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AIRSICKNESS TREATMENT AND PREVENTION: RECOMMENDATIONS REGARDING ANTIEMETICS AND/OR ACUSTIMULATION

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AIRSICKNESS TREATMENT AND PREVENTION: RECOMMENDATIONS REGARDING ANTIEMETICS AND/OR ACUSTIMULATION

by

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Airsickness Treatment & Prevention:
Recommendations Regarding Antiemetics and/or Acustimulation

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Airsickness has been an important concern for aviation since before World War II. Airsickness is still a topic of serious discussion in the aviation community, despite recent advances in medical science, aircraft engineering and performance. Symptoms of motion sickness range from mild to incapacitating in nature and can cause degradation in performance measures of reaction time, postural stability and cognitive functioning. This can result in unacceptable work force losses, incur significant costs, and ultimately result in mission compromise and/or missing critical objectives. Current pharmacological interventions may produce side effects such as sedation and diminished cognition.

Acustimulation at the median P6, or Neiguan, point has recently generated interest as a non-pharmacological means of preventing motion sickness. A recent study evaluating a popular acupressure wristband reported it to be effective in the suppression of the major symptoms (nausea and vomiting) of motion sickness. This study concluded

that continuous vigorous stimulation of the P6 point was required to achieve a significant benefit.

The commercially available Reliefband® provides electrical acustimulation at the P6 point thereby reportedly countering symptoms of chemotherapy-induced nausea and vomiting. Its makers market it as "the only FDA-cleared device for motion sickness". A literature search revealed that no published studies comparing currently available pharmacologic and non-pharmacologic (Reliefband®) motion sickness treatments in conjunction with rotary wing operations are available.

This capstone describes a randomized, double blind, cross over study comparing the effectiveness of four airsickness countermeasures to a placebo control and to each other on reaction time, postural stability, and cognition in relation to airsickness symptom severity and their ability to ameliorate performance declines following simulated rotary wing combat operations. The data suggest that only the combination of phenergan with caffeine was effective in achieving these measures. This study will help enable the aerospace medical community to make recommendations to military commanders and civilian policy makers concerning the ability of viable treatments to mitigate performance decrements seen because of rotary wing flight induced motion sickness.

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Chapter 1: Introduction

This capstone describes the authors' participation as co-investigator in a randomized, double blind, cross over study to compare the effectiveness of four airsickness countermeasures to a placebo control and each other. The specific aim of this study was to compare three pharmacological and one non-pharmacological counter measures versus placebo on their ability to ameliorate airsickness symptom severity and decrements in performance outcomes of reaction time, postural stability, and cognition following simulated rotary wing combat operations.

The results of this study will help enable the aerospace medical community to make recommendations to military commanders and civilian policy makers concerning the ability of viable treatments to mitigate performance decrements seen because of rotary wing flight induced motion sickness. Additionally, it is the aim of this research to provide direction and discussion for future research on the subject of airsickness treatment and prevention in conjunction with rotary-wing flight.

BACKGROUND AND SIGNIFICANCE

Airsickness has been an important aeromedical concern for both civilian and military aviation since World War II. Turner, Griffin and Holland (2000) report in a recent study that nearly 17 percent of commercial airline passengers suffer from motion sickness during short haul excursions. Moreover, Armstrong (1961) reported adverse flight conditions produced serious airsickness in as many as 70 percent of troops conducting airborne operations during World War II. Observers reported that airsickness virtually disabled a great number of the airborne soldiers prior to reaching their target

areas. Davis, Jennings, and Beck (1999), described the affects of Space Motion Sickness (SMS) on a significant number of both Space Shuttle and International Space Station crewmembers in their initial days of flight.

Despite recent advances in aircraft design and construction, airsickness is still a topic of serious concern in both civilian and military flight environments. Symptoms can range from mild nausea and discomfort to vomiting, drowsiness, lethargy, and apathy and can cause degradation in performance measures of reaction time, postural stability and cognitive functioning (Dehart & Davis, 2002). Certain in-flight conditions such as seat position, turbulence, heat, or degraded visual cues due to deteriorating weather or night flight can predispose aircrew members and passengers to significant symptomatology. Crowley (1987) reported that 40% of high flight time pilots performing AH-1 "Cobra" simulator duties reported symptoms of disequilibrium and motion sickness. Due to reduced experience with in-flight conditions, fatigue and the pressures of the operational mission set, soldiers transported to a mission under these conditions can be equally, if not more, affected by motion sickness (Armstrong, 1961; Crowley, 1987; Thornton & Vyrnwy-Jones, 1984).

In the civilian environment, motion sickness symptomatology can result in unacceptable work force losses, incur significant costs, and ultimately result in compromise of critical business objectives. The incidence of SMS during a first Space Shuttle flight for 85 crewmembers was 67 percent (57 cases) of which 26 were classified as mild (30 percent), 20 as moderate (24 percent), and 11 as severe (13 percent) enough to cause limitations in performance during flight as reported by Davis, Vanderploeg,

Santy, Jennings and Stewart (1988) in a retrospective study performed for the National Aeronautics and Space Administration (NASA) Johnson Space Center.

Physiological and performance problems associated with such situations during military operations can equally compromise mission effectiveness through degraded performance and can lead to significant morbidity and mortality with resultant failure to achieve mission objectives. Given that soldiers must be ready to execute missions at any given time during or immediately post flight it is critical to seek ways to minimize the symptoms of airsickness as well as to avoid and/or counter the deleterious effects of medications administered to treat it.

In the current military operational environment, airsickness should be treated with the most effective medications that yield the fewest negative side effects. Unfortunately, effective doses of traditional anti-emetics typically produce sedation. Several non-traditional motion sickness and nausea remedies are now gaining acceptance in the medical community and are being considered for their use in the context of military rotary wing flight operations. Interestingly, combinations of currently available pharmacologic and non-traditional treatments have not been fully studied in conjunction with rotary wing operations.

Study Focus and Aims

The study described herein focuses on a comparison of three currently recommended and one non-traditional motion sickness intervention on measures of motion sickness severity, performance, postural stability and cognition. This project seeks to answer the question "Is there a statistically significant difference between the four motion sickness countermeasures (three pharmacologic and one non-pharmacologic)

studied in relation to: 1) severity of motion sickness symptoms, 2) reaction times, 3) postural stability, and 4) cognition scores immediately following rotary-wing flight? The null hypothesis is that there is no statistically significant difference between the four motion sickness countermeasures. The hypothesis of this study is that there is a statistically significant difference between the four motion sickness countermeasures.

Chapter 2: Motion Sickness

The 2006 ICD-9-CM Diagnosis code for motion sickness (994.6) describes a disorder "caused by motion, as [in] sea sickness, train sickness, car sickness, or space motion sickness. It may include symptoms of nausea, vomiting and dizziness". The code contains 18 separate index entries ranging from airsickness to motion sickness caused by playing in a roundabout swing. Motion sickness, also known as "kinetosis", has been well-recognized and described for thousands of years.

The word "nausea" comes from the ancient Greek root "naus" which literally translates in modern English to "ship". Greek seafarers well understood the association between the movement of a ship on the open seas and the symptoms of motion sickness and wove this malady into the rich tapestry of their legends and myths.

In the ancient tale of the Ionian founding hero, Theseus, Plutarch (75 A.D.) describes the events in which Theseus defeats the half-man, half-bull Minotaur with the help of King Minos'daughter, Ariadne. The mythological tale recounts Ariadne's collusion with Theseus by providing him a ball of twine to find his way back through Daedalus' labyrinth. He ties the twine to a post at the entrance to the labyrinth, using it to find his way back after slaying the Minotaur. Ultimately, he escapes King Minos' Crete and emerges the ordeal as a Greek hero. As part of his oath to Ariadne, he takes her with him on his return journey to Greece, but eventually abandons her on the island of Naxos.

Various explanations are scattered throughout ancient mythology, but one stands out in juxtaposition to the more salacious accusations of a philandering Theseus. Plutarch explains Theseus' apparent abandonment of Ariadne on Naxos not because he

had another love interest back home as is often reported, but simply because she was extremely sea sick during the early portion of their journey and could not safely make the remainder of the Adriatic crossing to Greece.

Obviously, to which this tale alludes, early sea travelers were familiar with the concept of motion sickness. The ancient Roman lyric poet Quintus Horatius Flaccus, aka: Horace (20 A.D., as cited in Rolfe, 1904) in his *Epistularum liber primus (1st Book of Letters)*, made a comparison between the angst, trepidation and ill feelings associated with making an extremely difficult decision to the effects of sea sickness.

> How shall I hold this Proteus in my gripe?
> How fix him down in one enduring type?
> Turn to the poor: their megrims are as strange;
> Bath, cockloft, barber, eating-house, they change;
> They hire a boat; your born aristocrat
> Is not more squeamish, tossing in his yacht

Dizziness, nausea, vomiting, drowsiness, pallor, sweating, and overall malaise triggered by travel in a boat, car, train, plane and even travel by animal all fall into the category of motion sickness (Lawther & Griffin, 1988). Throughout ancient and modern times, early travelers described motion sickness occurring in various forms of travel. Accordingly, there are several famous literary references to motion sickness. The 17th century French anthropologist Paul du Chaillu (1871) wrote of his experience with "camel sickness" while traveling and exploring the border areas of the Sahara desert in northeastern Senegal.

> The long, swinging strides of my camel, to which, of course, I was not accustomed, did not seem to agree with me, and I was beginning to feel symptoms of seasickness. "What," said I to myself, "sea-sick on the back of a camel!" There was no mistake about it. It was a kind of camel-sickness.

The development of more modern forms of transportation has resulted in kinetosis becoming increasingly prevalent in our daily lives. A recent study suggests an association between childhood carsickness, adult motion sickness and migraine headache occurrence (Agrup, Gleeson, & Rudge, 2007). As previously mentioned, space-motion sickness occurs in well over 50% of shuttle astronauts and incapacitating airsickness occurs in upwards of 29% of airline pilots (James & Green, 1991).

Turner, Griffin, and Holland (2000) reported that 0.5% of passengers on short flights within the United Kingdom experienced vomiting, 8.4% reported nausea and 16.2% reported motion associated illness during flight. The magnitude of low-frequency lateral and vertical motion characteristic of smaller, more maneuverable short-haul aircraft was found to be significantly associated with the occurrence of symptomatology in the study group. Although neither motion uniquely predicted the occurrence of motion sickness, these findings correlated with previous studies showing the importance of visual and vestibular input mismatch in the generation of motion sickness (Eyeson-Annan, Peterken, Brown & Atchison, 1996).

THE HUMAN VESTIBULAR SYSTEM

The human vestibular system provides the structural and functional basis for reflexes that stabilize vision in relation to movement of the head and body. This system provides information in regards to linear and angular acceleration as well as gravitational and inertial forces about the human body, which translates into very specific spatial orientation. These highly specialized organs are the cochlea (essentially redundant and parallel linear accelerometers) that when coupled with the semi-circular canals (redundant and parallel angular accelerometers) provide accurate (in normal, static and

semi-static conditions) position and motion sensation to the human subject that allows reliable functioning in most situations.

The vestibular system feeds information to the brain to enable reflexive motor activities for functions such as stabilization and balance during ambulation and balance during periods of darkness or obscured vision where the vestibular system couples with input derived from the proprioceptive organs to provide feedback as to orientation within the three dimensional space surrounding the individual. Without this system, humans would not have the ability to stabilize a visual image on their retinas and vision would be blurred during movement or, while stationary, in regards to moving external stimuli.

MOTION SICKNESS THEORY

The most accepted current theories concerning the cause of motion sickness focus on sensory mismatch between the human visual and vestibular systems. Parmet and Gillingham (as cited in DeHart & Davis, 2002) espouse the "unified theory" of motion sickness that includes the interaction of the auditory and proprioceptive systems as well, rather than solely the interaction of "sensory" or "neural" inputs originally proposed by Claremont (1931) in which the generation of motion sickness arose primarily from conflict or mismatch, respectively, between the vestibular and visual systems alone.

Subsequent observation and experimentation has demonstrated that motion sickness can and does occur via conflict between not only the vestibular and visual systems, but, through conflicts between the auditory and the proprioceptive systems and variations of all these systems combined (Previc, 1990; Eyeson-Annan, Peterken, Brown, & Atchison, 1996; Parmet & Gillingham, 2002).

Three basic hypotheses attempt to explain the occurrence and cause of motion sickness in relation to the visual-vestibular system, 1) intra-vestibular conflict; 2) altered gain of vestibular-ocular reflexes (seen primarily in the micro-gravity environment); and 3) morphologic asymmetry and/or asymmetric functioning of the otolith organs.

The first is that intra-vestibular conflict with visual cues cause transmission of false signals in regards to ones angular velocity about a non-vertical axis. This mismatch between visual and vestibular cues results in the brain receiving non-confirmatory information in regards to a perceived (or actual) change in relative angular velocity, resulting in a high likelihood of developing symptoms of motion sickness.

The second theory (altered vestibular-ocular reflexes) espouses that conflict between actual and/or anticipated visual stimuli and perceived vestibular input arises from a gain in vestibular-ocular stimuli to the visual/proprioceptive coordination centers of the human brain as an adaptation to altered gravity (Parker, Reschke, & von Gierke, 1987).

A third theory proposes that compensation normally occurs for a morphologic asymmetry and/or asymmetric function of the left and right otolith organs of the inner ear in the normal human subject in the one gravity environment. During exposure to less-than-one gravity environmental conditions such as space flight, this compensation results in conflict between bilateral inputs of vestibular information (i.e., the left vestibular organ is feeding slightly different information regarding motion, velocity and position, than is the right vestibular organ) and (primarily) visual input which causes sensory conflict and neural mismatch along with conflicted information from the auditory and/or proprioceptive systems (Parker, et al., 1987).

Clearly, the common theme among these theories is the prevalence of some form of sensory-vestibular-neural conflict. A common practical demonstration of this theme in action is in the case of motion sick passengers on board a sea-going cruise ship in rough waters. It is fairly well known and well documented that passengers on cruise ships are far more likely to get seasick when below deck because their vestibular apparatus detects motion while their visual system does not (Gordon, Ben-Aryeh, Spitzer, Doweck, Gonen, Melamed, & Shupak, 1994). Standard advice for seasickness is to go up on deck where vestibular and visual inputs agree (Gordon, et al., 1994).

Motion sickness induced by air travel, however, is more problematic. An outside view does not necessarily help in aviation because flight constantly presents sensory conflicts. Pilots often report that passengers are far more prone to motion sickness than pilots' experience (James & Green, 1991). This is not surprising considering that motion sickness is often triggered by discrepancies between anticipated orientation and actual orientation. For pilots at the aircraft controls, knowledge of upcoming flight movements seems to offer some protection against acquiring the symptoms of airsickness as compared to passengers and crewmembers.

Additionally, with repeated exposure, pilots will desensitize to the effects of sensory mismatches (Gillingham & Previc, 1996). This desensitization often does not occur in passengers. In fact, the Navy has reported that 13.5 percent of all flights will lead to airsickness in non-pilot crewmembers (Guedry, 1991). Experience in recent combat operations has shown that airsickness is a significant problem for even seasoned Special Operations troops riding as passengers in rotary wing aircraft while under low- to no-light conditions.

Chapter 3: Motion Sickness Countermeasures

Nausea and vomiting are the most common complaints of motion sickness and are mediated by central neurotransmitters. In response to visual and vestibular input, increased levels of dopamine stimulate the medulla oblongata chemoreceptor trigger zone, which in turn stimulates the vomiting center within the reticular formation of the brain stem. The vomiting center is also directly stimulated by motion and by high levels of acetylcholine. Therefore, most drugs that are used to prevent or ameliorate motion sickness symptoms target these neurotransmitters.

While the precise action of medications targeting neurotransmitters in preventing motion sickness is not fully understood, most of these drugs fall into three classes: antidopaminergics, anticholinergics, and antihistamines (Killion, 2005). Given the frequently encountered side effects of these classes of drugs, sympathomimetic agents are often added to counter the somnolent side effects produced by therapeutic doses.

ANTIDOPAMINERGIC AGENTS

One of the most effective antidopaminergic agents currently approved for motion sickness is promethazine hydrochloride, a phenothiazine derivative with antihistamine, anti-cholinergic, and sedative effects. Promethazine has largely been used in situations of severe stimuli as both a prophylaxis and for treatment of established motion sickness (Kohl, Calkins, & Mandell, 1986). Unfortunately, promethazine causes more drowsiness than many of the other standard anti-emetic agents and is often used in conjunction with stimulant agents to offset this effect.

ANTICHOLINERGIC AGENTS

Currently, one of the most popular anticholinergic agents used for treatment of motion sickness is the centrally acting antimuscarinic alkaloid scopolamine hydrobromide delivered via a transdermal therapeutic system (Transderm-Scop or TTS-patch). Transderm-Scop is delivered via a cutaneous patch applied to the skin behind the ear and provides a continuous dose of scopolamine to the systemic circulation for up to three days. Scopolamine prevents motion-induced nausea by inhibiting vestibular input to the central nervous system (CNS), resulting in inhibition of the vomiting reflex (Brown & Taylor, 1996). According to some authors, scopolamine is considered the most effective single agent to prevent motion sickness (Renner, Oertel, & Kirch, 2005).

Of note, NASA, while endorsing the use of scopolamine as a first line agent, currently precludes the prophylactic use of a combination of oral scopolamine-dextroamphetamine (Scopdex) for space motion sickness. Rather they authorize its use for treatment of space motion sickness once symptoms have manifested themselves. They no longer recommend prophylaxis with Scopdex due to the occurrence of delayed symptom development and apparent variable absorption of oral medications during early flight days (Davis, et al., 1999).

ANTIHISTAMINE AGENTS

Numerous antihistamines are available to prevent motion sickness. According to studies by Babe and Serafin (1996), it is likely their benefit is derived from their intrinsic anticholinergic properties rather than their antihistamine properties. The most popular of these agents is meclizine hydrochloride, a histamine-receptor blocker that presumably prevents motion sickness by blocking muscarinic receptors in the CNS.

NON-PHARMACOLOGIC ALTERNATIVE REMEDIES

Alternative medicine remedies are becoming more popular and have been increasingly recommended for treatment of nausea and vomiting associated kinetosis. Acupressure and acustimulation have recently generated a great deal of interest as non-pharmacological means of preventing motion sickness as they have shown to be effective in the suppression of nausea and vomiting (Blumenthal, Goldberg, & Brinkman, 2000; Cummings & Ullman, 1997: Dobie & May, 1994; Ernst & Pittler, 2000). To control nausea and vomiting, pressure is applied to the P6 acupuncture point on the pericardial meridian, located about three cm from the distant palmar crease between the palmaris longus and flexor carpi radialis tendons.

Acupressure

Hu, Stritzel, Chandler, and Stern (1995) conducted a study involving a popular acupressure wristband that applies pressure to the P6 point and concluded that continuous vigorous stimulation of this point was required to achieve a "significant benefit". Acupressure is an extension of the ancient Chinese medical practice of acupuncture. Exertion of pressure at specific locations on a series of "meridians" is claimed to provide therapeutic effects for a host of medical ailments. In particular, the P6 or Neiguan acupoint (also known as the pericardium 6 point) is located on the inside of the wrist (approximately 3 cm above the wrist on the volar surface of the forearm) and is thought in traditional Chinese medicine to relieve nausea and vomiting (Kouzi, 2003). Although the mechanism of acupuncture, acupressure and/or acustimulation at the P6 point is undetermined, effects may be secondary to stimulation of the median nerve (Rosen, de Veciana, Miller, Stewart, Rebarber, & Slotnick, 2003).

Acustimulation

The newest version of the acustimulator wristband provides constant electrical stimulation to the P6 point. A commercially available acustimulation device (Reliefband®) is designed to provide electrical stimulation at the P6 point purportedly countering symptoms of chemotherapy-induced nausea and vomiting (Appendix E). The Reliefband® is openly marketed as "the only FDA-cleared device for motion sickness" (Skymall Magazine, 2006). A recent published study by Miller and Muth (2004) concluded that acustimulation provided to the P6 point (Reliefband®) was not effective in ameliorating symptoms of motion sickness induced in the laboratory setting.

SOMNOLENCE COUNTERMEASURES

Sympathomimetics

Sympathomimetic drugs (dextroamphetamine and ephedrine) counteract motion sickness both individually and in a synergistic combination with anticholinergic agents.

Dextroamphetamine and Ephedrine

Dextroamphetamine sulfate and various formulations of ephedrine are common sympathomimetic drugs used to counteract the somnolent effects of anti-motion sickness medications and may be used to avoid sedation in situations where alertness is required (Physician's Desk Reference, 2001). Dextroamphetamine induces release of the neurotransmitters dopamine and norepinephrine acting as a powerful psychostimulant ameliorating the effects of anti-motion sickness medications (Wood, Stewart, Wood, Manno, Manno, & Mims, 1990). Despite their efficacy, amphetamines are known to be extremely addictive and possess high abuse potential (Hoffman & Lefkowitz, 1990).

Even at recommended therapeutic doses, dextroamphetamine has been known to produce psychotic episodes, over-stimulation, restlessness, dizziness, insomnia, euphoria, tremors, and headaches. Another sympathomimetic agent, ephedrine, is a sympathomimetic amine similar in structure to the synthetic derivatives amphetamine and methamphetamine and has been heavily scrutinized and universally shunned as of late due to its association with significant morbidity and mortality (American Academy of Neurology Press Release, 1996; Samenuk, Link, Homoud, Contreras, Theoharides, Wang, & Estes, 2002; Haller & Benowitz, 2000).

Xanthine Alkaloids

Xanthine alkaloids are a group of alkaloids that are commonly used for their effects as mild stimulants and as bronchodilators, notably in treating the symptoms of asthma. They are by far less effective as stimulants than the sympathomimetic amines (i.e., dextroamphetamine and ephedrine). The most commonly therapeutic utilized xanthine alkaloid is caffeine.

Caffeine

Caffeine is a xanthine alkaloid compound that acts as a central nervous system stimulant in humans with the effect of temporarily warding off drowsiness and restoring alertness. It is arguably the world's most widely consumed psychoactive substance. In North America, 90 percent of adults consume caffeine daily (Lovett, 2005). The U.S. Food and Drug Administration lists caffeine as a "Multiple Purpose GRAS (Generally Recognized as Safe) Food Substance" (United States Code of Federal Regulations, 2003).

Caffeine stimulates the central nervous system initially at lower dosage levels, the cortex and medulla at moderate dosages, and finally the spinal cord at higher doses

(Bolton & Null, 1981). Mild cortex stimulation appears to be beneficial resulting in clearer thinking and less fatigue. Caffeine has also been shown to improve attention in a study that simulated night driving (Lienert & Huber, 1966). Caffeine is considered a non-addictive stimulant (American Psychiatric Association DSM IV, 1994) with many of the same behaviorally activating properties as the amphetamines and ephedrine compounds. It was chosen for use in this study, in combination with the standard anti-emetic agent phenergan, due to its low side-effect profile and availability.

Chapter 4: Methods

Our group conducted a randomized, double blind, cross over study to compare the effectiveness of four airsickness countermeasures to a placebo control and each other.

DEPENDANT VARIABLES

Dependent variables are listed here (described in detail later in this section): 1) motion sickness severity as measured by the results from a Motion Sickness Questionnaire (MSQ) instrument, 2) reaction time as measured by the Psychomotor Vigilance Test (PVT) instrument, 3) postural stability as measured by the Postural Balance Assessment instrument, and 4) cognitive function as measured by the Progressive Cognitive Capacity Checker (PC3) instrument.

INDEPENDENT VARIABLES

The independent variables are the specific countermeasures themselves: 1) oral combination phenergan/caffeine, 2) transdermal scopolamine, 3) oral meclizine, and 4) acustimulator Reliefband® applied at the P6 point on the wrist as previously described.

SUBJECTS

The target population of this study was limited to male, United States Army service members with a likelihood of participation in rotary-wing combat operations. Females were excluded as current Department of Defense policy precludes their participation in direct combat and thereby precludes their participation in rotary-wing combat operations. The study sample consisted of 64 non-aviator, volunteer male subjects, ages 18-34 years participating in initial military training with limited, to no,

rotary wing aircraft experience. Additionally, recruited subjects were screened for current and/or preexisting medical conditions that might prohibit administration of anti-motion sickness medications or participation in simulated rotary wing combat operations.

INCLUSION/EXCLUSION CRITERIA

Only male soldiers (ages 18 to 34) with limited (<10 hrs) rotary-wing flight experience were used in this study. As the degree and frequency of airsickness is known to decrease with repeated exposure, data on the effectiveness of the countermeasures could be compromised by using subjects with widely varying amounts of flight experience. Based on the target population (infantry, special operations troops), female soldiers were not used as volunteers as they are currently excluded from the infantry population.

Additionally, volunteers were excluded if they had a history or currently active condition of any of the following:

- Lactose intolerance
- HIV or Hepatitis B or C (acute state)
- Cardiovascular disease, Cardiac enlargement or heart murmur (other than functional murmur)
- Hepatosplenomegaly
- High blood pressure (to include a resting blood pressure greater than 140/90 during the screening visit that did not decrease on a second reading taken at least 15 minutes later in the screening visit)
- Asthma
- Renal or Gastrointestinal disease
- History of serious allergic reactions, immunological dysfunction, hematological disorders, cancer, endocrine or metabolic disorders, serious dermatologic

disorders, adverse drug reactions, or history of symptomatic motion sickness requiring medical care.

Depending on the severity of past conditions and possible continuation into the present, volunteers could be excluded from the study at the discretion of the examining physician or physician's assistant based on objective clinical determinants. Caffeine use in excess of 400 mg per day on average, use of any medication, prescribed or otherwise, deemed unable to be discontinued safely for the duration of the protocol by the physician investigator and use of any medication that might interact with any of the agents being used in this study would disqualify volunteers.

ETHICAL CONSIDERATIONS

This protocol was submitted for review and approved by the Institutional Review Board of the US Army Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia, as well as by the US Army Surgeon General's Human Subjects Review Board (HSRRB). In consideration of the medical risks and ethical concerns of this protocol, serious and unexpected adverse experiences of any nature were to be immediately reported by telephone to the Director of the Aircrew Health and Performance Division, the Science Program Director, and the Commander of the United States Army Aeronautics Research Laboratory. Immediately thereafter, unanticipated problems involving risk to subjects, adverse events related to participation in the study and all subject deaths were to be promptly reported by phone (301-619-2165), by email (hsrrb@det.amedd .army.mil), and/or by facsimile (301-619-7803) to the (HSRRB). A complete written report was to be placed immediately following the initial telephone call. In addition to the methods above, a complete report was to be sent to the United States

Army Medical Research and Materiel Command, ATTN: MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

A medical monitor (qualified flight physician) was on station during all subject recruiting, screening, evaluation and testing as well to review all unanticipated problems involving risk to subjects or others, serious adverse events and all subject deaths associated with the protocol and instructed to provide an unbiased written report of the event. At a minimum, the medical monitor was required to comment on the outcomes of the event or problem, and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The medical monitor was also instructed to indicate whether he/she concurred with the details of the report provided by the study investigator. Reports for events determined by either the investigator or medical monitor to be possibly or definitely related to participation and reports of events resulting in the death would be promptly forwarded to the HSRRB. Of note, no reportable events occurred, were reported and/or observed during the duration of the study.

INSTRUMENTS & DEVICES

Motion Sickness Questionnaire (MSQ)

Subjective sickness symptoms were measured using a lap top windows version of the Motion Sickness Questionnaire (Kellogg, Kennedy & Graybiel, 1965; Kennedy, 1975). The MSQ is a self-report form consisting of 28 items that are rated by the participant in terms of severity on a four-point scale. Responses from the MSQ were automatically scored and presented on the computer screen for the physician investigator to examine. This questionnaire takes approximately five minutes to administer.

Psychomotor Vigilance Test (PVT)

The Psychomotor Vigilance Test (PVT) device (Figure 1) is a portable simple reaction time test known to be sensitive to the effects of fatigue and sleepiness (Dinges, Pack, Williams, Gillen, Powell, Ott, Aptowicz, & Pack, 1997).

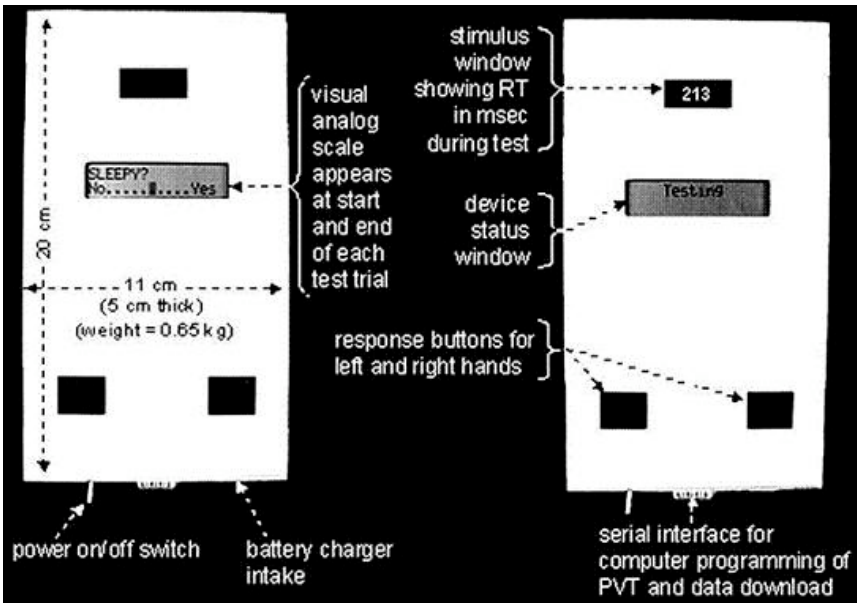


Figure 1. Psychomotor Vigilance Test device (PVT-192).

It visually displays a three-mm light in a window for up to 1.5 seconds during which time the subject responds by pressing a micro switch that allows reaction time to the stimulus light to be recorded. The inter-stimulus interval varies randomly from one to ten seconds (Appendix E).

Postural Balance Assessment (PBA)

Subjects were to complete a five-minute postural stability/equilibrium test according to the protocol specified by Gower and Fowkles (1989). There are three parts

to this test. The first is referred to as walk on floor with eyes closed (WOFEC) and requires that the subject take 12 heel-to-toe steps with his eyes closed and arms folded across his chest. The subject is scored (0-12) based on how many steps he is able to make without sidestepping or losing his balance. Three trials of this test were completed following each flight, and the scores from all three were averaged. The second is the standing on preferred leg with eyes closed (SOPLEC) test that requires the subject to stand on his preferred leg for 30 seconds with his eyes closed and arms folded across his chest. The subject is scored on the number of seconds he is able to remain upright (to within five degrees) without losing his balance. Three trials of this test were completed following each flight, and the scores were averaged together. The third test is the standing on non-preferred leg with eyes closed (SONLEC) test that is the same as SOPLEC except that the subject stands on the opposite leg. This test takes approximately five minutes.

Progressive Cognitive Capacity Checker (PC3)

The Progressive Cognitive Capacity Checker (PC3) tested participants' cognitive performance. This computerized test presents a number string and two comparison number strings beneath it. Individuals must identify which of the two strings is different from the top one and respond with a mouse press within 1.5 seconds. The test produces increasingly difficult levels and yields a chance corrected score and the total test time. This task takes approximately five minutes.

Acustimulator - Reliefband®

The Reliefband® is a wrist worn device that weighs 1.2 ounces and contains electronic modules plus a pair of coin-size lithium batteries. The underside of the device

has a pair of gold-plated electrodes that contact the skin and it is worn like a sports watch on the underside of the wrist. The face of the device has a dial that permits it to be turned on and off and adjusted to any of five stimulation levels. Upon the first signs of motion sickness symptomatology, the wearer turns the device on and adjusts the dial until a mild tingling sensation is felt. In this study, the Reliefband® were turned on during preflight and kept on until post-testing is completed. This device has received FDA clearance for treatment of nausea and vomiting due to pregnancy, chemotherapy, motion sickness, and as an adjunct to anti-emetics for postoperative nausea.

Chapter 5: Procedures

This study was conducted in conjunction with the United States Army Aeromedical Research Laboratory (USAARL) using the laboratory's JUH-60A at Lawson Army Airfield, Fort Benning, Georgia. The windows of the research aircraft were blocked with UH-60 blackout curtains so that no visual stimuli from outside the aircraft were accessible. The flight profile included a variety of maneuvers that caused the passengers to experience changing vestibular input without access to visual stimuli (Leduc, Johnson, Ruyak, Estrada, Jones, & Higdon, 1999). The flight profile included straight and level flight, hovers, turns, and ascents and descents at varying speeds. Each flight lasted approximately 30 minutes. A detailed flight profile is included in Appendix A. For each flight, the pilot in command recorded wind speed and temperature measurements. The same pilot was used to fly each study iteration in order to minimize variation in the flight profile.

A mixed, double-blinded, crossover design was used to compare the effectiveness of four airsickness countermeasures (three pharmacological and one non-pharmacological) to placebo control and to each other. Because the extent of airsickness symptomatology is extremely variable among individuals, each person received one treatment and one placebo control flight. Additionally, as most people become asymptomatic after repeated exposures and recent flight and extinction is an issue in the degree of symptomatology exhibited (DeHart, 1996) flights were scheduled and executed approximately seven days apart. Participants completed several questionnaires and tasks

assessing their symptomatology and physical and cognitive performance before and after each flight.

The USAARL JUH60A Blackhawk helicopter (Figure 2) was used as the test platform. Flight simulators were not used as they are fixed to the ground and thus, fail to duplicate the linear and angular accelerations experienced during actual flight. Additionally, aircraft simulators do not contain a passenger cabin. They are designed for aviation crew training and not passenger training, thus, have but one seat for an "observer" in the rear instructor/operator area. For these reasons, the simulator was deemed neither practical nor appropriate as a test platform for this study.

Figure 2. USAARL JUH-60A Black Hawk helicopter.

Sixty-four, male, non-aviator subjects (ages 18 to 34) were recruited to participate in this double blind, cross over study at Fort Benning, Georgia. Sixteen subjects were randomly assigned to each of four groups: 1) promethazine (25 mg) + caffeine (200 mg); 2) meclizine (25 mg); 3) Scopolamine patch (1.5 mg); 4) Reliefband®. Each individual

participated twice, once with the treatment and once with no active treatment (placebo). Due to the fact that three different types of treatments were used (drugs taken orally, drugs on a transdermal patch, and a wristband), to keep all participants unaware of their treatment group or treatment order, several placebo (non-active) measures were used.

For oral drugs, a placebo pill (lactose-filled capsule indistinguishable from the drug capsule) was used. A small patch of white, opaque bandage tape was placed over the site of the scopolamine patch, concealing the presence or absence of the medicated patch. The wristbands were worn backwards, with the stimulus producing side on the back of the wrist, away from the median nerve. An elastic wrist "sweatband" was worn over the Reliefband® to conceal device from investigators. Each participant will then spend one flight with one active measure and two placebo measures and one flight with three placebo measures. For example, an individual in the scopolamine patch treatment group experienced one flight with the active scopolamine patch, a placebo pill, and the wristband worn backwards and another flight with a placebo patch, placebo pill and the wristband worn backwards (Figure 3).

Figure 3. The wristband (ReliefBand®) being placed in the placebo position.

The aircraft accommodated eight subjects at a time and each flight included two subjects from each treatment group; one having been administered the treatment and the other placebo. Thus, each flight had four individuals using one of each treatment and four individuals posing as their placebo controls (Table 1).

Treatment Group	Number of Subjects	Experimental Treatments	Control Treatments
Promethazine 25 mg + Caffeine (200 mg)	16	Promethazine Placebo patch Wristband backwards	Placebo capsule Placebo patch Wristband backwards
Meclizine 25 mg	16	Meclizine Placebo patch Wristband backwards	Placebo capsule Placebo patch Wristband backwards
Scopolamine patch 1.5 mg	16	Placebo capsule Scopolamine patch Wristband backwards	Placebo capsule Placebo patch Wristband backwards
ReliefBand® Non-pharmacological	16	Placebo capsule Placebo patch ReliefBand®	Placebo capsule Placebo patch Wristband backwards

Table 1. Treatment and Control Procedures.

Prior to any recruitment attempts, the study team gained written approval (Memoranda for Record) from the participating units, medical facilities and pertinent entities with which the study group interacted. The study physician(s) provided detailed briefings to local unit Commanders explaining the purpose, procedures and risks of the study and the actions required of those personnel who volunteered to participate in the study. Particular emphasis was made of the requirement to participate in actual helicopter flight. Per United States Army Aviation Regulation 95-1 (2006), paragraph 3-12, service personnel are authorized to fly as passengers on Army aircraft while on duty and authorized by their command. Written approval for flight was obtained from the volunteers' command before each volunteer was allowed to participate.

Upon receiving Command approval, volunteers were recruited from personnel assigned to, or in a "hold status" pending class commencement in, the Infantry Officers Basic Course and the Infantry Advanced Individual Training Course at Fort Benning, Georgia. Recruitment flyers were placed in conspicuous locations such as dayrooms and bulletin boards, and were published in the Fort Benning, Georgia, Infantry newsletter.

The study physicians, in coordination with the military unit chain of command, briefed interested individuals by company at unit gatherings and/or individually, if necessary, as to the study's design and risks involved. The study physician(s) then left the room allowing the individuals to interact and ask questions of the ombudsman (a disinterested medic or nurse from the local hospital or Troop Medical Clinic). The ombudsman served as a participant advocate and was available to the participants throughout the course of the study. Individuals wishing to participate were asked to give their contact information to their chain of command or to contact the study group.

The study physicians were provided this contact information and scheduled a time with the interested volunteer during which time a medical record screening and individual focused history were conducted (Note that an attorney of the Ft. Benning Staff Judge Advocates Office [A. Norfolk, personal communication, December 17, 2004] advised that there is no legal objection to the review of a volunteer's medical records by a medical officer during a medical screening as long as the volunteer provides his consent and is present during the screening). The study physician received the appropriate medical record from the servicing facilities medical records clerk and returned them immediately following the medical screening. No protected health information was obtained from subjects or from their medical files prior to obtaining written consent from the subjects. All subjects filled out a DA Form 5006, Authorization for Disclosure of Information.

During the medical screenings, those soldiers consenting to a medical records review and electing to volunteer were supplied with a medical history questionnaire. Individuals with no history of any of the exclusion criteria (listed in the next section) and who were not acutely ill were deemed qualified for participation. Those deemed qualified by the study physician were randomly assigned a subject number, given an informed consent form to complete and be scheduled for a study date. Applicants were provided with a toll free number to report any change in health status that might occur following the screening and prior to study date.

TESTING PROCEDURES

Subjects were instructed to report to a designated meeting room on Monday of week one at 0700 hours. As per a set schedule they were briefed a second time about the

experiment and the extent of their participation. Each individual met with a study physician investigator or his designee (flight surgeon/medical officer) to ensure that they were fit to fly. Once group assignments were made, each volunteer was instructed when to return (day and time) to participate in the testing and flight. On the designated day and time, scopolamine patches or placebo patches were applied. Following placement of patches, baseline measures on the postural balance assessment, PVT, PC3, and MSQ were obtained. All participants received the same lunch meal to include a non-caffeinated beverage. On schedule, promethazine/caffeine, meclizine, or placebo capsules were given. Subjects were fitted with the Reliefband® and given either correct or placebo instructions on usage. When given correct instructions, the face of the Reliefband® was placed on the palm side (palmar or under side) of the wrist. When given incorrect instructions, the face of the Reliefband® was placed on the non-palm side (volar or top side) of the wrist. Preflight preparations were made at this time with subjects briefed and prepared for aircraft flight. A USAARL research aviator provided a preflight safety briefing and ensured ID tags and uniforms were properly worn for flight (sleeves down). The Reliefband® were turned on during the safety briefing and kept running until final post-testing was completed.

Volunteers were then loaded into the aircraft at the scheduled time for the group. Seating was arranged in a semi-random order. The order ensured that, by the conclusion of the data collection phase, two volunteers from each treatment group were seated in each of the eight available positions. The flights began approximately 2.5 hrs after the end of lunch. A flight medic accompanied the volunteers on each flight and the physician investigator remained in constant contact on the ground.

Immediately following flight termination post-flight measures on all tests were collected. There were four test stations. Volunteers spent approximately five minutes at each test station. The tests were administered in a round robin fashion. For example, subjects one and two started at test station one where they performed the PVT (Figure 4).

Figure 4. Volunteers performing the Psychomotor Vigilance Test (PVT).

Following PVT completion, they moved to station two where they performed the MSQ (Figure 5) and then moved to station three where they performed the PBA. Finally, the subjects ended with station four where they performed the PC3. Using this testing order and the semi random seating arrangement described above, each treatment group had four volunteers begin testing at each of the various stations.

Figure 5. Volunteers performing the Motion Sickness Questionnaire (MSQ).

All volunteers were cleared to return to duty by the physician investigator or his designee. Any volunteer who reported motion sickness symptoms greater than one SD (15 points) above zero on the Motion Sickness Questionnaire (MSQ) were kept at the test center and retested hourly until symptoms subsided and they were cleared by the physician investigator. Additionally, each subject was issued a "TravelJohn" emesis bag/urinal (Appendix E). These bags are specifically designed to absorb fluids and limit odors.

In the event that body fluids needed to be handled, universal precautions were used and in effect throughout the study. A dedicated biohazard container was made available on the flight line for each study flight. Disposal of any biohazard material was through the local medical facility. Contamination of aircraft surfaces were to be managed

according to standard aeromedical evacuation decontamination procedures. Of note, no body fluid contamination of the aircraft or study area occurred during the study protocol.

Due to the wide range of individual susceptibility to airsickness, subject recruitment and testing was scheduled to continue until the number of subjects completing both flights reaches the n of 64 (16 in each test group). An additional six subjects (10 percent of the total) were recruited initially to account for those who might withdraw during the study. A study cross-over design was used to ameliorate the differences in susceptibility to motion sickness due to demographics (i.e. age, personality type, level of aerobic conditioning) since subjects also served as their own controls. A subject might voluntarily withdraw from the study at any time, even during the flight. In the aircraft, each participant had a red flag card to indicate desire to terminate participation and were under constant observation by a flight medic. The flight medic would then notify the pilots of a volunteers desire to withdraw from the study. No in-flight withdrawals occurred during conduct of the study or in the between flight interval.

The flight profile was divided into two 15-minute segments. Between each of these segments, the helicopter passed over the start point on the runway (Appendix B). If a participant felt too sick to continue, the helicopter would land briefly, allowing the subject to disembark and be received by research staff. To minimize "sympathetic vomiting" by other passengers and aircrew, subjects who vomited would be left at the landing strip on the next available pass over the staging area. The flight was to continue after this brief pause, allowing the remaining participants to complete the flight. Subjects removed before the end of the flight would be allowed to recover sufficiently to take the four post-flight tests.

Chapter 6: Analysis

The preliminary means of data analysis used a two-factor model analysis of variance (ANOVA). Treatment group (promethazine, meclizine, scopolamine, and ReliefBand®) was the between-groups variable and the experimental sessions (treatment vs. placebo) was the within-subjects variable. Statistical significance set at an alpha level of .05 for all tests. The risk for type II error was nominally set at 0.2. Dependent variables from all performance tests were calculated as change scores: preflight scores minus post-flight scores. All statistical analyses were conducted using SPSS® 14.0.

Violations of normality and variance were assessed and appropriate measures taken to apply the correct statistic testing parameters. Alternative approaches to the ANOVA test were used depending on initial statistical evaluation of collected data sets. Given the nature of the non-normal distribution of the data from the MSQ, the non-parametric Wilcoxin Signed Ranks Test for the before versus after samples was determined to be the more appropriate statistical test to use to analyze this data. This was done within each treatment group.

RESULTS

Analyses found no statistically significant differences between the four treatment groups. However, within-subjects differences were observed and are described below.

Motion Sickness Questionnaire (MSQ)

The 28 responses on the motion sickness questionnaire (Appendix C) were automatically scored by computer. The variables used from this test include scores for nausea, oculomotor disturbance, disorientation, and a score for total motion sickness

symptom severity. Nausea scores are derived from the self-assessments of general discomfort, increased salivation, sweating, nausea, difficulty concentrating, stomach awareness, and confusion. Oculomotor disturbance scores are derived from self-assessments of general discomfort, fatigue, headache, eyestrain, difficulty focusing and concentrating, and blurred vision. Disorientation scores combine reports of difficultly focusing, nausea, fullness of the head, blurred vision, dizziness with eyes open and/or closed, and vertigo. The total symptom severity score is the aggregate of all of the symptoms.

Because distribution was not normal, the nonparametric Wilcoxon Signed Ranks Test for two related samples was used to analyze the data.

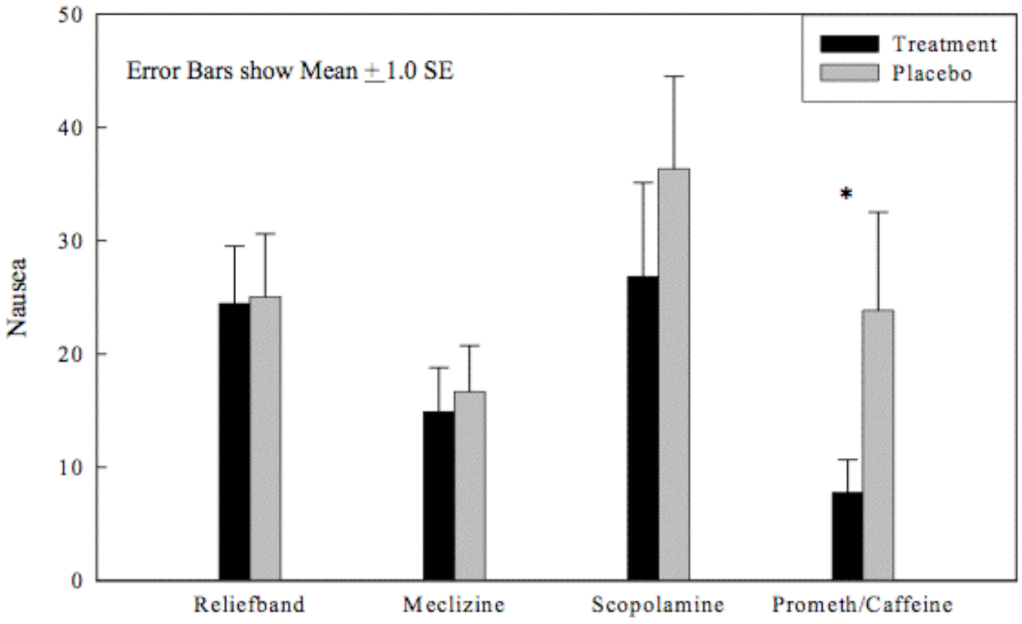


Figure 6. Nausea scores (* indicates statistically significant difference).

The tests revealed that the promethazine-caffeine combination was the only treatment to produce a statistically significant reduction of symptoms in any of the MSQ

variables as compared to its placebo treatment as seen in Figure 6 above. The results indicated a reduction in nausea score ($p = .010$) in the promethazine/caffeine combination group. Additionally, only the promethazine/caffeine combination group showed a statistically significant reduction ($p = .033$) in the total symptom severity score as shown in Figure 7 below.

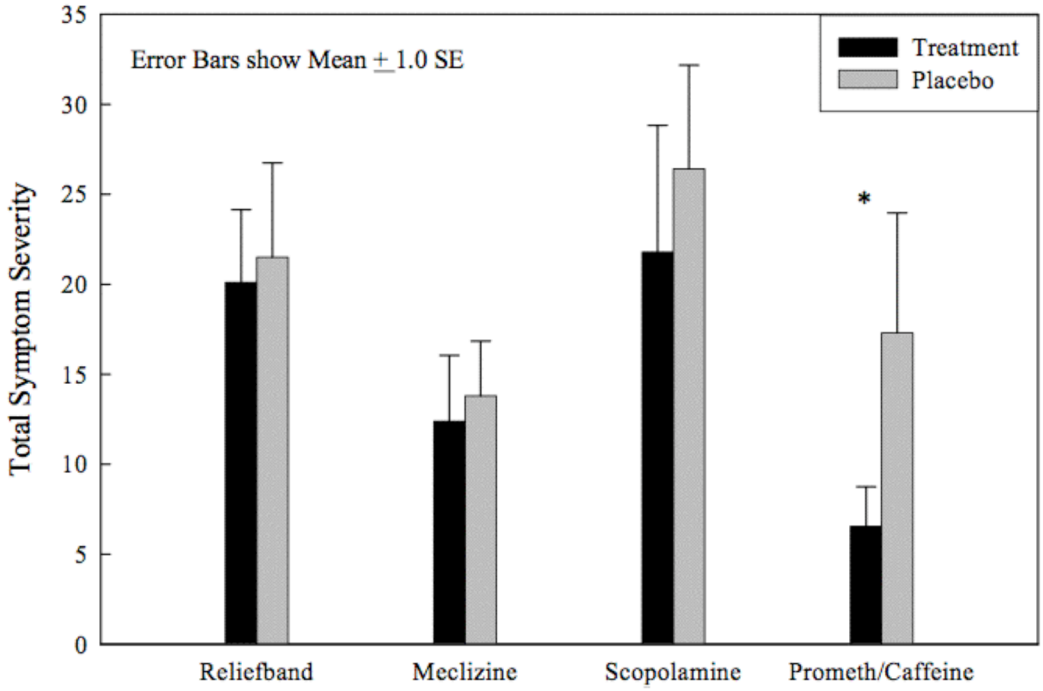


Figure 7. Total Symptom Severity scores (* indicates statistically significant difference).

Psychomotor Vigilance Test (PVT)

The reaction time was recorded for each PVT stimulus and was analyzed in two ways: the mean of the reaction times and the number of reaction times greater than 500 milliseconds (PVT lapses).

The Wilcoxon Signed Ranks Test was used to analyze the PVT lapse data because of non-normal distribution of the data. Two measures (ReliefBand® and Meclizine) achieved statistical significance (Figure 8). Whereas some performance decrement would be expected in the active antihistamine drug group (Paul, MacLellan, & Gray, 2005; Kohl, et al., 1986; & Wood, et al., 1990), surprisingly the group using ReliefBand® in the active condition also revealed an increase in the number of reaction times greater than 500 milliseconds (i.e. lapses) compared to those wearing its placebo control (p = .014).

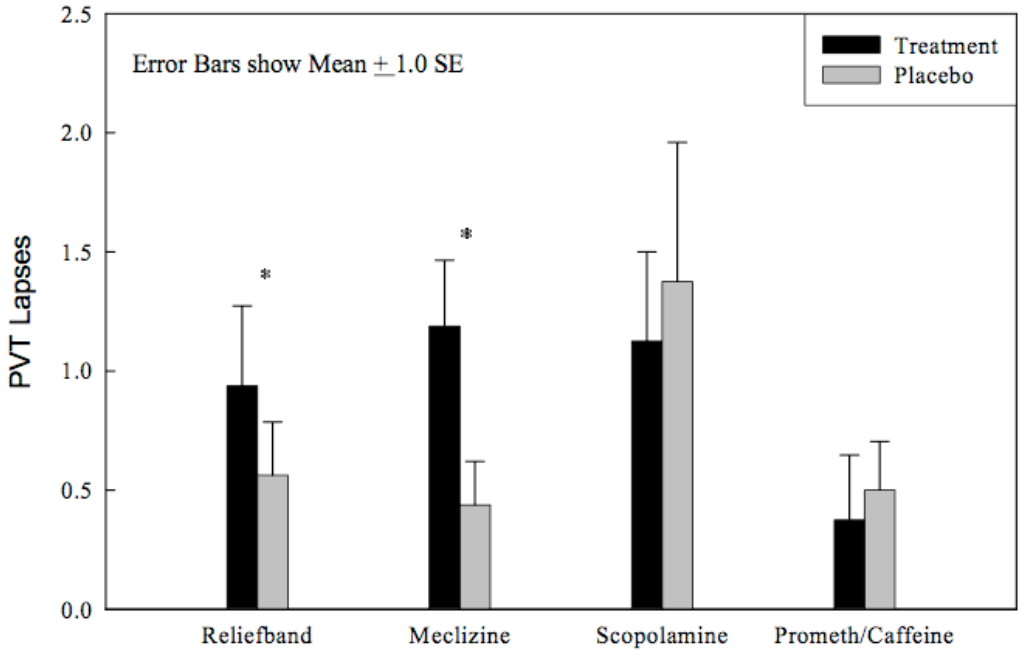


Figure 8. PVT lapses (* indicates statistically significant difference).

Analysis of the mean PVT Reaction Time data (Figure 9) revealed a significant improvement in the combination promethazine-caffeine group over placebo (p = .030). These findings mirror those of previous studies by Kohl, et al., (1986) and Paul, et al.,

(2005) in which the addition of a sympathomimetic pharmaceutical agent was shown effective in counteracting the somnolent side effect profile of the given anti-motion sickness agent.

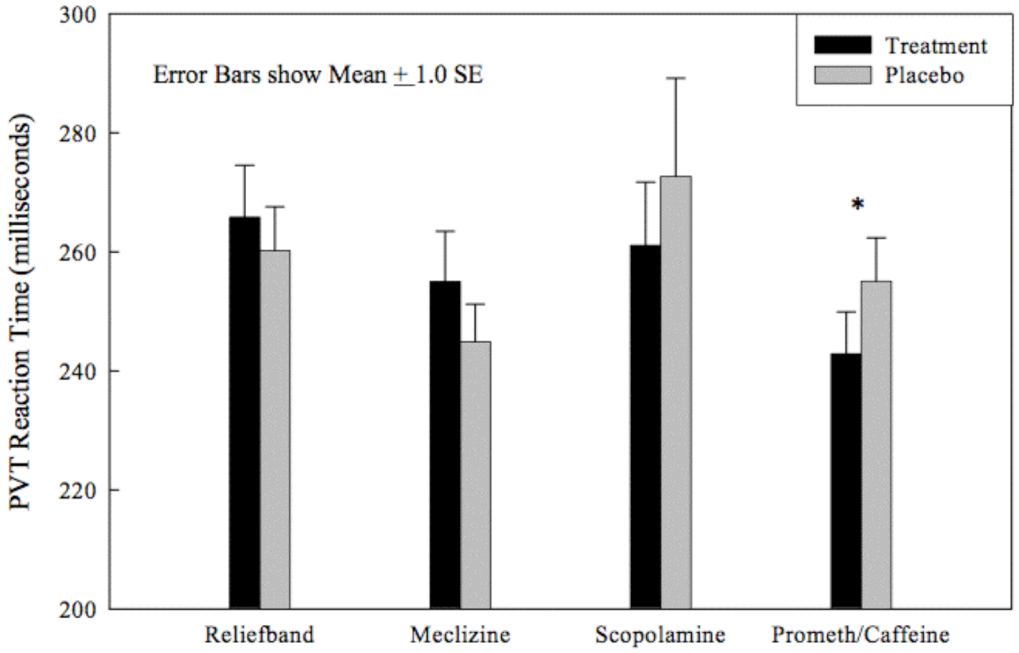


Figure 9. PVT reaction times (* indicates statistically significant difference).

Postural Balance Assessment (PBA)

Because the distribution was normal, the data from each variable were analyzed using paired samples t-tests. The two-tailed t-tests revealed that none of the motion sickness treatments showed any statistically significant difference in any measures of the participants' postural stability when compared to its placebo.

Progressive Cognitive Capacity Checker (PC3)

As with the previous tests in which change scores were used for the analysis, the change scores derived from subtracting post-flight PC3 chance-corrected scores from preflight chance- corrected scores are compared in this analysis. Once again, the Wilcoxon Signed Ranks Test was used due to a lack of distribution normality. No treatment demonstrated a statistically significant improvement in cognitive performance over its placebo control.

Chapter 7: Discussion

The results of this study indicate that the promethazine-caffeine combination produced significant reductions in self-reported nausea, total motion sickness severity, and improved reaction times when compared to placebo. None of the other countermeasures, pharmacologic and non-pharmacologic, tested showed any beneficial effects on airsickness symptoms.

Although no between-groups comparisons achieved statistical significance, the consistency of promethazine-caffeine to produce beneficial results over the other countermeasures warrants mention. Interestingly, there were seven episodes of airsickness so severe that vomiting occurred during the flight. Of those, two subjects were on placebo, two were wearing active ReliefBands®, two had been administered active scopolamine patches, and one had been administered the meclizine dose. No one in the promethazine-caffeine group experienced vomiting.

One can reasonably infer that the promethazine-caffeine countermeasure was the reason for the improved mean reaction time when compared to its placebo control. However, the reason for the increased number of reaction times greater than 500 milliseconds by active ReliefBand® users was initially puzzling. After conferring with the medical personnel involved in this study and reviewing the data collection procedures, it was noted that 15 of the 16 active ReliefBand® users were right-handed and used this hand to perform the PVT task.

MOTION SICKNESS AND PERFORMANCE

In his 2005 study, Introduction to and Review of Simulator Sickness Research, Johnson, citing Reason and Brand (1975) and Kennedy and Frank (1985), reports that motion sickness does not harm performance. Johnson contends that motivation is the reason that performance is not harmed and that motion sickness "does not impair one's capability to perform; it impairs one's proclivity to perform." He suggests that if an individual can be induced to perform, he or she will perform at an acceptable level. Johnson does not address how a task is characterized as performed at an acceptable level in the context of task complexity. Johnson's assertions may be true when the tasks are simple as in running or firing a weapon when chased by enemy troops. However, based on empirical observations during this study, some participants were so debilitated that even simple tasks such as running would not likely have been possible.

Parmet and Gillingham (as cited in DeHart & Davis, 2002) write that recent studies of the incidence of airsickness in United States and British military flight training found that 15 percent to 18 percent of student pilots experience motion sickness severe enough to interfere with control of the aircraft. In light of this, it can be argued that performance on tasks requiring higher order cognitive function or precision execution could be seriously compromised in personnel suffering from motion sickness.

FLIGHT PROFILE

It is apparent by the generation of motion sickness symptoms in the volunteer group that the flight profile (Figure 5 and Appendix B) employed to produce airsickness was effective. Of note, this author could not find any other published, standardized rotary wing in-flight protocol designed to elicit symptoms of motion sickness and thus

the profile designed by LeDuc and colleagues (1999) may be considered the gold standard for future rotary wing airsickness studies. A full range of symptoms (from asymptomatic to nausea to active vomiting) were produced during each flight. Future studies employing this profile could include the collection of objective measures of aircraft control and subject acceleration exposure.

ORDER EFFECTS

The research design used in this study controlled for order effects in that half of each randomly assigned countermeasure group (eight) experienced their first flight under placebo, while the other half experienced their first flight under treatment. For assurance, however, a multivariate analysis was conducted on the post-flight scores of the population with order as the factor and the results indicated that there was no evidence of order effects.

HEAT EFFECTS

The data collection flights for this study were conducted in June 2005 at Lawson Army Airfield (LAAF), Fort Benning, GA. Temperatures experienced during the two weeks of the research flights ranged from 88º to 102º F. According to the United States Department of Commerce National Climatic Data Center (NCDC) the conditions in June 2005 encountered were similar to those experienced in Iraq (85º to 95º F). In order to determine whether the ambient heat affected the results, the heat index was chosen as a factor for analysis. According to the NCDC the heat index (or apparent temperature) is a measure of the contribution that high temperature and high humidity (expressed either as relative humidity (RH) or dew point temperature) make in reducing the body's ability to

cool itself. In other words, it is a measure of the temperature the body feels when heat and humidity are combined.

The heat index of each test day's 1.5-hour flight period (1330 – 1500 hours) was recorded. The indices were provided by the Air Force Weather Station located at LAAF. An ANOVA was performed of all performance data using heat index as a continuous variable. Results indicated that there were no statistically significant differences between the performance measures of the treatment groups for any of the test days and thus, no apparent heat-related effects.

SYMPATHETIC VOMITING

Post study review of all the in-flight videotapes revealed that no subject sitting next to or even near a vomiting participant vomited during any flight. In addition, no participant reported, either verbally or in writing that he vomited due to a sympathetic response. The use of colloid gel-filled disposable (TravelJohn™) female urinals as odorless emesis bags may have contributed to the control of a potentially confounding factor by limiting/reducing olfactory stimulation induced symptoms.

LIMITATIONS

The limitations of this study are the level of measurement of the data itself, the study population limitations (male, 18-34 years old), and the tests used to measure the desired outcomes. Optimally, use of data sets that are at the level of measurement of ratio (distance, age, time, weight, etc.) would be desired. Following ratio measurements, interval (calendar years, intelligence quotient, degree Fahrenheit/Celsius, etc.) level of measurement would be preferable over ordinal data (manual muscle test results, functional status, pain scale, etc.) This study uses a combination of interval and ordinal

level of measurement data that may be skewed beyond a normal distribution pattern that will require non-parametric statistical analysis. Future studies could be designed to take advantage of ratio and interval level of measurement data to overcome some of these issues.

The study population made this study narrowly applicable to a general population and must be considered prior to making conclusions and/or recommendations based upon the study results. The procedures and tests used herein have been used in prior, similar studies, but one must consider that it is possible that the tests employed in this study have not accurately measured the outcomes desired.

IMPLICATIONS

The implications for finding support for this study entail the possibility of making recommendations either for or against current countermeasures for rotary wing induced motion sickness. Alternatively, the implications for not finding support for these studies results would not negate the findings from previous studies but may serve as a basis for improvement on future studies and/or indirectly validate the findings of other investigations. It must be stated that the results of this study may only be valid for a very narrowly defined population but may serve as the basis for further investigation of the effects of countermeasures used for prevention and treatment of motion sickness.

Chapter 8: Conclusions

According to United States Army Aeromedical Policy Letter (1997), the current motion sickness treatment for aircrew members is either promethazine (25 mg) combined with ephedrine (25 mg) or L-scopolamine hydrobromide alone or in combination with dextroamphetamine. These are allowed for up to three occasions for flight candidates. However, there is no comparable guidance for non-aircrew passengers. Data from this study indicate that, of the countermeasures tested, promethazine plus caffeine is the most effective at reducing airsickness with minimal adverse side effects for helicopter passengers. The most common side effects of promethazine are sedation, sleepiness, occasional blurred vision, and dryness of mouth.

However, the reason for the increased number of reaction times greater than 500 milliseconds by active ReliefBand® users was initially puzzling. After conferring with the medical personnel involved in this study and reviewing the data collection procedures, it was noted that 15 of the 16 active ReliefBand® users were right-handed and used this hand to perform the PVT task. All members of this test group wore the ReliefBand® on their right wrists and thus, experienced thirty-plus minutes of acustimulation to the Neiguan acupoint (pericardium 6 or P6) of their right hand. The acupoint P6 is located on the inside of the wrist (approximately 3 cm above the wrist on the volar surface of the forearm) and is thought in traditional Chinese medicine to relieve nausea and vomiting (Kouzi, 2003). Although the mechanism of [acustimulation] at the P6 point is undetermined, effects may be secondary to stimulation of the median nerve (Rosen, et al., 2003). It is possible that the prolonged stimulation of this nerve produced

neuromuscular fatigue causing slower response times of the thumb flexors (hypothenar muscle group). According to aviation medical subject matter experts J. Campbell (personal communication, February 09, 2006) and R. Taarea (personal communication, February 10, 2006) this hypothesis was agreed to be a plausible explanation for this observation.

Additionally, the lack of significant effect of previously proven motion sickness remedies is surprising. The addition of caffeine or dextroamphetamine to the scopolamine and meclizine treatments might alter the results. A recent study of motion sickness medications by Paul, MacLellan, and Gray (2005) reports that "relative to placebo, promethazine, meclizine, and promethazine plus pseudo-ephedrine impaired performance" on all four of the metrics (tasks) used in the study. They concluded, "Only promethazine plus d-amphetamine [dextroamphetamine] was free from impact on psychomotor performance and did not increase sleepiness." It is apparent from their report and other studies that promethazine is effective as an antiemetic, but requires the counterpart of a stimulant to counteract its adverse side effect: drowsiness. This study demonstrates that caffeine can serve as the stimulant counterpart and when compared to d-amphetamine, is perhaps more appealing, as it is available without a prescription, is relatively inexpensive, and has minimal potential for undesirable side effects and addiction.

RECOMMENDATIONS

Given the results of this study the author(s) suggest that the use of promethazine plus caffeine is a safe and effective countermeasure that does not appear to produce notable performance decrements. This advice complies with the current United States

Army Aeromedical Policy Letter (1997) that the use of any motion sickness remedies with potential adverse effects on performance should be closely monitored by unit medical personnel and the chain of command. We recommend that further testing and research of other treatments (drug and non-drug) be continued in order to provide the user with the most effective airsickness countermeasures. Specifically, it would be useful to assess, using methods similar to those employed in the present study, other known motion sickness remedies in combination with caffeine, as well as novel approaches that stabilize the retinal image in various ways (Reschke, Somers, & Ford, 2006).

Appendix A: Flight Profile

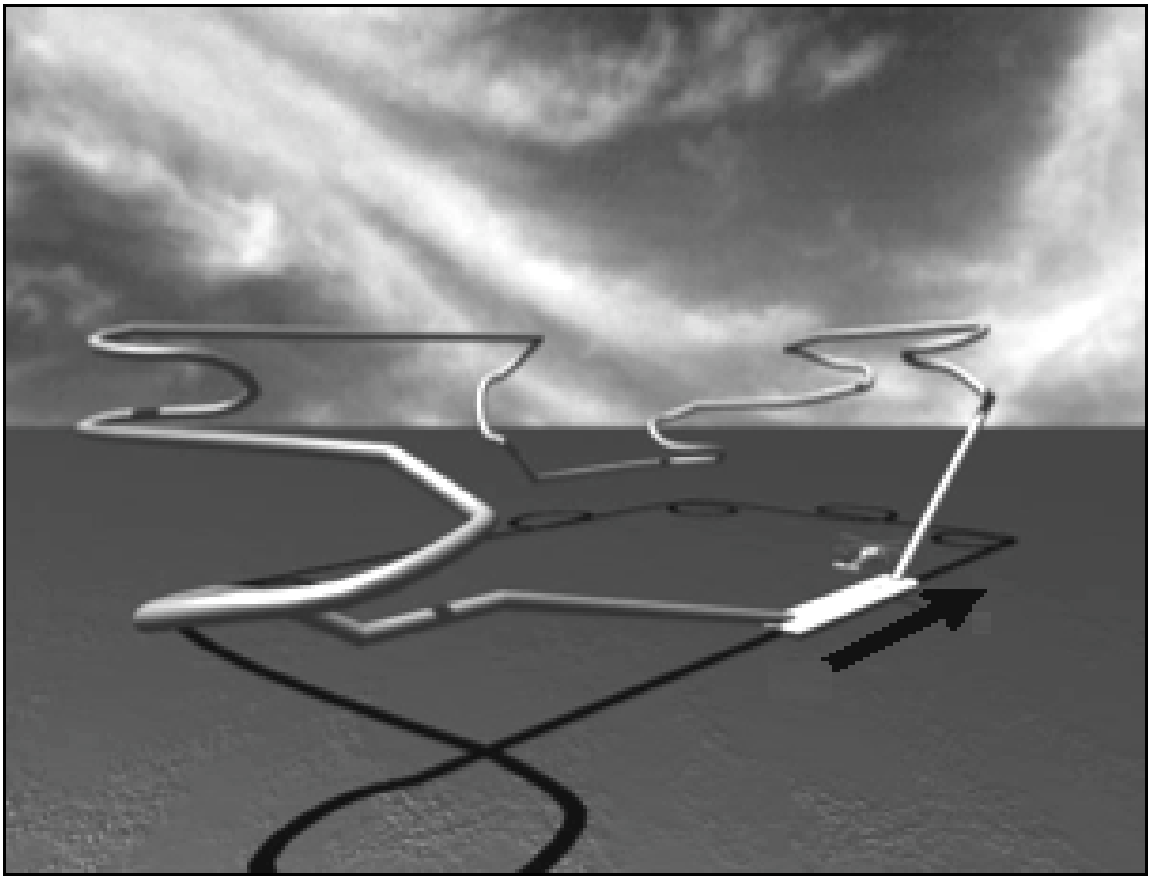
Man #	Maneuver Description	Headings	Altitude (FEET)	AS
Notes:	Ensure blackout curtains are in place.	n/a	n/a	n/a
	Turn SAS – OFF before takeoff.	n/a	n/a	n/a
1	Straight Climb (Upwind) – Allow acft to PR&Y with inputs	Hdg 030 or 210	0' AGL →1000' MSL	0→80
2	LCT (450 degrees to Crosswind) –Vary climb rate	Hdg 030 or 210 →Hdg 300 or 120	1000' MSL →1500' MSL	80
3	RDT (360 degrees) –Vary descent rate	Hdg 300 or 120 →Hdg 300 or 120	1500' MSL →1000' MSL	80
4	LDT (450 degrees to Downwind) –Vary descent rate	Hdg 300 or 120 →Hdg 210 or 030	1000' MSL →500' MSL	80
5	RCT (360 degrees) –Vary climb rate	Hdg 210 or 030 →Hdg 210 or 030	500' MSL →1500' MSL	80
6	Straight Flight (Downwind) –Allow acft to PR&Y with inputs	Hdg 030 or 210	1500' MSL	80
7	LDT (450 degrees to Base) –Vary descent rate	Hdg 210 or 030 →Hdg 120 or 300	1500' MSL →1000' MSL	80
8	RDT (270 degrees to Final) – Vary descent rate	Hdg 120 or 300 →Hdg 030 or 210	1000' MSL →500' MSL	80
9	Straight Descent to touchdown –Allow acft to PR&Y with inputs	Hdg 030 or 210	500' MSL →0' AGL	80→0

Note: Repeat two times.

Flight Profile Glossary

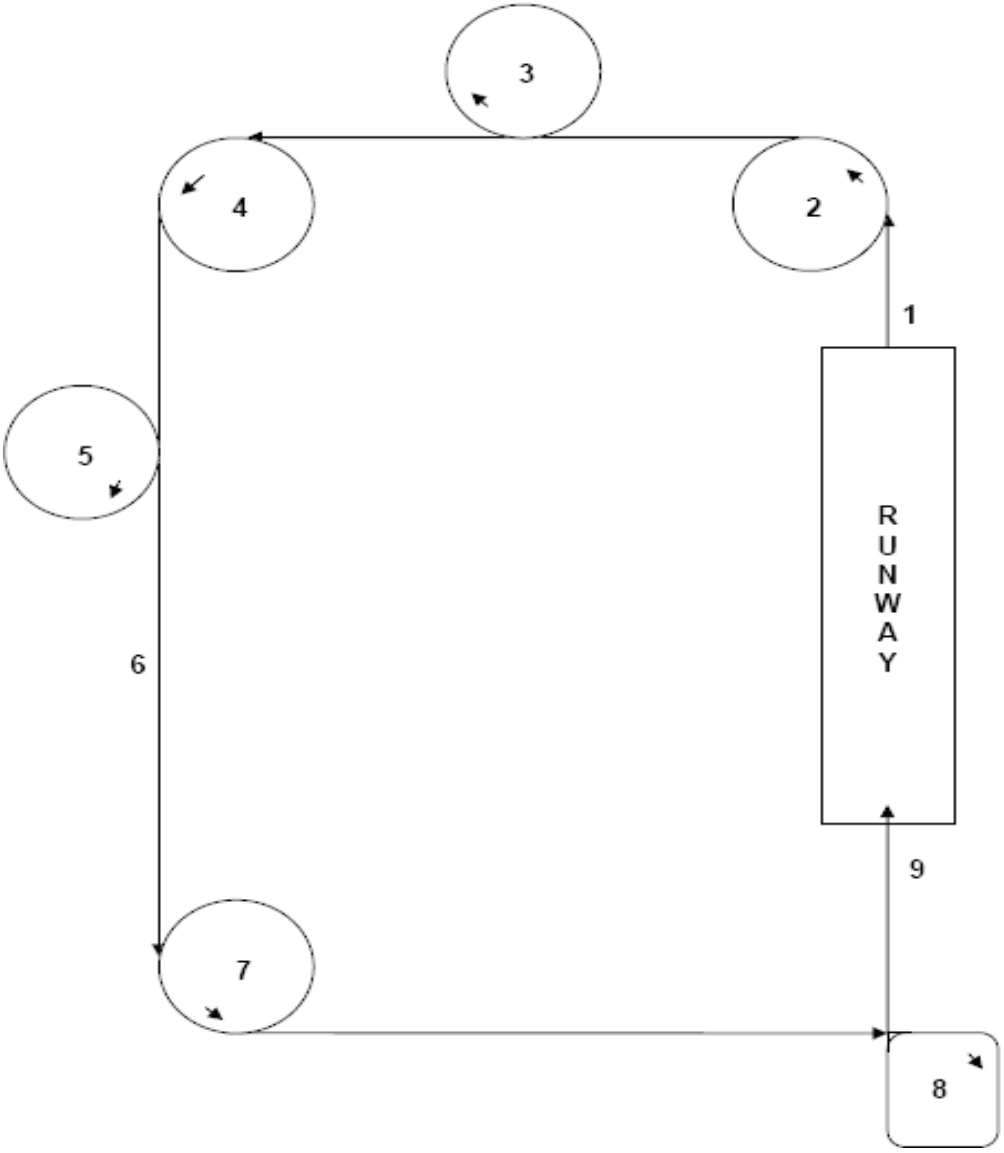
AGL – Above ground level
AS – Air Speed
Hdg – Heading
LCT – Left climbing turn
LDT – Left descending turn
MAN – Maneuver
MSL – Mean sea level
PR&Y – Pitch, roll, and yaw
RCT – Right climbing turn
RDT – Right descending turn
SAS – Stability Augmentation System

Appendix B: Three Dimensional Representation of Air Sickness Prevention Flight Profile



Note: Arrow denotes direction of flight

Appendix C: Two Dimensional Representation of Air Sickness Prevention Flight Profile



Note: Two iterations per flight

Appendix D: Motion Sickness Questionnaire

For each symptom, please circle the rating that applies to you **RIGHT NOW**.

	1	2	3	4
General discomfort	None	Slight	Moderate	Severe
Fatigue	None	Slight	Moderate	Severe
Boredom	None	Slight	Moderate	Severe
Drowsiness	None	Slight	Moderate	Severe
Headache	None	Slight	Moderate	Severe
Eye Strain	None	Slight	Moderate	Severe
Difficulty focusing	None	Slight	Moderate	Severe
Increased salivation	None	Slight	Moderate	Severe
Decreased salivation	None	Slight	Moderate	Severe
*Sweating	None	Slight	Moderate	Severe
Nausea	None	Slight	Moderate	Severe
Difficulty concentrating	None	Slight	Moderate	Severe
Mental depression	No	Yes		
"Fullness of the head"	No	Yes		
Blurred vision	No	Yes		
Dizziness with eyes open	No	Yes		
Dizziness with eyes closed	No	Yes		
Vertigo	No	Yes		
**Visual flashbacks	No	Yes		
Faintness	No	Yes		
Aware of breathing	No	Yes		
***Stomach awareness	No	Yes		
Loss of appetite	No	Yes		
Increased appetite	No	Yes		
Desire to move bowels	No	Yes		
Confusion	No	Yes		
Burping	No	Yes		
Vomiting	No	Yes		

Other: please specify_____

_____

* Sweating "Cold sweats" due to discomfort not due to physical exertion.

** Visual flashback – Illusion of movement or false sensation similar to aircraft dynamics when not in the simulator or aircraft.

*** Stomach Awareness – used to indicate a feeling of discomfort just short of nausea.

Appendix E: Manufacturer's List

ReliefBand® Device
Abbot Laboratories
Abbott Park, Illinois
847-937-6100
http://www.abbott.com

Psychomotor Vigilance Test Device (PVT-192)
Ambulatory Monitoring, Inc.
731 Saw Mill River Road
PO Box 609
Ardsley, NY 10502
800-341-0066
http://www.ambulatory-monitoring.com

TravelJohn™ Disposable Urinal
Reach Global Industries, Inc.
30 Corporate Park, Suite 107
Irvine, CA 92606
888-518-8389
http://www.traveljohn.com

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VITA

Shean Eric Phelps was born in Lubbock, Texas, United States of America, on December 26, 1961, to MSgt Richard Frank Phelps and 1st Lt Martha Irene Abeyta-Phelps. He enlisted in the United States Army in May 1981 and served ten years as a Special Forces senior non-commissioned officer before being selected to attend the Reserve Officer Training Corps program at Campbell University, Buies Creek, North Carolina where he graduated with a Bachelor's Degree in Biology in May 1992. He completed a structural chemistry internship with the X-ray Crystallography team at Glaxxo-Wellcome Pharmaceutical Corporation, Research Triangle Park, North Carolina prior to attending the Uniformed Services University of the Health Sciences, F. Edward Hébert School of Medicine, in Bethesda, Maryland. Upon graduation in May 1996, he attended Family Practice residency training at Fort Benning, Georgia from June 1996 to July 1999. After graduation from residency, he served as clinic commander in Friedberg, Germany (1999 to 2001); performed dual roles as Battalion and Command Surgeon for the 1st Battalion, 10th Special Forces Group (Airborne) & United States Special Operations Command-Europe, respectively, in Stuttgart, Germany (2001 to 2003); and taught at the Family Practice residency training program at Fort Benning, Georgia (2003 to 2005). In the spring of 2005, he was selected to attend the University of Texas Medical Branch Masters of Public Health degree program as part of a second residency. He is finishing Aerospace Medicine residency training at the Naval Aviation Medical Institute at Naval Air Station-Pensacola, Florida. He has two children, Brenna Michelle and Jonathan Patrick, with his spouse, the former D'Lynn Michelle Stoehr.

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Summary of Capstone

Airsickness, also known as "motion sickness" and/or "kinetosis", is a topic of serious discussion in the aviation community. Despite recent advances in medical science, aircraft engineering and performance, airsickness continues to result in unacceptable work force losses and incurs significant costs to both the civilian and military sector.

Symptoms of motion sickness range from mild to incapacitating in nature and can cause degradation in performance measures of reaction time, postural stability and cognitive functioning. Current pharmacological interventions may produce undesirable side effects such as sedation, diminished cognition and reduced performance of critical duties and tasks amongst aircrew and passengers alike.

Recent studies evaluating non-pharmacological interventions have been reported to be effective in the suppression of the major symptoms (nausea and vomiting) of motion sickness. The commercially available Reliefband® is designed to provide electrical acustimulation at the P6 point thereby reportedly countering symptoms of chemotherapy-induced nausea and vomiting and is openly marketed as "the only FDA-cleared device for motion sickness". Neither currently available pharmacologic nor Reliefband® treatment has been fully studied in conjunction with rotary wing operations.

This capstone describes the author's participation as a researcher in the conduct of a randomized, double blind, placebo control, cross-over study comparing the effectiveness of four airsickness countermeasures (three pharmacologic, one non-pharmacologic) on reaction time, postural stability, and cognition in relation to airsickness symptom severity and their ability to ameliorate performance declines following simulated rotary wing combat operations. The resultant data suggest that only the combination of phenergan with caffeine was effective in achieving these measures.

The aim of this study is to enable the aerospace medical community to make viable recommendations to military commanders and civilian policy makers concerning the ability and efficacy of both pharmacologic and non-pharmacologic treatments in mitigating performance decrements seen due to rotary wing flight induced motion sickness.

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