Tolerance of Centrifuge-Simulated Suborbital Spaceflight in Subjects with Implanted Insulin Pumps

Dana R. Levin; Rebecca S. Blue; Tarah L. Castleberry; James M. Vanderploeg

INTRODUCTION: With commercial spaceflight comes the possibility of spaceflight participants (SFPs) with significant medical conditions. Those with previously untested medical conditions, such as diabetes mellitus (DM) and the use of indwelling medical devices, represent a unique challenge. It is unclear how SFPs with such devices will react to the stresses of spaceflight. This case report describes two subjects with Type I DM using insulin pumps who underwent simulated dynamic phases of spaceflight via centrifuge G force exposure.

CASE REPORT: Two Type I diabetic subjects with indwelling Humalog insulin pumps, a 23-yr-old man averaging 50 u of Humalog daily and a 27-yr-old man averaging 60 u of Humalog daily, underwent seven centrifuge runs over 48 h. Day 1 consisted of two $+G_z$ runs (peak = +3.5 G_z, run 2) and two $+G_x$ runs (peak = +6.0 G_x, run 4). Day 2 consisted of three runs approximating suborbital spaceflight profiles (combined $+G_x$ and $+G_z$). Data collected included blood pressure, electrocardiogram, pulse oximetry, neurovestibular evaluation, and questionnaires regarding motion sickness, disorientation, greyout, and other symptoms. Neither subject experienced adverse clinical responses to the centrifuge exposure. Both maintained blood glucose levels between 110–206 $mg \cdot dl^{-1}$.

DISCUSSION: Potential risks to SFPs with insulin pump dependent DM include hypo/hyperglycemia, pump damage, neurovestibular dysfunction, skin breakdown, and abnormal stress responses. A search of prior literature did not reveal any previous studies of individuals with DM on insulin pumps exposed to prolonged accelerations. These cases suggest that individuals with conditions dependent on continuous medication delivery might tolerate the accelerations anticipated for commercial spaceflight.

KEYWORDS: diabetes mellitus, insulin-dependent, hypergravity, implanted medical device, spaceflight participant, commercial spaceflight.

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A diagnosis of diabetes mellitus (DM) exposes an individual to multiple metabolic abnormalities, degraded neural function, loss of eyesight, and significant risk to essential organs like the kidneys, heart, and brain.[7] For these reasons, worldwide space programs have traditionally disqualified individuals with DM from selection as astronauts despite multiple treatment options available for management of this condition, resulting in a paucity of actual operational data concerning diabetics' ability to tolerate the spaceflight environment.

One effective treatment for the sequelae of diabetes is the subcutaneous injection of insulin.[7] This can be accomplished with hypodermic needles or with an indwelling pump using a refillable reservoir to deliver insulin through a semipermanently implanted needle. However, if too much insulin is delivered, or if insulin is delivered at the wrong time, the individual may develop sudden and profound hypoglycemia. This bears the risk of causing major lapses in judgment, decreased executive function, dizziness, fatigue, tremulousness, seizures, or even coma and death, again causing concern over diabetic tolerance and the effectiveness of medication treatment and delivery options within high-performance environments.[5,7] If an individual using an insulin pump is exposed to the high acceleration forces (G forces) involved in the launch and re-entry

From the University of Texas Medical Branch, Galveston, TX.

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Address correspondence to: James M. Vanderploeg, M.D., M.P.H., Department of Preventive Medicine and Community Health, University of Texas Medical Branch, 301 University Blvd, Galveston, TX 77555-1110; jmvander@utmb.edu.

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profiles of spaceflight, these stressors could disrupt the pump's function and cause anything from a simple dislodgment of the needle to an inappropriately timed or dosed bolus of insulin, potentially rendering that individual incapacitated from hypo/hyperglycemia.[3]

There is limited information regarding the tolerance of commercial spaceflight participants, who are expected to have a much wider range of physical and medical conditions than the well-trained career astronaut, to the acceleration profiles of a commercial spaceflight.[3] Currently, much speculation exists regarding whether or not commercial spaceflight poses increased risk to individuals with medical disease or other physiological limitations.[1,2] Interestingly, the advent of commercial spaceflight does change the risk profile of spaceflight missions, as commercial spaceflight participants (SFPs) are, for now, simply passengers with no mission critical tasks to perform.[6] Thus, if an SFP is incapacitated from a medical problem, the SFP poses a far lower risk to the remaining passengers, pilot, and vehicle than the traditional mission-critical astronaut.[1,2,4] This change in risk profile permits a tolerance for many of the chronic medical problems associated with DM, but does not change the personal risks associated with rapid, dramatic shifts in blood glucose levels. If the individual uses an implantable pump these risks may be even higher. A search of the literature did not reveal any studies addressing the tolerance of high-acceleration flight profiles in diabetics. Further, no studies were found regarding exposure of individuals with implantable insulin pumps to the acceleration forces expected during spaceflight. This case report details the experience of two insulin-dependent Type I diabetics with implanted insulin pumps exposed to sustained acceleration forces in a centrifuge as a part of a larger study regarding layperson tolerance to acceleration.[3]

CASE REPORT

Two subjects with Type I DM, both with indwelling Humalog insulin pumps, volunteered to participate in centrifuge trials. Subject 1 was a 23-yr-old man diagnosed with DM at age 16, averaging 50 u of Humalog daily via insulin pump. Subject 2 was a 27-yr-old man diagnosed with DM at age 11, averaging 60 u of Humalog daily via insulin pump. Past medical history for both subjects was otherwise unremarkable.

Both subjects underwent seven centrifuge runs over 2 d at the National Aerospace Training and Research (NASTAR) Center centrifuge (Environmental Tectonics Corp., Southampton, PA) as a part of a larger trial.[3] Day 1 consisted of two $+G_z$ runs (peak = +3.5 G_z, run 2) and two $+G_x$ runs (peak = +6.0 G_x, run 4). Day 2 consisted of three runs approximating suborbital spaceflight profiles (combined $+G_x/+G_z$).[3]

Participants experienced training runs in a high-performance centrifuge with both rapid onset acceleration and sustained acceleration capabilities. The passenger gondola contains a passenger seat and a high-fidelity multimedia system designed to provide audiovisual simulation to enhance the realism of the spaceflight experience. Audio communication with the participants was provided through speakers in the gondola and a live microphone. Real-time video imaging of the test subject's face and torso was projected to the test operator, test director, and medical monitors at all times. A three-lead electrocardiogram, automatic blood pressure cuff, and finger pulse oximetry were used to monitor the participants. While subjects were not required to monitor their blood glucose, both subjects voluntarily monitored their own glucose levels using a finger stick-based point-of-care blood glucose analyzer following the centrifuge experiences.

At the testing facility, resting blood pressure and heart rate were recorded prior to initiating the centrifuge runs. The participants were taught the basics of anti-G straining and the "hook" maneuver. They were advised to strain as needed by pressing on adjustable rigid pedals located on the floor of the gondola, but to use the hook maneuver only in the event of greyout symptoms. Audiovisual simulation consisted of a projected monitor screen with cockpit-simulated views of Earth and space images imitating real-time views throughout the flight profile, with matching flight-related sounds such as rocket engines firing. These simulated audiovisual profiles were designed to create an experience for the participants as close to an actual suborbital flight as possible.[3]

Neither subject experienced adverse clinical responses to the centrifuge exposure. Both individuals periodically checked their own blood glucose levels and noted blood glucose levels maintained between 110–206 $mg \cdot dl^{-1}$. Detailed information and timing of glucose checks were not recorded and are not available for disclosure. Neither subject reported any subjective symptoms or had any abnormal exam findings pre, post, or during their spin. Physiologically, their experience was similar to the average response of all 86 trial participants (see **Table I**) and did not deviate significantly from the experience of normal healthy test subjects for their age group.[3] Both subjects complained of mild disequilibrium upon initial ambulation after finishing each of the centrifuge runs which resolved within 3-5 steps outside of the gondola. This was a common complaint seen in 28–48% of subjects per run in the larger study.[3] Neither subject experienced nausea. Subject 1 experienced mild greyout, described as "a little tunnel vision" during the launch and reentry phases of the final two combined

Table I. Mean Hemodynamic Responses by Flight Phase for Diabetic Subjects Compared to Average Response of All 86 Trial Subjects.

FLIGHT PHASE	SUBJECT 1	SUBJECT 2	AVERAGE RESPONSE
Pre-spin systolic (mmHg)	147	131	140 ± 14
Pre-spin diastolic (mmHg)	72	66	69 ± 8
Postspin systolic (mmHg)	151	128	143 ± 17
Postspin diastolic (mmHg)	82	82	89 ± 10
Pre-spin heart rate (bpm)	93	76	82 ± 14
Postspin heart rate (bpm)	87	85	82 ± 12
Heart rate at peak acceleration (bpm)	122	95	115 ± 22

Average subject data is as reported in the larger trial.[3]

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profiles (runs 6 and 7) on the second day (peak = +3.5 G_z/+4.0 G_x during both run 6 and 7 launch phases; run 6 reentry peak = +6.0 G_x; run 7 reentry peak = +4.0 G_z/4.5 G_x). The subject reported resolution of all symptoms with anti-G straining. Subject 2 denied greyout symptoms for all runs. Visual examination of the insulin pump insertion site demonstrated no dermatologic insult or breakdown following any of the centrifuge runs. Further, there was no visual abnormality of either pump following any acceleration exposure; both pumps continued to work normally throughout the experience and neither participant complained of any operational abnormality of their pump at the time of follow-up approximately 1 mo after completion of the centrifuge experience.

DISCUSSION

While it is difficult to extrapolate from case reports alone, these cases suggest that the acceleration forces anticipated for commercial suborbital spaceflight are tolerable for both insulin-dependent diabetics in otherwise good health and for indwelling medical devices such as insulin pumps. The data gathered from these two individuals suggest that there may be little risk to blood glucose levels and the function of exogenous insulin pumps simply from exposure to sustained acceleration forces. As there is minimal prior literature regarding the performance of individuals with diabetes exposed to the acceleration forces anticipated for commercial spaceflight, these reports are some of the first indicators that SFPs with diabetes could tolerate suborbital flight with little difficulty.

There are several limitations to drawing conclusions from these cases alone. First, the predominant form of DM in the developed world is an acquired insulin resistance (Type II DM) rather than the autoimmune form of the disease.[7] Type II diabetics often have many other comorbidities and have a different underlying pathology compared to those with Type I DM.[5] While blood glucose levels and response to insulin did not appear to change to dangerous levels as a function of sustained acceleration, a Type II diabetic wishing to be a commercial SFP would likely need further screening and more careful consideration on a case-by-case basis. Additionally, the use of a centrifuge as an analogue for suborbital spaceflight is useful to study the effects of hypergravity, but cannot simulate microgravity, controlled atmospheres, and other details of an actual spaceflight, all of which may have their own unique effects on insulin pumps and blood glucose levels. Understanding those effects will require further investigation. Finally, this report highlights two cases of otherwise healthy and physically fit individuals with Type I DM. Detailed information regarding infusion rates of the insulin pumps and exact pre/postspin changes in blood glucose were not recorded by either participant and are therefore unavailable. Increasing the sample size of diabetics, particularly those with common comorbidities, who have been subjected to such acceleration exposures will lend greater insight into the effects of hypergravity on this disease and the devices used for disease control, as would detailed and controlled data collection regarding blood glucose levels and insulin infusion rates.

Despite these limitations, these cases suggest that the acceleration forces anticipated for commercial suborbital spaceflight may pose little risk for insulin-dependent diabetics in otherwise good health and may have no apparent effect on indwelling medical devices such as insulin pumps. This report is the first indication that SFPs with indwelling insulin pumps to control DM might tolerate suborbital spaceflight with little difficulty.

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Authors and affiliations: Dana R. Levin, M.D., New York Presbyerian, University Hospital of Cornell and Columbia, New York, NY; and Rebecca S. Blue, M.D., M.P.H., Tarah L. Castleberry, D.O., M.P.H., and James M. Vanderploeg, M.D., M.P.H., Department of Preventive Medicine and Community Health, University of Texas Medical Branch, Galveston, TX.

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