Validation of On-Orbit Methodology for the Assessment of Cardiac Function and Changes in the Circulating Volume Using Ultrasound and "Braslet-M" Occlusion Cuffs

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Introduction

Recent advances in remotely guided imaging techniques on ISS allow the acquisition of high quality ultrasound data using crewmember operators with no medical background and minimal training. However, ongoing efforts are required to develop and validate methodology for complex imaging protocols to ensure their repeatability, efficiency, and suitability for use aboard the ISS. This Station Developmental Test Objective (SDTO) tests a cardiovascular evaluation methodology that takes advantage of the ISS Ultrasound capability, the Braslet-M device, and modified respiratory maneuvers (Valsalva and Mueller), to broaden the spectrum of anatomical and functional information on human cardiovascular system during long-duration space missions.

The proposed methodology optimizes and combines new and previously demonstrated methods, and is expected to benefit medically indicated assessments, operational research protocols, and data collections for science. Braslet-M is a current Russian operational countermeasure that compresses the upper thigh to impede the venous return from lower extremities. The goal of the SDTO is to establish and validate a repeatable ultrasound-based methodology for the assessment of a number of cardiovascular criteria in microgravity. Braslet-M device is used as a means to acutely alter volume distribution while focused ultrasound measurements are performed. Modified respiratory maneuvers are done upon volume manipulations to record commensurate changes in anatomical and functional parameters. The overall cardiovascular effects of the Braslet-M device are not completely understood, and although not a primary objective of this SDTO, this effort will provide pilot data regarding the suitability of Braslet-M for its intended purpose, effects, and the indications for its use.

Experiment Development

This SDTO is an operationally oriented activity by a NASA-Roscosmos team of physicians and scientists. Extensive planning and simulation activities have occurred in the Payload Development Laboratory (PDL) and the Cardiovascular Laboratory at the Johnson Space Center.

The Cardiovascular Laboratory at the Johnson Space Center has an ultrasound system similar to the ISS Ultrasound system. This facility was used to develop and rehearse the flight protocol presented in Figure 1.

The PDL is a mock up of the U.S. lab module with a fully functional ultrasound system and a remote guidance capability. Simulated sessions have resulted in confident completion of the entire experiment protocol within the suggested 60-minute timeline using remotely guided ultrasound operators of non-medical vocations (astronaut analoques).





Experiment Protocol

Ten sessions have been requested on five long-duration subjects (two sessions each). The study protocol was approved by the NASA Committee for the Protection of Human Subjects (CPHS), similar committees at Roscosmos and other ISS partner agencies, and the ISS Human Research Multilateral Review board. All potential subject have given their informed consent.

Experiment Protocol (continued)

At the beginning of the protocol, a set of baseline cardiovascular measurements is taken on the subject, including standard echocardiography views, Doppler flow and tissue measurements, as well as high-resolution images of femoral and jugular vein. The Braslet devices are then applied (~10 minutes) and measurements are repeated. Standardized Valsalva and Mueller maneuvers are used throughout the procedure. The Braslets are then released and the cardiovascular "recovery" process is monitored in a single view. The entire sequence is accomplished by means of real-time remote guidance from the ground.

Data are stored aboard the ISS and dowlinked after each session. Full-relolution image frames are then analyzed on the ground.

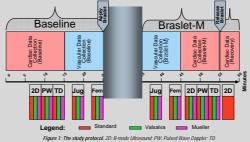
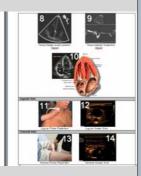


Figure 1: The study protocol. 2D: B-mode Ultrasound; PW: Pulsed Wave Doppler; TD Tissue Doppler; Jug: Internal Jugular Vein; Fem: Femoral Vein.





Experiment Status as of Feb 01, 2008

- This SDTO is scheduled for Expeditions 16 and 18.
- Three sessions have taken place in ISS-16 (one incomplete due to hardware fault).
- Study procedure and protocol are sound and realistic.
- The protocol appears to be sensitive to the effects introduced by Braslet-M.
- Most likely, ISS-16 will not complete all sessions; the remaining data collection opportunities are being requested for ISS-18

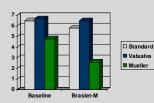


Preliminary Data Review (continued)

Data are purposefully collected on:

- ergonomic factors, such as subject and operator positioning, since they play an important role in remote-guided imaging methodology.
- remote guidance technique is continually refined, including discourse quality and terminology, modularity and prioritization of procedures, and solutions for image recovery and optimization.
- · respiratory maneuver techniques for microgravity and space flight
- procedures for integration of cardiac and vascular imaging with respiratory maneuvers; these are tested for repeatability and reliability
- 0-g echocardiography techniques and possibilities to predict imaging window degradation or loss
- demonstration of the effects of Braslet-M application and/or release on a number of vascular and cardiac parameters (both anatomical and physiological)
- data recording format that will allow legitimate analysis and conclusions regarding the capability of the experiment protocol to assess the volume status changes in longduration space flight crew (Figure 2 below is a preliminary data analysis and depiction sample).

Figure 2: Preliminary observation: The effect of Mueller and Valsalva maneuvers on the jugular vein. Numbers represent cross-section area of the Internal Jugular Vein.



Conclusions

The products of this activity are expected to benefit both the operational space medicine and the human research communities. Specific aspects of operational space medicine include clinical assessment and management of volume shifts and volume status, diagnostic ultrasound imaging, and telemedicine.

Methodology developed and validated through this proposal will be suitable for assessing crewmember cardiovascular responses to disturbances (from gravity change to pathological conditions such as volume overload, hemorrhage, and others) using ultrasound imaging in combination with respiratory maneuvers, with or without volume manipulations.

This methodology will enable further investigations of steady-state space cardiovascular physiology during long-duration space flight, and will yield valuable operational experience and physiological data for planning and support of missions to the moon and other destinations.

Data collected throughout the experiment will be analyzed and published to ensure utmost benefit to the current and future space flight programs as well as the public.

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