

Centrifuge-Simulated Suborbital Spaceflight in Subjects with Cardiac Implanted Devices

Rebecca S. Blue; David P. Reyes; Tarah L. Castleberry; James M. Vanderploeg

- INTRODUCTION:** Future commercial spaceflight participants (SFPs) with conditions requiring personal medical devices represent a unique challenge. The behavior under stress of cardiac implanted devices (CIDs) such as pacemakers is of special concern. No known data currently exist on how such devices may react to the stresses of spaceflight. We examined the responses of two volunteer subjects with CIDs to G forces in a centrifuge to evaluate how similar potential commercial SFPs might tolerate the forces of spaceflight.
- CASE REPORT:** Two subjects, 75- and 79-yr-old men with histories of atrial fibrillation and implanted dual-lead, rate-responsive pacemakers, underwent seven centrifuge runs over 2 d. 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). Data collected included blood pressures, electrocardiograms, pulse oximetry, neurovestibular exams, and post-run questionnaires regarding motion sickness, disorientation, greyout, and other symptoms. Despite both subjects' significant medical histories, neither had abnormal physiological responses. Post-spin analysis demonstrated no lead displacement, damage, or malfunction of either CID.
- DISCUSSION:** Potential risks to SFPs with CIDs include increased arrhythmogenesis, lead displacement, and device damage. There are no known prior studies of individuals with CIDs exposed to accelerations anticipated during the dynamic phases of suborbital spaceflight. These cases demonstrate that even individuals with significant medical histories and implanted devices can tolerate the acceleration exposures of commercial spaceflight. Further investigation will determine which personal medical devices present significant risks during suborbital flight and beyond.
- KEYWORDS:** centrifuge, pacemaker, implanted medical devices, atrial fibrillation, spaceflight participant, commercial spaceflight.

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Commercial spaceflight participants (SFPs) with conditions that require implanted medical devices represent a unique challenge to the aerospace medical community. The function of cardiac implanted devices (CIDs) under the G forces of spaceflight is of special concern. The diseases for which CIDs are used are disqualifying for career astronauts, aviators, and the selection of commercial SFPs in the past. For this reason, no known data exist regarding how these devices will react to the stresses of spaceflight. The failure of a CID during spaceflight could prove fatal in a device-dependent individual. In the United States, approximately 3 million pacemakers and 1 million defibrillators were implanted between 1993 and 2008, while in 2009 alone over 1 million pacemakers and 300,000 defibrillators were implanted worldwide.¹² The prevalence of these devices suggests that, with the advent of commercial spaceflight and broad consumer participation, there will be

SFPs with a history of cardiac dysrhythmias and the need for CIDs.

Both animal and human studies have demonstrated that acceleration exposure increases the excitability of heart muscle, leading to cardiac rhythm anomalies that can be further aggravated by anti-G straining maneuvers (AGSM) used to increase acceleration tolerance.^{7,9} Continuous cardiac monitoring during high acceleration exposure has demonstrated premature

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atrial or ventricular contractions (PACs/PVCs), bigeminy/trigeminy, sinus dysrhythmias, or occasionally even nonsustained ventricular tachycardia.^{1,2,7} In a patient with known cardiac dysrhythmias at baseline, the additional stress of acceleration might induce significant dysrhythmias that place the patient at risk for adverse outcomes, such as incapacitation, cardiac dysfunction, and death.⁶

Potential concerns for the use of CIDs in spaceflight include acceleration exposure causing lead displacement and loss of effective pacing, device malfunction, and increased arrhythmogenesis that exceeds the pacing capabilities of the CID. Individuals requiring the use of an implanted automated defibrillator have, by definition, serious medical conditions that pose significant risk during spaceflight. In addition, defibrillation devices pose other risks, including potential misinterpretation of altered rhythms (such as the presence of increased numbers of PACs and PVCs as would be expected during acceleration) with administration of unnecessary shock, inadvertent transfer of electricity during defibrillation to the vehicle systems or other occupants, and the incapacitation of an individual following defibrillation.

The prevalence of CIDs and the lack of understanding of the risks involved during spaceflight for device-dependent individuals have led to a need to address this knowledge gap. For this reason, we examined the responses of two volunteer subjects with CIDs to G forces in a centrifuge to evaluate how similar commercial SFPs might tolerate the acceleration forces involved in the launch and reentry profiles of commercial spaceflight. Their participation was part of a larger trial that has been previously published.¹

CASE REPORTS

Two subjects, 75- and 79-yr-old men with histories of atrial fibrillation and implanted continuous pacemakers volunteered for the study. Subject 1, the 75-yr-old subject, had a history of atrial fibrillation and flutter with a history of multiple cardioversion attempts followed by ablation in 2009 without improvement. A permanent, dual-lead, rate-responsive pacemaker was placed in 2010. He had no history of syncope related to his dysrhythmias and had been approved by the Federal Aviation Administration (FAA) for a special issuance authorization for a third-class medical certificate for flight as a private pilot. He participated in regular single-pilot flying as recently as 2 yr prior to his participation in the centrifuge study. His medical history also includes hypertension and prostate cancer, for which he had undergone surgery under general anesthetic 11 mo prior to his participation with no reported complications. Electrocardiograms (EKGs) demonstrated pacer spikes with successful capture, with sinus rhythm at 70 bpm. His medications include hydrochlorothiazide (25 mg daily), simvastatin (40 mg daily), and sotalol (80 mg three times daily).

Subject 2 is 79-yr-old with a history of atrial fibrillation, with multiple episodes of syncope related to his atrial fibrillation and chemical cardioversion for his dysrhythmias. This subject underwent permanent dual-lead, rate-responsive pacemaker

placement in 2004, without further incident of syncope or dysrhythmia-related symptoms. The original device was replaced in 2012 without issues. He has a further history of hypertension and his medications include amlodipine (5 mg daily), lisinopril (40 mg daily), and rivaroxaban (10 mg daily). EKGs demonstrated pacer spikes with successful capture, with sinus rhythm at 76 bpm. This subject is very physically active, with regular cardiovascular and weight-training exercise multiple times per week.

Both subjects underwent 7 centrifuge runs over 2 d as a part of a larger trial of 86 individuals conducted at the National AeroSpace Training and Research (NASTAR, Environmental Tectonics Corp., Southampton, PA) Center centrifuge.¹ 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). Data collected included blood pressures, EKGs, pulse oximetry, neurovestibular exams, and postrun questionnaires regarding motion sickness, disorientation, greyout, and other symptoms.

Despite both subjects' significant medical histories, neither had abnormal physiological responses. Both subjects demonstrated lower average heart rate response during peak accelerations of all profiles when compared to subjects in the larger trial, though this finding was not statistically significant.¹ The hemodynamic responses of the two subjects compared to average responses of subjects in the larger trial are provided in **Table I**. Subject 1 demonstrated a single PVC during the launch phase of Run 6, the first full-strength integrated spaceflight profile. There were no other abnormal rhythms observed in this subject. He reported no subjective symptoms of palpitations, light-headedness, or discomfort during any of the runs, and his neurovestibular exams demonstrated no alteration from baseline after any of the centrifuge exposures. Subject 2 demonstrated multiple single-episode PACs and PVCs during all dynamic phases of all seven centrifuge runs. He did not report any symptoms of palpitations, light-headedness, or discomfort during any run. This subject demonstrated mild increasing neurovestibular imbalance after later centrifuge runs, not significantly different from expected imbalance following repetitive centrifuge exposure.¹

Both subjects were evaluated by their personal physicians and cardiologists following the centrifuge trials, and both

Table I. Mean Hemodynamic Responses by Flight Phase for Pacemaker Subjects vs. Average Response of All 86 Trial Subjects.

| | SUBJECT 1 | SUBJECT 2 | AVERAGE RESPONSE |
|---------------------------------------|-----------|-----------|------------------|
| Pre-spin systolic (mmHg) | 149 | 158 | 140 ± 14 |
| Pre-spin diastolic (mmHg) | 62 | 83 | 69 ± 8 |
| Post-spin systolic (mmHg) | 150 | 155 | 143 ± 17 |
| Post-spin diastolic (mmHg) | 85 | 99 | 89 ± 10 |
| Pre-spin heart rate (bpm) | 65 | 83 | 82 ± 14 |
| Post-spin heart rate (bpm) | 65 | 78 | 82 ± 12 |
| Heart rate at peak acceleration (bpm) | 84 | 98 | 115 ± 22 |

All subject "average response" data are as reported in the larger trial.¹

underwent interrogation of their pacemakers. Post-spin evaluation demonstrated no lead displacement, damage, or malfunction of either CID. While interrogation data were not made available for a direct comparison between pacemaker data and data recorded by medical monitors during the centrifuge runs, pacemaker interrogation demonstrated no abnormal rhythms recorded at the time of the trials or any programming abnormalities, and the devices demonstrated normal battery usage. Neither subject reported any abnormal symptoms or side effects following the centrifuge trials.

DISCUSSION

This report represents the first known published cases of pacemaker-dependent individuals undergoing exposure to increased acceleration forces as would be seen during the launch and landing phases of commercial spaceflight. As increased dysrhythmias have been seen during acceleration exposure of individuals with normal cardiac rhythms, there is significant concern regarding the ability of an individual with a predilection toward abnormal cardiac rhythms, such as the subjects discussed here, to tolerate the dysrhythmic effects of increased $+G_z$ exposure.^{6,7} Despite concerns, the subjects described here experienced no apparent adverse effects from the centrifuge runs. One subject demonstrated rhythm stability while the other demonstrated multiple PACs and PVCs; neither was symptomatic, and the subject experiencing PVCs retained successful rhythm capture despite the abnormal beats.

Other concerns for pacemaker-dependent subjects undergoing $+G_z$ acceleration exposure include the possibility of lead displacement with loss of device function. The subjects here had no such difficulties, and post-trial analysis of the devices demonstrated no damage or abnormalities due to centrifuge exposure. Previous studies have demonstrated that the heart can shift caudally within the thoracic cavity by an average of 1.5 cm during acceleration exposure of $+3 G_z$; concerns have been raised that such caudal shifting could adversely strain pacemaker leads, potentially dislodging or damaging lead wires.^{5,8} Most studies suggest that pacemaker lead position may change, particularly during the first year after placement; however, delayed dislodgement of a pacemaker lead is rare.³ It is unlikely that the relatively slow onset of acceleration forces, as seen in both centrifuge and anticipated commercial spaceflight profiles, would be sufficient to cause lead displacement, even with caudal heart displacement. Further, pacemaker leads are placed so as to provide enough slack that patients are able to perform activities of daily life without concern of lead displacement or fracture; similarly, heart displacement secondary to these relatively low $+G_z$ exposures is not likely to exceed normal heart displacement during daily routines or the tolerance provided by normal lead slack.

A case report was published in 1999 that discussed cardiac pacemaker failure in a pilot due to myocardial scarring and a fractured pacemaker lead unrelated to flight activities.¹⁰ In that case, the most pressing concern was for sudden incapacitation

and hemodynamic compromise in an airman flying a vehicle. As SFPs have a largely passive role during flight, sudden incapacitation due to pacemaker malfunction or failure does not carry the same risks for an SFP as it would for a pilot or crewmember. In addition, there are very low rates of lead failures leading to loss of pacing capability (most studies report rates of less than 1% after the initial month following surgery), thus the likelihood of an in-flight incapacitating event for a passenger can be considered to be very unlikely.^{3,11}

Prior to flight, an SFP with a CID should be screened carefully to ensure full medical disclosure of all conditions, medications, and the specifications of the device. CIDs should be evaluated by a treating cardiologist to ensure proper function, sufficient battery life, and appropriate device programming.¹² The symptoms of CID malfunction or failure should be reviewed with SFPs prior to launch so that they may rapidly recognize any problems and can alert flight crew for notification of ground medical teams.¹² Ground crews should be fully equipped to respond to in-flight medical emergencies immediately upon landing, with available external pacing, defibrillation, and life support capabilities.

While the cases reviewed here have highlighted the potential for individuals with CIDs to tolerate the acceleration forces of commercial suborbital spaceflight, further investigation is warranted to identify any additional limitations imposed by specific medical conditions and medications taken in conjunction with the use of CIDs. These cases do not address the ongoing concerns of implanted defibrillation devices, as the risks associated, particularly the possibility of inappropriate shock secondary to acceleration-induced dysrhythmias, were considered too significant to be evaluated in this setting. It may be that the use of an implanted automated defibrillator in a space vehicle poses risks that may simply prohibit the inclusion of persons requiring such devices from spaceflight.

In addition, the cases presented here did not address the radiation environment of space, which may have deleterious effects on implanted medical devices. Previous work has addressed this issue for commercial spaceflight and suggests that short-duration, suborbital flights pose little risk regarding radiation affecting device function, though the issue should be readdressed prior to longer-duration, orbital spaceflight.¹² Finally, the use of electrical devices within a space vehicle should be preceded by the evaluation of the device to ensure that the device itself does not interfere with the avionics equipment required for vehicle operations, nor that the avionics equipment in any way interferes with the proper function of the medical device.^{4,11,12}

The expansion of the number of commercial SFPs will necessitate a paradigm shift within aerospace medicine. Aerospace medicine specialists must become more comfortable with individuals who may have significant medical conditions participating in spaceflight. While individual cases still warrant evaluation and risk assessment, the cases discussed here show that even individuals with significant cardiovascular disease history and implanted medical devices may be able to tolerate the acceleration exposures of commercial spaceflight.

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