Cardiovascular Risk Assessment in Pilots

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BACKGROUND: For over 30 yr the global medical community has attempted to define the acceptable cardiovascular risk in pilots. This challenge is compounded by the ever-changing technological and medical landscape of air travel. We aimed to review the existing literature on estimating the risk of pilot cardiovascular incapacitation and determine if the current guidelines are founded in the best available evidence.

METHODS: A detailed review of the guidelines and literature that supports them was completed. Relevant articles were identified by review of the source literature of the guidelines and the references of these source documents. All articles referenced were reviewed in full by both authors. Data that informed the existing recommendations were reviewed and compared to available modern data. The results of these findings were incorporated into a formula that allows for the calculation of acceptable pilot cardiovascular risk given any operator-determined set of variables.

RESULTS: Among the evidence that informs current guidelines, there exists a need for further updating. A number of assumptions have been made in creating guidelines and these may no longer reflect the current technological or medical aviation environment. Incorporating the identified variables into a formula allows for the calculation of acceptable cardiovascular risk. This formula was tested using past data and reproduced existing results.

DISCUSSION: Current guidelines for pilot cardiovascular risk assessment require review by the international aviation medical community. We propose a novel formula that may serve as a template for future guidelines and may be adapted as aviation technology and health data evolve.

KEYWORDS: pilot screening, cardiology, risk assessment.

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Determining the acceptable cardiovascular risk for pilots has been a goal of the aviation medicine community for over 30 yr.[18] The 1% rule has long served as a possible standard, and is endorsed as the threshold of choice by the International Civil Aviation Organization (ICAO).[12] This rule states that no pilot should have an annual risk of cardiovascular incapacitation exceeding 1%. The method of determining the risk of an individual pilot varies by jurisdiction. While some aviation authorities such as the Australian Civil Aviation Safety Authority (CASA) have developed proprietary risk assessment tools,[7] other jurisdictions such as Transport Canada use existing clinical risk scores such as the Framingham Risk Calculator. For conditions outside of coronary artery disease, clinical literature can be used to identify the risk of individual medical conditions. However, even among those agencies that have agreed to use a numerical risk assessment, there is no international consensus on the acceptable risk threshold itself. For example, the Federal Aviation Administration (FAA), while not referring directly to the 1% rule in its guidelines, operates in line with the ICAO recommendation with respect to disqualifying conditions.[9] European Aviation Safety Agency (EASA) guidelines, in turn, continue to abide by the 1% rule previously adopted by the Joint Aviation Authorities (JAA),[8,16] but have not been updated since the formation of the EASA. Transport Canada, however, uses a threshold of 2% annual risk of incapacitation (morbidity and mortality) for all classes of certification, and allows up to 5% annual risk of incapacitation for pilots who fly with a certified safety-copilot.[20] Finally, The Australian CASA uses a Coronary Heart Disease Risk Factor Prediction Chart to stratify pilot risk, with no specific reference to a numerical risk threshold.[7]

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Other methods for determining the allowable cardiovascular risk in pilots have been proposed and are in use. One recent example of this is the three-dimensional risk matrix approach described by Gray et al.[11] This method considers the probability of a medical event, the severity of its outcome, and the operational role of the individual in question to stratify allowable risk. By acknowledging that the allowable rate of medical events will not be equal for all individuals, for all medical conditions, in all situations, the risk matrix approach serves as a procedural framework by which allowable risk can be determined. While this framework can be applied to a wide variety of clinical situations, it does not instruct a user as to what the allowable risk threshold should be in a given instance, and defers this conclusion to the user. As a result, there continues to exist a need to reach international consensus on the allowable cardiovascular risk in the specific instance of cardiovascular incapacitation in commercial pilots.

This review chronicles the development of the 1% rule and its modifications, revisits the assumptions made in its development and distills the process of risk quantification to its base variables. In doing so, we propose the need for international consensus and suggest a formulaic approach to facilitate this process.

To identify an acceptable cardiovascular risk in pilots, a mechanism must be established by which medical risk, expressed in events per 10^6 per year, can be compared to aviation risk, expressed in fatal accidents per 10^6 flying hours. To accomplish this, a medical risk of 1% per year is expressed as 1 per 100 yr, or (given that there are 8760 h/yr), approximately 1 per 10^6 hours. This allows medical risk and aviation risk to be directly compared.[18]

In determining the acceptable risk of medical incapacitation, an acceptable total fatal accident rate must also be established. Lloyd and Tye[14] produced data identifying the fatal accident rate for commercial jet aircraft in 1980 as 0.5 accidents per million hours flown. Chaplin[2], presuming future improvements in flight safety, therefore determined that an acceptable fatal accident rate would be approximately 0.1 per million hours of flight (1 per 10^7 flight hours). It has been traditionally established that the operational risk, of which pilots are a component, should not constitute more than 10% of the total risk. Pilot medical incapacitation, as a subsystem of the operational risk, should additionally not constitute more than10% of the total operational risk. Combining these risk tolerances yields a total allowable risk of medical incapacitation causing an accident of 1 per 10^9 flying hours ($1/10^7 * 0.1 * 0.1$).

Potential mitigating factors which might reduce risk must also be taken into account. First, it may be posited that incapacitation in a multipilot scenario only poses a risk during critical flight periods. For the purpose of the original calculations of the 1% rule, this was estimated to be the 3 min both after takeoff and before landing. Given an average flight duration at that time of 1 h, these critical 6 min represent 10% of the total flight duration. Secondly, should incapacitation occur during this critical period, there remains the possibility of successful handover of aircraft control to a copilot. Data from a 1984 simulator study suggested a rate of failed handover of 1 in 400.[3] To account for a potential increased risk of failed handover in a real-world scenario, this has historically been assumed to be 1 in 100. Taken together, the proportional duration of the critical flight period and the presumed 1 in 100 risk of failed handover reduce the effective risk of an incapacitation leading to an accident by a factor of 1000. If one allows for a total risk of medical incapacitation causing an accident of 1 per 10^9 flying hours, this 1000-times safety factor increases the allowable medical risk to 1 per 10^6 hours, or 1% per annum.

Applying population mortality statistics to this model requires one final assumption. Any given cardiovascular event has the potential to yield one of four outcomes: 1) a sudden, fatal, incapacitating event; 2) a sudden, nonfatal, incapacitating event; 3) a nonfatal, nonincapacitating event; and 4) a fatal event with sufficient prodrome to alert the pilot to seek medical attention prior to takeoff or to allow safe operation of the aircraft until landing. Data from a 1975 registry suggest that the rate of nonfatal plus fatal cardiac events is approximately double that of fatal events alone.[19] Additionally, a 1968 study by Keele[13] concluded that 30% of patients suffering from a myocardial infarction were capable of continuing their activities uninterrupted for at least 2 h. These data informed the original conclusion that, if one subtracts those pilots who experience nonincapacitating symptoms prior to death, and those who have symptoms which precede their flight and disqualify them from flying, approximately 50% of fatal events will be suddenly incapacitating. If the same assumption is then applied to nonfatal events (a similar occurrence rate with half being suddenly incapacitating), then overall mortality statistics can be assumed to be representative of the rate of all sudden, incapacitating events.[18]

Although the 1% rule remains the most widely accepted threshold for pilot cardiovascular risk assessment, some modernization of the rule has been suggested, primarily by Mitchell and Evans in 2004.[15] Two primary assumptions made in the development of the 1% rule can be modified: 1) by the year 2000, average flight duration increased to 2 h;[4] and 2) given simulator data suggesting a failed handover rate of 1 in 400, a real-world failed handover rate of 1 in 200 (rather than the original 1 in 100) might be proposed as a safe estimate. The cumulative effect of these revised assumptions demonstrates that the 1% rule can be modified to as high as 6% without an expected decrease in flight safety. Applying the doubling of average flight duration alone, a simpler modification to a 2% rule has been proposed.

These theoretical modifications to the 1% rule were applied to population-level data, taking into account the age distribution of pilots (in the UK Civil Aviation Authority Medical Division Database), the proportion of pilots who would be expected to fall into a higher risk category, and the proportion of a pilot's time spent in flight. Taken together, this allows for the calculation of a predicted absolute rate of in-flight cardiovascular incapacitations per year. For theoretical risk thresholds of 1%, 2%, and 5%, these rates were 0.75, 0.90, and 1.35 incapacitations per year, respectively. This further supports Mitchell and Evans'[15] conclusion that an increase in allowable pilot cardiovascular risk to 2% (to update only for an increase in average flight duration) would not result in a significant increase in yearly incapacitations or accidents.

METHODS

In order to create a more standardized risk threshold, a review of existing recommendations was completed. The history of the 1% rule and its modifications was compiled by reviewing the source documents of existing pilot medical screening guidelines from ICAO, FAA, EASA, CASA, and Transport Canada. The references of the source documents were also extracted and all papers were reviewed in full by both authors.

Common Themes

Common themes and variables emerge in both the development of the 1% rule and its subsequent proposed modernization. Flight duration, the duration of the critical phase of flight, the likelihood of successful handover to a copilot, societally accepted risk, and the proportion of total risk that should be medical are all factored into the determination of acceptable pilot cardiovascular risk. The use of this approach has both allowed for a statistically consistent risk calculation while also highlighting areas that continue to require attention. Notably, the modernization of the 1% rule by Mitchell and Evans[15] highlights how the values attributed to each of these variables are subject to change over time, and must be routinely reassessed. Efforts to develop and subsequently modify the 1% rule are in many ways analogous to the effort undertaken by the Canadian Cardiovascular Society to standardize motorist risk assessment through the Risk of Harm formula.[1]

A Systematic Approach to Estimating Risk

To address the need for a systematic approach to estimating the medical risk of motor vehicle accidents, the Canadian Cardiovascular Society developed the Risk of Harm formula.[1] To create this formula, variables impacting this risk were first identified. These variables are

- [TD]: time spent driving over a given time period;
- [V]: the type of vehicle being driven;
- [SCI]: the risk of sudden cardiac incapacitation; and
- [Ac]: the probability that an event will result in injury or fatality to the driver or others.

These four variables are combined to produce the following formula estimating the risk of a motor vehicle accident causing injury or fatality:

$$\text{Risk of Harm} = \text{TD} * \text{V} * \text{SCI} * \text{Ac}$$

Values were assigned to these variables based on best available data for both private drivers and commercial truck drivers. Assuming that no commercial driver could be assigned a risk of cardiac death below 1% per year (based on available screening tools), the lowest possible risk of harm attributable to commercial truck drivers in Canada was calculated. This was then assumed to be an acceptable risk to Canadians.

The advantage of this formula over a qualitative or semi-quantitative method is that it can be applied equally to private drivers (who spend less time driving and have a lower vehicular risk of harm), commercial truck drivers (more time driving and higher vehicular risk of harm), and commercial drivers of light vehicles such as taxis (more time driving with lower vehicular risk of harm). The agile nature of this formula has also allowed for its application to noncardiac causes of incapacitation such as vasovagal syncope,[17] and may serve as a model for ongoing efforts to update and standardize pilot cardiovascular risk assessment.

Risk of Harm in Flight

If international consensus is to be reached with respect to acceptable cardiovascular risk, it follows that consensus must first be reached on the relevant variables and the values assigned to them. These variables have been described and modified since the 1% rule was first proposed. If an analogous approach to the Canadian Cardiovascular Society Risk of Harm formula is applied to pilot cardiovascular risk, then the derivation of acceptable pilot cardiovascular incapacitation risk is as follows:

- [AAR]: acceptable yearly flight accident rate;
- [M]: annual pilot incapacitation rate (estimated by annual mortality);
- [CFD]: critical flight duration;
- [AFD]: average total flight duration;
- [FHR]: anticipated rate of failure to hand over in the event of incapacitation;
- [OR]: acceptable proportion of total risk which is pilot-related; and
- [MR]: acceptable proportion of pilot-related-risk which is medical.

Expressed as a formula, this is:

$$AAR * OR * MR = M * \frac{CFD}{AFD} * FHR$$

As originally calculated by Tunstall-Pedoe, the formula yields the 1% rule:

$$\frac{1}{10^7} * \frac{1}{10} * \frac{1}{10} = \frac{1}{10^6} * \frac{6}{60} * \frac{1}{100}$$

Where M = $1/10^6$ h or 1% per annum.

This formula, like its motor vehicle counterpart, can also be rearranged and modified to calculate an acceptable annual pilot incapacitation rate for any given set of variables. For example, Mitchell and Evans'[15] derivation of the 2% rule would be written as follows:

$$M = \frac{AAR * OR * MR}{\left(CFD/_{AFD}\right) * FHR}$$

$$M = \frac{1/10^7 * 1/10 * 1/10}{6/120 * 1/100}$$

$$M = \frac{2}{10^6} = 2\%\ per\ annum$$

A formulaic approach to the determination of acceptable pilot risk, of which the above example is only one possibility, allows for the flexibility to both quickly update variables over time, as well as to apply the same logic to alternative scenarios, including noncardiovascular conditions. For example, in the case of solo pilots, [AAR] might be increased to represent the higher accident rate associated with solo flight, while the variables [CFD/AFD] and [FHR] would be set to 1 to represent the unavailability of a copilot to take control in the event of an incapacitation (or < 1 in the presence of a safety copilot). Overall, this formula serves as but one possible example of how the assessment of cardiovascular risk in pilots might be standardized and potentially modified in a systematic fashion.

DISCUSSION

Thus far, efforts to standardize commercial pilot cardiovascular risk assessment have focused on identifying and quantifying relevant pilot, operational, and societal variables which impact risk tolerance. These efforts have resulted in the 1% rule and its modifications, as well as a three-dimensional matrix framework in which regulatory bodies can work. Efforts to quantify acceptable cardiovascular risk in commercial pilots have required a number of assumptions that require continual reassessment by regulatory bodies.

We propose that ICAO lead an international review of these assumptions to arrive at a consensus regarding acceptable risk of commercial pilot cardiovascular incapacitation. Some assumptions that might be revisited by the international regulatory community include:

- Is a total risk of an accident of 1 per 10^7 flying hours still appropriate today? Should this be updated to reflect the 2002–2011 fatal accident rate of 0.4 per million hours flown?[5]
- Is the assumption that nonfatal and fatal events occur at similar rates still valid?[19]
- What effect, if any, has further automation had on the duration of the critical flight period?
- What is a reasonable assumption to make with respect to rate of failed handover between pilot and copilot?
- Should further modification be made to the acceptable risk of incapacitation given that the average flight duration has increased from 1 h in 1984 to 2 h in 2000 and then to 2.5 h in 2017?[6]

A review of the assumptions and data that have led to the 1% rule may be of particular relevance now, in the face of a growing demand for pilots.[10] As cardiovascular risk increases proportionally with age, it is possible that an increase in the allowable risk threshold could result in a lower number of pilots being deemed long-term unfit, and allow experienced pilots to continue flying longer.[15]

Finally, we propose one possible mechanism by which risk assessment might be standardized, in the form of the Acceptable Annual Risk formula. This approach is analogous to one developed to assess motorist risk, but adapted to represent the unique variables inherent in flight. This formula, while described here in the setting of commercial pilots and cardiovascular risk, could equally be adapted for use in noncardiac conditions and in scenarios outside of the commercial pilot, effectively integrating it into a three-dimensional risk assessment approach.

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