Evaluating Trauma Sonography for Operational Use in the Microgravity Environment

Andrew W. Kirkpatrick MD FACS
Foothills Medical Centre.
Calgary, Alberta T2N 2T9
Jeffrey A. Jones, M.D.
NASA/Johnson Space Center
Houston, Texas 77058
Ashot Sargsyan MD
Wyle Laboratories, Inc.
Houston, Texas 77058
Douglas Hamilton MD FRCPC PhD
Ashot Sargsyan MD
Wyle Laboratories, Inc.
Houston, Texas 77058
Shannon Melton MSc
Wyle Laboratories, Inc.
Houston, Texas 77058
George Beck
Wyle Laboratories, Inc.
Houston, Texas 77058
Savvas Nicolaou MD FRCSC
Vancouver Hospital & Health Sciences Centre
Vancouver, British Columbia
Mark Campbell MD FACS
McCaiston Medical Centre
Paris, Texas
Scott Dulchavsky MD PhD
Henry Ford Medical Centre
Detroit, Michigan

Running Title: Clinical ultrasound testing in weightlessness

Key Words: microgravity, sonography, abdominal injury, thoracic injury, human space flight, International Space Station

Manuscript Metrics: Word count for abstract – 226
Word count for narrative test - 2350
Number of References – 53
Number of Tables – 1
Number of Figures – 3

Correspondence: Andrew W Kirkpatrick MD .D.
Foothills Medical Centre
Calgary, Alberta, T2N 2T9
Houston, Texas 77058
Telephone: 403-944-426
FAX: 403-944-1277
e-mail: andrew.kirkpatrick@calgaryhealthregion.ca

The views expressed herein are those of the authors and do not reflect the official policies of the National Aeronautics and Space Administration or other departments of the governments of the United States or Canada.

This manuscript has been adapted with permission from a manuscript originally published in the McGill Journal of Medicine
Abstract

Sonography is the only medical imaging modality aboard the ISS, and is likely to remain the leading imaging modality in future human space flight programs. While trauma sonography (TS) has been well recognized for terrestrial trauma settings, the technique had to be evaluated for suitability in space flight prior to adopting it as an operational capability. The authors found the following four-phased evaluative approach applicable to this task: 1) identifying standard or novel terrestrial techniques for potential use in space medicine; 2) developing and testing these techniques with suggested modifications on the ground (1g) either in clinical settings or in animal models, as appropriate; 3) evaluating and refining the techniques in parabolic flight (0g); and 4) validating and implementing for clinical use in space. In Phase I of the TS project, expert opinion and literature review suggested TS to be a potential screening tool for trauma in space. In Phase II, animal models were developed and tested in ground studies, and clinical studies were carried out in collaborating trauma centers. In Phase III, animal models were flight-tested in the NASA KC-135 Reduced Gravity Laboratory. Preliminary results of the first three phases demonstrated potential clinical utility of TS in microgravity. Phase IV studies have begun to address crew training issues, on-board imaging protocols, and data transfer procedures necessary to offer the modified TS technique for space use.

Keywords: microgravity, sonography, abdominal injury, thoracic injury, human space flight, International Space Station
1. **Introduction**

Practical restrictions on mass, power, volume, communications, and training of space crews have resulted in a very modest medical capability aboard the International Space Station (ISS). The current response to a serious trauma sustained on Space Shuttle or the ISS is intended to be immediate evacuation to a definitive care facility on Earth. The Soyuz capsule continues to be the main means of evacuation from ISS. The probability and the severity of injury in space will increase due to the greater number of hours spent on orbit and the multitude of demanding tasks including movement and construction of large masses, which, once accelerated in weightlessness, could deliver crushing or lacerating blows[19,23,24,36]. Given such risks, diagnostic capabilities on board the ISS should be maximized to prevent unnecessary medical evacuation on the one hand, and to increase the chances of survival and recovery if the trauma sustained results in a serious injury, on the other.

2. **Trauma Capability Requirements for ISS**

In rating the “probable incidence versus impact on mission and health” for space missions, the National Aeronautics and Space Administration (NASA) places trauma at the highest level[2]. With accurate diagnosis, many traumatic injuries could be temporized or treated by relatively simple measures. In previous reviews, inadequate volume resuscitation, poor airway control, and delayed or missed appreciation of abdominal and chest injuries were the main causes of preventable death in isolated and rural treatment facilities [11,17,20,50]. Physical examination is often not sensitive for detecting intra-peritoneal injuries, especially with a concomitant central nervous system injury or altered level of consciousness [41,53]. While the need for rapid clinical diagnosis of hemo- or pneumothorax is
an emphasized principle in trauma care, many cases are easily missed and only diagnosed by chest radiography (X-ray). Standard techniques for imaging injuries include conventional X-ray, sonography, computed tomography (CT), and invasive procedures such as diagnostic peritoneal lavage (DPL) and surgical endoscopy. The ISS is not equipped to support CT, radiography, or surgical endoscopy, and a DPL carries greater risks of iatrogenic injuries due to the lack of gravitational bowel retraction away from the anterior abdominal wall[9].

In space, any suspected abdominal or thoracic trauma would need to be treated as a surgical emergency until proven otherwise, possibly mandating evacuation to a tertiary care facility on the ground. An unnecessary evacuation would cause significant mission impact and a very high expense. As an ultrasound system was present onboard the ISS as a research device, a potential was recognized for its use as an accurate and safe diagnostic and interventional tool that could be used in multiple anatomical areas if proper techniques were developed for its effective operational application.

3. **Trauma Sonography**

The ISS Human Research Facility (HRF) Phillips HDI 5000 ultrasound system has been specially modified for space flight to support biomedical research on ISS, and could provide the capability to perform sonographic examinations. Trauma sonography (TS) is noninvasive, fast, safe, effective, repeatable, and tele-transmittable, and can screen for the presence of intra-cavitary (peritoneal, pericardial, and pleural) hemorrhage or visceral leakage [3,5,28,29,43,44]. The most established terrestrial indication for TS is screening for injury after abdominal trauma. This has been defined as the
Focused Assessment with Sonography for Trauma (FAST), an exam that does not look for individual organ injuries, but instead focuses on the detection of intra-peritoneal fluid [47]. Recently, ultrasound has also been used to detect fluid collections in the pleural space and pericardium, and plays an increasing role in penetrating abdominal trauma [4,30,44,48,51]. Another potential component of TS involves the diagnosis of a pneumothorax. Unlike abdominal injury, the sonographic detection of pneumothorax had never been evaluated for accuracy in the acute trauma resuscitation setting. The direct detection of a pneumothorax by sonography is presumably hampered by the high acoustic impedance of air-containing structures [49], and only artifacts are expected to be seen at the visceral-parietal pleural interface. By demonstrating this interface with real time sonography though, investigations had discovered that thoracic injuries such as pneumothorax and hemothorax could be reliably excluded with an expanded TS technique[13-15,26,27,33,34,42,46].

Before TS could be adopted for use in space medicine, potential limitations needed to be addressed. TS relies on the demonstration of gravitationally dependent sonolucent areas (fluid stripes) in typical anatomic locations. Understanding the behavior of intra-cavitary fluid in weightlessness (0-g) is important; if the fluid does not localize to the expected anatomical sites, erroneous interpretations of trauma sonograms could render the study non-diagnostic or even misleading. The clinical use of sonography to detect pneumothorax in acute trauma was previously unexplored even for conventional use in 1-g.

4. The Clinical Care Capability Development Program (CCCDP)
The Clinical Care Capability Development Program (CCCDP) was initiated at the Johnson Space Center to enhance the medical capabilities onboard the ISS. It was recognized that in the weightless environment, standard medical techniques and devices, such as gravity-driven intravenous (IV) infusions, spinal anesthesia, or suction devices, would be ineffective. The NASA Reduced Gravity Research Program uses a KC-135 aircraft to achieve effective microgravity for intervals of up to 30 seconds during flight with parabolic manoeuvres. Short segments of 0-g alternate with 1.8-g intervals during “pull-up” manoeuvres, requiring the lengthy procedures to be broken up into multiple 20-25 second segments. Experiments aboard the KC-135 on training mannequins or animal models have demonstrated the feasibility of endotracheal intubation, mechanical ventilation, cardiopulmonary resuscitation (CPR), IV infusions, IV anaesthesia, central arterial, venous, and intracranial pressure monitoring, wound debridement and closure, splinting and casting of limbs, and insertion of urinary or nasogastric catheters[9,35,36]. Open surgical procedures on anaesthetised animal models have included exploratory laparotomy with visceral and vascular procedures[8]. Endoscopic procedures have included laparoscopy[7,10], thoracoscopy[10], and cystoscopy[22].

5. The Operational Ultrasound Project

The Operational Ultrasound Project was a specific NASA initiative to study the suitability of TS for operational space medicine use, using the four phase approach (Table 1.). Commitment to each subsequent level was contingent upon success of the previous level. In general, if sufficient evidence of efficacy already exists, phase II trial may be considered unnecessary. Both phases II and III might require animal studies prior to human investigations due to ethical considerations. In the case of TS, all four phases were deemed sequentially appropriate[39].
Phase I: Identification of an effective standard terrestrial technique, or recognition of a potential non-standard or novel potential technique

The trauma study was conceptualized and organized into two main portions; 1) abdominal sonography, evaluating the FAST in 0g, and 2) thoracic sonography, evaluating the effectiveness of ultrasound imaging for the diagnosis of hemo- and pneumothorax. In this initial phase, it was recognized that abdominal TS has replaced Diagnostic Peritoneal Lavage (DPL) as the screening test of choice for blunt abdominal trauma in the majority of North American trauma centers [3]. The potential use of sonography to detect pneumothoraces was also recognized[14,40]. These indications thus warranted further evaluation of TS for space, as sonography is the imaging modality most suitable for use in space medicine.

Phase II: Validation of the technique in clinical practice or animal models (1g)

Many FAST trials have been conducted in clinical practice to demonstrate its excellent accuracy and safety [5,6,31,37,38,43,44,52]. The Phase II of our study, therefore, specifically focused on refining the technique for future microgravity use. For the detection of abdominal fluid, ground studies were only required to validate the porcine model for human TS. In fully anesthetized animals, we studied the ability of sonography to detect aliquots of fluid injected into specific intraperitoneal locations. In contrast with some previous reports [1], we found good correlation between the known volumes of fluid and the imaging data [25].

The ability to diagnose pneumothorax has a high priority in space medicine, given the severe consequences of a failure to identify pneumothorax, the difficulty a non-clinician would have in making
a clinical diagnosis with a stethoscope in a noisy environment[21], and the need to avoid the risks of unnecessary tube thoracostomy. Unlike FAST, the sonographic diagnosis of pneumothoraces was still a largely unproven technology. To investigate this potential, both animal and human studies were undertaken in normal gravity before any evaluation in Phase III could be considered.

Clinical human studies were conducted to evaluate the effectiveness of sonography in detecting pneumothoraces in trauma victims at two international trauma centers. A pilot prospective study at the Detroit Receiving Hospital demonstrated reliable detection of pneumothorax, and revealed that normal sonographic findings had a negative predictive value of 100% [15]. Data from companion studies at the Vancouver General Hospital using CT as the gold standard correlated well with the Detroit findings [32,42]. All studies suggested that chest sonography may be more accurate than supine chest radiography in detecting traumatic pneumothorax [15,26,32,42]. Pleural fluid and air behavior and their sonographic representations were also further examined in Vancouver. A porcine model of pneumothorax was created and validated, with controlled introduction of air aliquots in an anesthetized animal with sonographic monitoring. After subsequent evacuation of air, the normal pattern of pleural motion consistently returned [46].

**Phase III: Validation and refinement of the technique in microgravity environment (0g)**

After the phase II success, a decision was made to proceed with an evaluation of TS in parabolic flight. A series of KC-135 microgravity flights were performed to determine the ability to diagnose abdominal and chest trauma in a porcine model using sonography equipment with both an advanced high-definition system (HDI-5000, ATL/Phillips, Bothell, WA) and a 2.4 kg portable ultrasound
scanner (Sonosite-180, Sonosite Inc., Bothell, WA). Prior to flight, catheters were either laparoscopically pre-positioned, or inserted blindly using a closed DPL technique in the abdomen for air or fluid introduction during 0g exposures. Fluid was injected during periods of microgravity to simulate the effects of traumatic injury in low earth orbit[25]. Laparoscopic and thoracoscopic visualization of these catheters and other surgical procedures were also performed. The ability to detect fluid and air in the thorax using sonography in microgravity was also investigated[18]. A catheter was placed in the right chest cavity during a level flight (1-g), to introduce air and fluid during the following 0-g exposures.

From all the videotapes of the main TS studies, individual segments corresponding to each hypergravity and microgravity period were randomized and combined into a series of segments on a videotape, with references to time and gravitational configuration removed. A CD ROM describing the project and explaining a standardized scoring system was sent to noted experts in sonography. This blinded review subsequently confirmed that TS in parabolic flight is a suitable technique with accuracy comparable to that on the ground, and that the FAST exam could be completed with a thoracic component without significant time penalty and with considerable clinical gain [25]. One limitation of this study though, was the posterior loculation of intra-abdominal fluid during the 1.8-g pullout maneuver. Injected fluid was found to form at the catheter injection site during 0-g and did not loculate to the 1-g conventional ultrasound portals until the 1.8-g pullout.

After the initial phase III studies had provided proof of concept using the animal models, further flights were carried out to refine the techniques to provide ultrasound image acquisition with human test subjects. Initially, the procedures for two-person (operator and subject) scanning were developed. The
most effective means to restrain both the operator and the patient was the ISS crew medical restraint system (figure 1). Next, the procedures for remote guidance of a non-skilled ultrasound operator by telemedicine transmission were developed with an expert either on the ground, or onboard but isolated from the operator. Finally, multiple techniques of self-scanning were attempted by operators of varying skill levels and the position and techniques of choice for self-scanning were determined (figure 2.). Following the KC-135 procedural validation, a procedure set for ISS on-orbit scanning was written, with plans for further space flight validation.

**Phase IV: Operational implementation of the technique for use in space (0g)**

Implementation of an ultrasound examination such as the FAST on-orbit required end-to-end testing to validate the procedures not only for the imaging itself, but also for deployment of the hardware, configuration of power, cooling, data storage and protection, and communications. The protocols also included both two-person and self scanning by the Crew Medical Officer, depending on who the test subject is. To evaluate this concept, a complete FAST examination with a thoracic component was performed aboard the ISS using a self-scanning technique under remote guidance from the ground (Figure 3.)[45]. To further explore the potential of the on-board US; just-in-time training, combined with remote experienced physician guidance was evaluated to evaluate the ability to perform detailed analyses of the rotator cuff and the eye[12,16]. Both examinations provided diagnostic quality images that were downlinked to remote experts who provided both positioning feedback as well as remote interpretation. Such techniques may provide a useful approach to complex medical tasks performed by nonexperienced personnel in a variety of remote settings, including current and future space programs. Further reports regarding other sonographic applications and resulting data for a range of space medicine questions are expected in the near future.
8. Conclusions

The seamless integration of a standard accepted terrestrial technique (FAST) and a novel largely unproven diagnostic strategy (sonography for pneumothoraces) into the same organizational and logistical research methodology illustrates the adaptability and flexibility of the four-phased hierarchal approach. We believe that this approach will provide an approach to evaluating other future potential technologies for operational space medicine. The current translation of the successful results of the Phase I-III phases into an operationally tested technique for the limited space medicine armamentarium is an ongoing task. One of the major limiting factors is the nonmedical background of the operators; for this reason, interest is currently focused not only on the delivery of expertise from the ground as appropriate in the Low Earth Orbit scenario, but also on increasing the autonomy of the mission through adaptive tutorials, guidance algorithms, and other proficiency enhancement software, non-real-time focused telementoring, and telemedical methodology. The knowledge learned in these investigations will allow continued research and planning for the space medicine capabilities for future space exploration. Telemedical aspects of these developments are directly applicable to many terrestrial settings with limited medical resources and specialized expertise.
Reference List


Table 1. The Clinical Care Capability Development Project (CCCDP) Approach

**PHASE I:** Identification of an effective current terrestrial standard technique used on humans
or
recognition of a non-standard or novel potential technique.

**PHASE II:** Validation of the technique in clinical practice or animal models (1-g).

**PHASE III:** Validation and refinement of the technique in a microgravity analogue environment (0-g)

**PHASE IV:** Operational implementation of the technique for use on humans in space (0-g).
List of Figures

Figure 1. Two-crew-member sonographic technique for ISS being simulated in parabolic flight (patient and examiner)

Figure 2. One-person sonographic technique for ISS being simulated in parabolic flight (patient is the examiner)

Figure 3. Astronaut Peggy Whitson performing self-imaging FAST examination aboard the International Space Station
Figure 1. Two-crew-member sonographic technique for ISS being simulated in parabolic flight (patient and examiner)
Figure 2. One-person sonographic technique for ISS being simulated in parabolic flight (patient is the examiner)
Figure 3. Astronaut Peggy Whitson performing self-imaging FAST examination aboard the International Space Station