at 3.2 (95% CI 1.7 to 6.3.) Of the 102 significant hazards, 97 were due to coronary artery disease.

Of the 102 pilots with significant hazards found on autopsy, 4 were pilot-passengers without access to the controls and could not have contributed to the accident. The National Transportation Safety Board (NTSB) cited medical issues as causal or contributory factors in 15 cases, with 24 cases still pending NTSB decision. Of those 15 cases, 12 were due to cardiovascular conditions. The others were due to Berry aneurysm, unspecified neurological impairment, and renal failure due to ethylene glycol poisoning.

Toxicology was performed on 92% (431/467) of pilots, including 93% (374/403) of medically certified and 90% (57/64) of uncertified pilots. The presence or absence of a hazard to flight safety could be determined in 61% (263/431) of the pilots, including 60% (223/374) of certified pilots and 70% (40/57) of uncertified pilots. No significant difference was found in the proportions of significant hazards identified from toxicology reports between the certified and uncertified pilots, 13% (29/223) and 13% (5/40) of cases, respectively. A post hoc power analysis for sensitivity revealed that to detect a difference in proportions of significant hazards between certified and uncertified pilots for this sample size with a power of 80% would require a proportion of toxicology hazards in sport pilots of 31% or greater. A significant hazard to flight safety due to alcohol was identified in 2% (4/263) of cases in which a toxicology hazard could be determined with 1% (3/223) in medically certified pilots and 3% (1/40) in uncertified pilots.

A trend analysis of the toxicology findings was also carried out. However, trend results for positive ethanol tests were not analyzed due to the uncertainties regarding the source of postmortem ethanol and its redistribution. Also, pilots in whom carboxyhemoglobin was the only finding reported by the toxicology laboratory were excluded. Of the certified pilots, 56% (209/374) were reported positive for any drug or substance compared to 68% (39/57) of the uncertified pilots; however, this difference was not statistically significant.

Cardiovascular medications were most commonly reported in 19% (82/431) of cases, followed by nonsteroidal anti-inflammatory drugs, including acetaminophen and antihistaminics, at 15% (66/431) and 13% (54/431), respectively. When comparing cardiovascular medications found in certified vs. uncertified pilots, a statistically significant difference in proportions was found: 16% (61/374) vs. 37% (21/57), respectively ($P < 0.001$). This difference continued to be statistically significant in a logistic regression model adjusting for age ($P = 0.006$). None of the cardiovascular medications were found to have potential adverse effects rising to the level of a significant hazard to flight safety.

Toxicology was performed on 431 cases with significant hazards. Identified were 20 different substances and the most commonly found were ethanol (4 cases), diphenhydramine (4 cases), tetrahydrocannabinol (3 cases), bupropion (3 cases), and doxylamine (2 cases). In addition, three cases of hyperglycemia were rated as significant hazards. In 7 of the 34 cases, a second drug was detected that also caused a significant hazard to flight safety. When reviewing the NTSB's findings as to the cause of the accident in these 34 pilots, we found that 6 cases matched with the NTSB probable cause; however, 9 were preliminary reports with probable cause not yet determined. Diphenhydramine and tetrahydrocannabinol were cited by the NTSB in two cases each, while ethanol and methamphetamine were cited in one case each.

DISCUSSION

The relative aeromedical risk for flight operations that require medical certification compared to those that do not require medical certification is currently a topic of great interest in the international aviation community. The U.S. sport pilot regulations implemented in 2004 have promoted an increased interest in nonmedical certificate flying of larger, heavier, faster, and more complex aircraft. Multiple accidents due to aeromedical issues have been documented in sport pilot operations, but missing were the total number of these pilots and their flight time, which would be needed to determine the rate of these adverse aeromedical events. This study explored a surrogate measure of aeromedical risk in the medically uncertified sport pilots and the group of pilots flying with a valid third-class medical certificate. This surrogate measure is based on hazards to flight safety identified by an aerospace medicine physician's review of autopsy and postmortem toxicology records for pilots fatally injured in aviation mishaps. Medical conditions that were identified as significant hazards, such as significant coronary artery disease, are well validated risk factors for future

medical incapacitation events. It is reasonable to use proportions of significant hazards as a surrogate measure of risk, since a resulting increased risk of medical incapacitation in flight should translate to an increased risk of an accident. In addition, the medical hazards were not causal to the accident in most of the cases, so these samples should be representative of the medical status for each group.

The results show that pilots flying without a valid medical certificate were significantly more likely to have hazards to flight safety identified on autopsy (59% vs. 25%). The sport pilot group was older than the medically certified group (63 yr old vs. 56 yr old); however, after adjusting for age, the odds of sport pilots having a hazard to flight safety remained greater than that of certified pilots. The authors are not surprised since one reason pilots may choose sport pilot operations is that they may believe they are not healthy enough to obtain a medical certificate. Both of these issues also help to explain the significantly larger proportion of sport pilots having cardiovascular medications identified by toxicology (37% vs. 16%), an important finding since coronary artery disease accounted for most of the hazards identified by autopsy and is well recognized as a flight hazard by all aeromedical certification authorities.[8]

The review of hazards to flight safety identified by postmortem toxicology testing showed no statistical difference in proportions, with 13% in both groups. The drugs identified as hazards were almost all based on sedative or other psychotropic effects (30/34). At least one drug was detected on toxicology in 58% of these cases, including 56% of medically certified pilots and 68% of uncertified pilots. This difference was not statistically significant.

Our findings agreed with the NTSB probable cause or contributing factor in 16% of the hazards identified on autopsy and in 18% of hazards identified on toxicology, which may increase when the NTSB determines the probable causes of the remaining accidents (24 autopsy cases and 9 toxicology cases). This is not unexpected, since the finding of a hazard to flight safety in this study is not intended to signify that it was causal or contributory to a specific accident, but rather that it has the potential to cause an in-flight medical incapacitation, leading to an accident. Therefore, these results cannot be extrapolated to actual accident risk.

A major limitation of this study is the use of hazards to flight safety as a surrogate measure of risk in fatal aircraft accidents only. This approach was necessary because we lacked the data needed to calculate accident risk per 100,000 flight hours in the medically uncertified pilot group (number of pilots and their flight time). The time frame was limited to take advantage of improved reviewer rating consistency and enhancements in methodology. Although autopsy and toxicology data were available for the majority of fatal accidents, only five hazards were found by toxicology review in the uncertified group, which limited the statistical power for this comparison. Determination of hazard level was subjective and challenging, though less so for cardiac-related hazards, which were more precisely defined by the Likert scale. Fortunately, greater than 85% of the cases were assessed by the same aerospace medicine physician who had 3 yr experience performing assessments for this registry prior to the study, which might have improved consistency across cases.

In conclusion, the results of this study suggest that risk of an adverse medical event is reduced in pilots required to possess a valid medical certificate. We believe expansion of medically uncertified flight operations should include the probability of adverse medical events found tolerable by an engineering risk analysis. For a more precise assessment of risk for medically uncertified pilots, we recommend that sufficient data (such as number of pilots and their flight hours) be collected to allow calculation of actual accident risk. This would support further studies that could provide information necessary for evidence-based decisions involving the role of aeromedical certification requirements in the future.

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