Contents available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

Aircrat pilot licence and diabetes

S. Gentile [a,*,1], A. Furia [b], F Strollo [c]

[a] Campania University "Luigi Vanvitelli", Naples, Italy
[b] Aeromedical Section, Italian National Civil Aviation Authority – ENAC, Italy
[c] Elle-Di and San Raffaele Research Institute, Rome, Italy

1. Introduction

People with diabetes actually do any sort of job. However, in some countries they are banned from certain professions including flying an airplane. The latter is a highly demanding activity for which several long-standing requirements have to be met as regards skills, knowledge and medical fitness mainly aimed to prevent sudden incapacitation (including hypoglycemia-related unconsciousness, for instance), which should by now be updated in light of the latest knowledge and internationally harmonized.

Indeed, any advances in aircraft technology or, as in the case of diabetes, management criteria and tools, should encourage the same rule adjustments worldwide. This is not the case, unfortunately, because the criteria for granting flight licenses are not the same all over the world. The regulatory incoherencies extend to the different treatment qualified for in case of a young fellow with type 1 diabetes (T1DM) denied the license straight away or of a person diagnosed with type 2 diabetes (T2DM) during his/her private or commercial pilot life who, depending on single national rules, might be either certified as fully fit or accepted for dual flight.

In the United States, the Federal Aviation Administration (FAA) does not certify people on insulin as fit to operate commercial aircrafts, still is opened to them in terms of a third-class medical certificate, which allows private and recreational operations like student pilot, flight instructor, or sport pilot activities [1]. Anyway, where regulations are restrictive, a licensed professional with T2DM might get grounded as soon as becoming insulin-requiring and thus be no longer allowed to do a job for which he/she has achieved a specific qualification and has spent plenty of human and economic resources.

The ADA is currently "developing recommendations to share with the US FAA that would enable the FAA to identify pilots who are at no greater risk for incapacitation than any other pilot" according to the association's position statement [2]. The ADA opposes a "blanket ban" and instead takes the position that individual assessment of people with diabetes is the appropriate approach to determining whether a person is qualified to perform certain activities. Based on that, as there are only few studies and little data substantiating the current situation, choices seem to be driven by single physician's personal opinions and diabetes knowledge. According to the experts, defining the degree of ability or inability to perform a given professional task by ICD codes rather than by overall individual operational level would cause unwarranted discrimination [3]. This approach is the one to go for, because it would be unfair to consider fully functional people with a given diagnosis as handicapped, thus unduly preventing them from practicing a given profession. As from recent the U.S. experience with third-class medical certification, the FFA approved an estimated 1500 waivers on insulin treatment over 8 years, with a total of 450 active waivers as of December 31, 2014: the latter were involved in 25 accidents, none of which, however, was attributed to medical issues, despite the fact that a few insulin waivers (only 8%) were grounded for diabetes complications (mostly severe coronary artery disease) in the end. Furthermore, when data of insulin waivers were compared with those of a suitable control group, no statistically significant relationship was found between insulin treatment and incident risk: the overall accident rate was of 7.0 per 100,000 flight hours in both overall third-class pilots and pilots on insulin successfully complying with FAA's stringent medical certification protocol for insulin treated diabetes [4].

All this implies that a typically international profession lacks harmonization among different states so that who is allowed to fly in his own country might be expected to reach a final destination where his/her license is not accepted.

* Corresponding author at: Professor of Internal Medicine, Campania University "Luigi Vanvitelli", Naples, Italy
E-mail address: s.gentile1949@gmail.com (S. Gentile).
[1] Nefrocenter Research & Nyx Start-UP Study Group Coordinator.
https://doi.org/10.1016/j.diabres.2020.108047

Please cite this article as: S. Gentile, A. Furia and F. Strollo, Aircrat pilot licence and diabetes, Diabetes Research and Clinical Practice, https://doi.org/10.1016/j.diabres.2020.108047

Recent changes in aeromedical certification in Australia will give pilots with diabetes more freedom to exercise the privileges of their license, while adopting mechanisms to ensure the safety of air navigation [5].

In U.K., as documented by the only one study we are aware of before the new millennium, only glider pilots were allowed to fly on insulin [6] until 2012 when a stringent experimental protocol was set forth allowing pilots with T2DM on insulin to fly [7], and in 2017 a new paper was published on results obtained with such protocol. The UK, Austria and Ireland now adhere to such protocol [8].

So the United Kingdom became the second country in the world —after Canada— to issue class 1 medical certificates for commercial pilot licenses (CPLs) to people with diabetes on insulin (or sulfonylureas/glinides) who are deemed to be at low risk for hypoglycemic events and follow a specific protocol for glucose monitoring and treatment adjustments [9]. The prerequisites are participating in a high-quality diabetes training and being free of any diabetes related late complications. Approximately 70 people have been granted such CPLs thus far. Data for 26 of those individuals were presented at the EASD 2016 meeting [9,10]. Over an average follow-up of nearly 2 years, more than 95% of glucose readings were in the designated "safe" range of 90–270 mg/dL, and no episodes of pilot medical incapacitation due to low or high blood sugar were reported.

The above mentioned protocol has been directly overseen by the UK Civil Aviation Authority (CAA) medical department since the beginning and includes the following elements: (i) three specified glucose ranges, corresponding to levels considered either *safe for flying* ("*green*": 90–270 mg/dL), or *requiring attention* and designated corrective actions ("*amber*") for hypoglycemia (72–90 mg/dL) / hyperglycemia (270–360 mg/dL); or even *of urgency* ("*red*") warranting priority action ($\leq$72 mg/dl or $\geq$360 mg/dL), respectively; (ii) blood glucose measurements (BGMs) to be performed at least 2 h before and at least 1 h prior to flying for commercial pilots reporting for duty and again less than 30 min before flight in order to prevent from flying a pilot within the "red" zone; (iii) BGM to be repeated during flight at least once an hour in case of insulin treatment or at least every 2 h for those on sulfonylureas or glinides; (iv) BGM testing to be done again within 30 min prior to landing, with repeat if approach or landing is unexpectedly delayed; (v) BGM testing to be done whenever experiencing any diabetic symptoms; (vi) controls to be handed over the to the copilot in the occurrence of any "red" range; (vii) BGM testing to be cut back on formal rest breaks and restarted prior to resuming control of the plane; (viii) clinical surveillance by the CAA every 6 months (or 12 for private pilots); (ix) permission to use insulin pumps and continuous glucose monitoring systems (CGM) as adjuncts, along with BGM testing as per protocol and backup injected insulin supplies at hand (not being CGM validated at high altitude).

The 26 insulin-treated pilots issued class 1 medical certificates were all male, with an average age of 41 years. Most (85%) had T1DM, with an average diabetes duration of 8.1 years. The average follow-up duration post–license issue was 19.5 months. 8897 BGM values were recorded during 4,900 flight hours, with a median of 332 per pilot and HbA1c levels kept stable from pre– to post–license issue (from about 7.0% to 7.2%, p = .25). As for 6-hour flights, 97% of 1068 readings were within the "green" and only 19 (0.2%) within the "red" range but no reports occurred of pilots experiencing medical incapacitation due to hypo- or hyperglycemia. The pilots found the protocol handy, feasible in the cockpit and compatible with safe performance of their other flying duties.

One limit of this study was that it was conducted only in men who developed diabetes during their pilot life, but now the research team is collecting safety data for young men or women with long-standing diabetes training to become certified pilots in view of satisfying European Aviation Safety Agency requirements.

Despite the interest expressed by several other European states in the program, some concerns arise from the analysis of this protocol:

1. as far as we know neither SMBG or CGM systems are certified for altitudes above 5500 m (only old data are available for obsolete meters no longer in use) [11];
2. no information is available on the reliability of the enzymatic and electrochemical systems underlying glucose measurement device functioning in hypobaric conditions or in case of rapid decompression, and in other extreme flight events;
3. at the time of the publication of the protocol, only CGM systems required repeated BGM-based calibration while nowadays standalone CGM devices are available;
4. blood glucose and HbA1c levels considered as safe in the protocol keep far from the ADA / EASD standards and therefore fall outside the criteria for correct diabetes management;
5. due to their inherent hypoglycemic potential, sulfonylureas and glinides are now almost fully replaced by other equally effective and much safer drugs such as GLP1-Ras, DPP-4is, and SGLT2-is.

All of the above points deserve reconsideration in the light of new knowledge especially because it would be desirable for other countries to join the protocol not only for scientific interest but also to verify its effectiveness and eventually make a substantial contribution to those professionals. Furthermore, the issue should be carefully examined by the regulatory authorities not only for pilots requesting license renewal, but also for people first applying for a license.

It would be necessary nowadays for manufacturers of real time-CGM and flash-CGM devices to test their own instruments in different flight conditions, not only for the benefit of aircraft crews, but also of other people performing any flight-related tasks, as well as, for all people with DM undertaking a flight.

To summarize all the above considerations, flying an airplane is complex and requires a fitness check based on technological and physical requirements. As several means and tools are available nowadays to attain a high degree of safety even against any pending hypoglycemic episodes [12], the request to fly at high blood glucose values well beyond optimal range is not warranted any more, as violating in itself a right to good standards of care or work [13,14]. Due to that,

Please cite this article as: S. Gentile, A. Furia and F. Strollo, Aircrat pilot licence and diabetes, Diabetes Research and Clinical Practice, https://doi.org/10.1016/j.diabres.2020.108047

although some regulatory bodies in the world are adopting restrictive criteria for good, we urgently need to go further by learning from the most advanced and permissive countries while trying to accumulate enough data on new technologies as adapted to flight [15]. A suitable solution might be an international registry for all data from active pilots on insulin as of today. As regards to that we should avoid discriminatory security citations based on a stereotyped diagnostic label and provide licenses only on the basis of objective parameters including standardized checks of applicant's education on disease management and, for instance, on the ability to manage the trend arrows of most advanced CGM devices.

There is also a great need to make the layman fully aware that a pilot on insulin can fly safely since very efficient ultrafast and flat, spike-free basal analogues are now available thus allowing any insulin-treated patient to meet carefully personalized glucose targets virtually without any risk of running into hypoglycemic events. This way it might be easier for regulatory bodies to issue less restrictive rules in the absence of any kind of negative, unduly fearful public feeling and thus get rid of another source of unwarranted discrimination.

Funding

The paper was supported by a non-conditioning special grant of NYX startup, Naples, Italy for article processing charges, logistic assistance to authors, paying travel expenses, providing meeting room, conference call, and support for bibliographic research.

Authorship: All authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and that it will not be published elsewhere in the same form, in English or in any other language, including electronically, and have given their approval for this version to be published.

Authorship Contributions: SG, T D-C and FS created the paper and wrote it. All have complied with data collection, critically assessed the results, and approved the final text.

Compliance with ethical standards: Ours was a spontaneous, unconditioned study.

Ethical standard: This study was conducted in conformance with good clinical practice standards. The study was led in accordance with the Declaration of Helsinki 1975, as revised in 2008.

Human and animal rights: This article does not directly use experimental data on humans or animals, but reports data derived from the literature.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgment

Thanks are due to the non-conditioning logistic support offered by Nefrocenter Research Network & Nyx, reserach start-up, Naples, Italy.

REFERENCES

[1] Almekinder E. Can you be a pilot with diabetes? August 14, 2016. <https://www.thediabetescouncil.com/canyou-be-a-pilot-with-diabetes>. [Accessed January 19, 2020].
[2] American Diabetes Association. Pilots and diabetes discrimination. September 23, 2016 <http://www.diabetes.org/living-with-diabetes/know-your-rights/discrimination/employment-discrimination/pilots-and-diabetes-discrimination/?referrer=https://www.google.de> [Accessed January 19, 2020].
[3] Jendle J, Rinnert K, Westman A, Heinemann L. Pilots and diabetes technology: functional health. J Diab Sci Technol 2017;11(2):191–4.
[4] Mills WD, DeJohn CA, Alaziz M, The US. Experience with waivers for insulin-treated pilots. Aerosp Med Hum Perform. 2017;88(1):34–41. https://doi.org/10.3357/AMHP.4726.2017.
[5] Fitzgerald DJ, Navathe PD, Drane AM. Insulin-dependent diabetes and aeromedical certification – the Australian perspective. Med J Aust 2010;193(8):469–71.
[6] Saundby RP. Case reports of insulin-dependent glider pilots in the United Kingdom. Aviat Space Environ Med 1998;69(10):995–8.
[7] UK Civil Aviation Authority. Medical Department. Diabetes Certification Guidance 03/2013 v2.0 <http://www.caa.co.uk/Aeromedical-Examiners/Medical-standards/Pilots-(EASA)/Conditions/Metabolic-and-endocrinology/Metabolic-and-endocrinology-guidance-material-GM/#DM>.
[8] Mitchell SJ, Hine J, Vening J, Montague J, Evans S, Shaw KM, et al. A UK Civil Aviation Authority protocol to allow pilots with insulin-treated diabetes to fly commercial aircraft. Lancet Diabetes Endocrinol 2017;5(9):677–9. https://doi.org/10.1016/S2213-8587(17)30264-4.
[9] Tucker ME. Insulin users can be safe pilots (when following a protocol). Diabetologia 2016;51(suppl 1):P73.
[10] Mitchell SJ, Vening J, Montague J et al. Development of a protocol to allow commercial pilots with insulin-treated diabetes to fly. Available at: https://owncloud.wellbehavedsoftware. com/index.php/s/e56SmJIuONc29YA. [Accessed October 27, 2016].
[11] Adolfsson P, Ornhagen H, Eriksson BM, Cooper K, Jendle J. Continuous glucose monitoring—a study of the Enlite sensor during hypo- and hyperbaric conditions. Diabetes Technol Ther 2012;14:527–32.
[12] Inkster B, Frier BM. The effect of acute hypoglycaemia on cognitive function in type 1 diabetes. Br J Diabetes Vasc Dis 2012;12:221–6.
[13] International Charter of Rights and Responsibilities of People with Diabetes. Date: 2011. <https://www.idf.org/about-diabetes/charter-of-rights.html>.
[14] Wientjens W, Cairns D. Fighting discrimination. Diabetes Res Clin Pract 2012;98:33–7.
[15] Simons R, Koopman H, Osinga M. Would you fly with a pilot on insulin?. Lancet Diabetes Endocrinol 2013;2:446–7.

Please cite this article as: S. Gentile, A. Furia and F. Strollo, Aircrat pilot licence and diabetes, Diabetes Research and Clinical Practice, https://doi.org/10.1016/j.diabres.2020.108047