Developing Individualized Ground Testing Protocols for Use of Sleep Medications in Spaceflight

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by

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Developing Individualized Ground Testing Protocols for Use of Sleep Medications in Spaceflight

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Dedication

This is dedicated to the numerous people who have helped me throughout my career. The first person I would like to mention is my father, the late Dr. Kirit Kumar Purohit who has always been a role model for me in medicine and in life. I would also like to thank my mother Mrs. Kumud Purohit, who has always supported me ever since I was a child. I would also like to thank my brother, Mr. Ketan Purohit and his wife, Mrs. Ashley Pace Purohit who have always helped to keep me on this career path, even when I thought about qutting. I need to thank my favorite professor from college, Dr. Patricia Buckendahl, who got me interested in research, space flight and life sciences. I would also like to mention my favorite attending from medical school, Dr. John Pino, who taught me there is more to being a physician than just medical treatment and diagnosis. There are so many other people who have helped me throughout my career and I know that I can never thank all of them individually. The people that have helped me know who they are, but there is not enough space to thank each person individually.

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During spaceflight, sleep time are markedly reduced for astronauts. Sleep medications are used by astronauts during space mission for sleep. Spaceflight is an environment where abrupt alarm awakening is always a possibility and during that time high cognitive function and performance may be needed to prevent loss of life of crew. Zolpidem has been used on spaceflight after ground testing. The medication has been tested and studies have shown few side effects after a complete night of sleep. Few studies have been done on abrupt awakening after taking this medication. This study was done to test the effects of this medication on abrupt awakening after taking this medication and comparing to placebo. Seven subjects were selected and tested over two nights, one night with zolpidem and one night with placebo. Using a randomized single blind crossover design and testing cognitive function using a standard battery of computer based tests. Subjects were abruptly awakened after 2 hours of taking placebo and zolpidem. Subjects were videotaped, wore an actigraph and completed standard tasks and computer based testing bouts. When compared to placebo, on the night subjects were given zolpidem, subjects showed greater delay to alarm shut off, increased lapses of attention, and a large amount of variation between subjects. Actigraphy and video tape data correlated with the results of the computer based testing. Actigraph data also showed that subjects had similar average amounts of sleep with placebo and zolpidem. This study was not a traditional sleep study, it was operational study with practical testing of abrupt awakening and its effect on cognitive function. This study also provides evidence in support of developing a practical, individualized ground-based protocol for evaluating the cognitive performance deficits of sleep medications commonly used in spaceflight by NASA astronauts. The results of this study can be applicable to other fields where fatigue and sleep are an issue (military, shift work, etc). This protocol can also be used to test alertness medications in a similar way.

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CHAPTER 1

INTRODUCTION

During spaceflight, sleep times can be markedly reduced. Astronauts on space shuttle missions have averaged six hours or less of sleep in a 24 hour period (Gundel et al. 1997). Sleep medication has been used on space flight missions to promote sleep (Mallis et al. 2005). Terrestrial studies have shown that residual effects of these medications after a night's sleep are minimal (Hindmarch et al. 2001; Drover 2004).

Few studies have examined the effects of sleep medication compared to placebo on cognitive performance after abrupt awakenings. Space flight is a high risk environment with the possibility of alarm awakening and the need to perform critical duties (Thirsk et al. 2009). Due to this possibility and the use of sleep medications in space flight, a need exists for characterizing and mitigating the risk of cognitive impairment for astronauts, and providing each astronaut an individualized recommendation related to medications and dosages.

Informal ground testing of sleep medications in space crew members has been done in the past and serves as a useful aspect of the training experience. This research project will evaluate the response to an abrupt awakening while varying medication and dosage. It will also help in a practical way to inform individual astronauts and flight surgeons of optimum medication and dosage to use in operational environments.

The medications most commonly used for sleep initiation and the treatment of insomnia are zolpidem (Ambien), zaleplon (Sonata), eszopiclone (Lunesta), and ramelteon (Rozerem). Ramelteon is a melatonin receptor agonist used for the treatment of insomnia. The other commonly used medications stated are classified as non-benzodiazepine hypnotics. Zolpidem is

an imidazopyridine which acts as an alpha 1, GABA A receptor agonist. Zaleplon is a pyrazolopyrimidine which also acts as an alpha 1, GABA A receptor agonist. Eszopiclone is a pyrrolopyrazine which acts as a GABA receptor agonist. These hypnotic medications have been studied in clinical and operational environments and have been used safely for sleep onset with minimal side effects after a restful night of sleep. The safety margin with using these medications comes from their relatively short half-lives and lack of effects after an eight hours sleep period (Caldwell et al. 2005).

Before safe operational usage of a hypnotic sleep medication can be assured, testing must be done in a manner similar to its use in spaceflight. This brings up the concept of utilizing analog environments for studying the potential space flight behavioral health and performance risks. In our study, the analog for space flight was the crew quarters at the National Aeronautics and Space Administration (NASA) Johnson Space Center (JSC) in Houston, Texas also known as the Astronaut Quarantine Facility (AQF). Using this analog environment, the effects of sleep medication on abrupt awakening can be studied. This was done by observing the performance effects of sleep medication on abrupt awakening in comparison to placebo. This information can then be used to determine optimal medication and dosage for each individual.

CHAPTER 2

SPECIFIC AIMS

The goal of this study is to develop a practical, individualized ground-based protocol for evaluating the performance decrement produced by a hypnotic sleep medication commonly used in space flight, zolpidem (Caldwell et al, 2005). This protocol includes an educational component and will serve as standard operating procedure for astronauts in future space flight missions.

The aim of the study is to test the hypnotic medication most commonly used by astronauts for promoting sleep in spaceflight. This will be accomplished by determining the individual astronaut performance change from the sedating effects of the hypnotic upon abrupt termination of sleep (during the eight hour sleep period). The key question is to determine if there is a change in performance that is different from sleep inertia, and if the impact of that change in performance is clinically important and statistically significant. This information would be important to develop best practice protocols for medical operations.

A second goal is to develop an educational briefing for flight surgeons and astronauts on sleep and fatigue-related problems during spaceflight. This can be accomplished through performance testing and videotaping subjects on medication and placebo and showing the recorded evidence of performance. Since each individual has a slightly different reaction to the medications (Caldwell et al. 2009), the goal is to individualize medication selection and dosage to optimize effects.

The specific aims in this study are related to operational testing of a sleep medication. This is different from a formal sleep study in a sleep lab. While information from a formal sleep

study may be useful from a research and medical perspective, it may not necessarily be useful information in an operational setting. The goal in this study is to use the real world simulation of an abrupt awakening and cognitive and performance measures to determine appropriate medication and dosage in an operational setting. By informing subjects and their physicians of the objective decrease in performance with the treatment compared to placebo, better medical decisions can be made.

CHAPTER 3

BACKGROUND AND SIGNIFICANCE

This study is designed to help answer questions related to hypnotic induced performance errors due to fatigue, sleep inertia, and medication effects. The first question this work will attempt to answer concerns the level of performance risks of specific hypnotic medications during flight. A related question this work will address is what are the best individual dosing requirement and protocols for hypnotic medications during spaceflight? This study will also help in developing countermeasures to prevent or mitigate adverse outcomes of human health and performance risks relevant to space flight. Relevant information will also be provided by this study to determine which hypnotic sleep medication is optimal for sleep during spaceflight with minimal residual effects for individual astronauts.

The results of this study will provide information to aid individual astronauts in choosing the optimal hypnotic sleep medication for training and spaceflight missions. The data will provide a base line for individuals that can be validated during future missions, and discrepancy between medication effect on the ground and in flight can be determined.

While the results of this study may benefit astronauts, there are implications for other populations. Military aviation uses sleep medication with its personnel as a treatment for sleep initiation (Caldwell et al. 2005). Military ground personnel may benefit from the protocol development because combat has become a continuous endeavor and performance after abrupt awakening may mean the difference between life and death.

CHAPTER 4

METHODS

The pilot study subjects included seven NASA flight surgeons. The study was conducted at the Astronaut Quarantine Facility (AQF) at NASA, JSC in Houston, Texas, under the direction of the principal investigator, Dr. Smith Johnston, a NASA Flight surgeon.

Participants served as their own controls in a paired comparison design (a randomized, single-blind, placebo controlled cross over design) that required participants to spend two nights in the AQF. This study was used to test the feasibility of the protocol. The order of the drug, non drug conditions was randomized and blinded so subjects did not know in advance whether drug or placebo was given.

An educational program was provided to all participants along with the ground testing. In addition, a questionnaire about sleep habits was administered prior to the scheduled two nights at the AQF. Approximately two to four days prior to the start of the study, participants were requested to complete two other short questionnaires: the Morningness/Eveningness Questionnaire and the Pittsburg Sleep Quality Index (PSQI). The Morningness/Eveningness Questionnaire provides information on an individual's sleep/wake cycle and the PSQI provides clinical reliability, validity, and standardized measure of sleep quality.

All participants wore an actigraph during their participation in the study in order to have objective data on sleep/wake behavior. An actigraph is a non-invasive wrist watch device used for monitoring rest and activity cycles. Participants were requested to wear the actigraph prior to participation in the study for 2-4 days prior to the start of the study in order to obtain baseline data on sleep/wake activity.

Performance measures utilized in the study included a 3 minute PVT Self Test, a 1.5 minute Digital Symbol Substitution Test, and a 2 minute Descending Subtraction Test. The 3 minute PVT Self Test assesses vigilant attention (both lapses and premature responses) and psychomotor speed. The PVT has been documented to be sensitive to sleep inertia and drug effects (Van Dongen et al. 2001). The DSST assesses cognitive throughput and speed, and has been accepted by the FDA as a measure of drug carry over effects. It takes approximately 1.5 minutes to complete. The 2 minute DST was developed specifically for measuring the effects of sleep inertia on working memory (Dinges 1993). All tests were conducted on a laptop computer programmed for test subject use, which will also contained a visual analog ratings scale for assessing fatigue, alertness, and mental sharpness. Seven computer based test bouts were completed by the subjects each night with three completed at the beginning of the evening, two completed after abrupt awakening, and two completed after awakening in the morning.

Each subject arrived at the AQF in the evening of their scheduled test nights. They ate dinner prior to arrival, and limited caffeine and alcohol intake for both test nights. Participants were told that "lights out" would be at 2330, when the standardized protocol was implemented. Blinded medication was provided to the subject at the time of lights out at 2330. In this study, all subjects were given placebo on one night and 10mg of zolpidem on the other night. The wake-up (with an alarm) was close to T max (time at which concentration is maximum in the body), which is approximately 2 hours after ingestion for zolpidem. At approximately 0130, participants were awakened by an alarm (similar to the emergency alarm system used in spaceflight). Each subject then performed a predetermined set of activities: (1) turn on room light, (2) turn on laptop, (3) check alarm status, and (4) phone mission control via intercom to inform them of the alarm/emergency status (see figure 4.1).

Upon awakening, room lights were turned on and maintained at an illumination similar to ISS during the testing periods. In addition, the awakening alarm and other background noise were similar to what occurs on ISS missions.

After contacting mission control, each participant completed a set of three performance tests requiring approximately 10-15 minutes on the laptop. A brief 1-2 minute questionnaire targeting self report of grogginess and fatigue was also administered via a programmed set of visual analogs on the computer. Participants were then told to read a book for 20 minutes then complete the same test battery. Participants then went back to sleep and were awakened with an alarm, at approximately 0630-0730, following a sleep period of approximately 5 to 6 hours (see figure 4.1). Upon awakening, participants again took the performance battery on the computer, waited twenty minutes, and then completed another bout of computer based testing.

After completion of the performance tests and the self report questionnaires, participants were provided breakfast and returned to the facility for a second night at the convenience of the subject, but within two weeks of the first night. During the second night of testing, the subjects repeated the procedures from the first night but with a different medication status.

A number of performance measures were obtained at each test bout. These included the mean latency to contacting ground control upon abrupt awakening to the alarm, mean psychomotor response speed (from the PVT), number of lapses of attention (from PVT), number of response errors (from PVT), change in subjective fatigue pretest to posttest, cognitive speed and throughput (from DSST), and waking memory speed and accuracy (from DST).

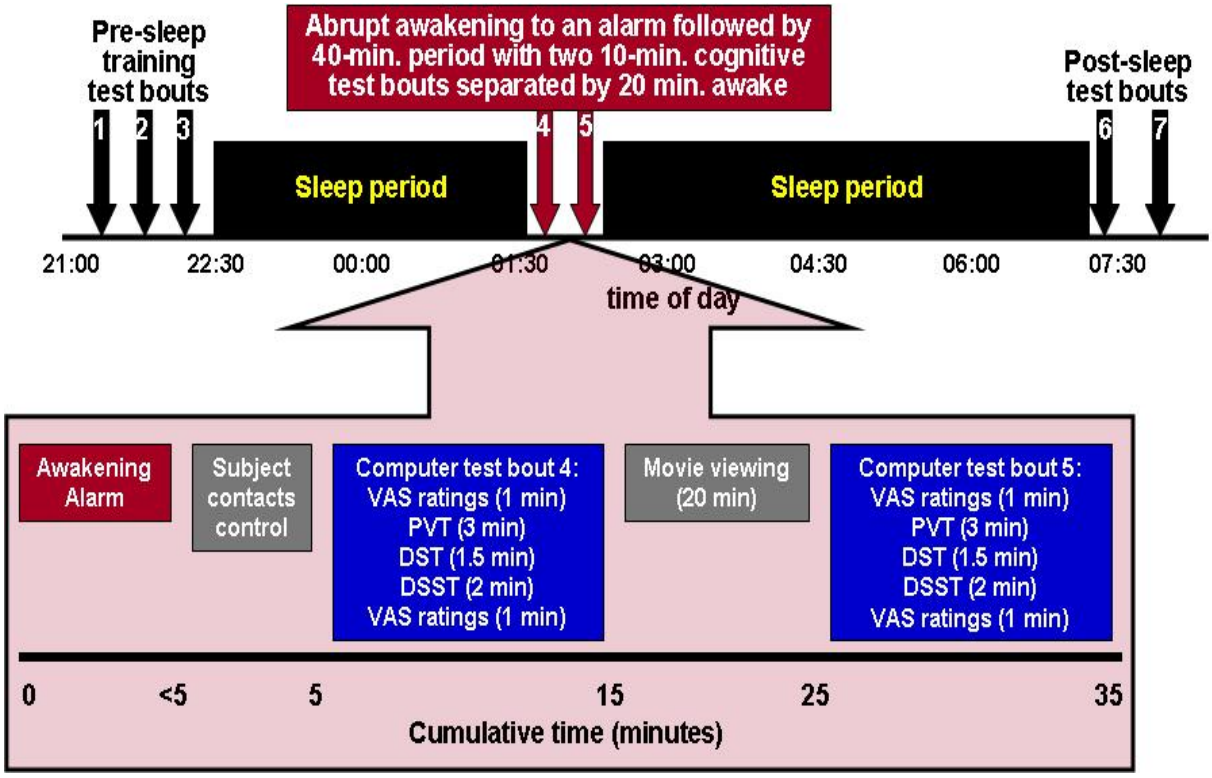
A camera recorded responses during alarm awakening and testing portions of the study (see Figure 4.2).The camera recorded the subject's entire stay in the observation room. These

recordings documented reaction responses to the alarm. A qualitative questionnaire was administered the morning prior to the subject's departure from the AQF. The subject was asked about the alarm and their memory of the testing. The subject observed the video of their awakening and commented on the response

All study participants were given the same hypnotic sleep medication and dosage – zolpidem 10mg. This was done in an effort to standardize the protocol and minimize confounding. Each participant was requested to sleep two nights (one on placebo and one on active medication in random order) at the AQF.

The study protocol was reviewed by the Committee for the Protection of Human Subjects of the NASA Institutional Review Board. Following the study, investigators managed all data. The data remained confidential, and data released to co-investigators did not have any identifying information. All data reported and presented was non-attributable, with no information associated to any individual.

FIGURE 4.1: Summary of Protocol



This figure shows a summary of the testing protocol. Included are the timing of the computer testing bouts, sleep periods and other tasks that needed to be completed. Also shown are the times of night when each task was scheduled to be completed [1] [2].

[1] Reprinted with permission from Dr. Smith Johnston from NASA/JSC

[2] PVT = Presistant Vigilence Test, DST = Desccending Subtraction Test, DSST= Digital Symbol Substitution Test

FIGURE 4.2: Example of Video Observations

This picture is an example of the video data that was collected for each subject for each night of the protocol. Subjects were recorded for their entire stay including abrupt awakening, test bouts, and while they slept[3].

[3] Reprinted with permission from Dr. Smith Johnston of NASA/JSC

CHAPTER 5

RESULTS

The effects of the hypnotic sleep medication were evaluated and compared within participants (each participant served as their own control). The primary comparison was the magnitude and time course of sedation effects on objective and subjective outcomes immediately after abrupt awakening while under the influence of the hypnotic compared with placebo.

Using this approach, the sedating effects of the hypnotic sleep medication were compared to the naturally occurring sleep inertia that follows abrupt awakening from sleep early in the night. This approach permitted a calibration of residual sedation relative to natural sleep inertia. If the hypnotic sleep medication produced residual effects on neurobehavioral outcomes that were different from the effects of natural sleep inertia from an abrupt awakening early in the night, the operational implications are considerable. In this case, a lower dosage or a different hypnotic should be explored. Alternatively, if residual sedation is no worse than natural sleep inertia, this has other operational implications. In this case, this information could guide a medical recommendation on usage of this medication.

After all subjects had completed the protocol, data were analyzed using standard statistical methods. In particular, a two tailed paired t-test was used to compare placebo to hypnotic. The video was reviewed and compared to results from the computer-based testing for each subject. The video reviewer was blinded to whether the subject was given placebo or hypnotic. The blinding was done to prevent bias in observations. Observations were recorded for beginning of night, abrupt awakening, testing bouts, and time sleeping and awakening in the morning. The video for each subject was also examined for any sleep disturbances and behaviors

during the entire testing process. After viewing video data for all subjects, the reviewer was told which night the subject was given placebo and medication.

Seven subjects completed the protocol. Of these seven subjects, another person was observed for a third night at the AQF. This extra night was done because the subject felt ill during the first night of testing. Data was collected from all testing bouts, actigraphy, video tape, and questionnaires.

5.1 DATA ANALYSIS

In this study, the seven subjects abruptly awakened two hours after taking zolpidem ingestion exhibited a greater mean delay in time to alarm shut off when compared to placebo (20 seconds for placebo versus 60 seconds for hypnotic, p=0.058). Also, subjects showed increases in lapses of attention on the night they ingested sleep medication compared to placebo (3 lapses on placebo versus 6 lapses on hypnotic, p = 0.037). On nights when subjects took zolpidem, they showed slowing in fastest psychomotor reactions during the first awakening compared to placebo, as measured by the 3-minute Psychomotor Vigilance Task Self Test (PVT Self Test)(250 msec for placebo versus 290 mseec for hypnotic, p = 0.007). Large variation was noted between subjects. Several individuals demonstrated few performance effects, while others (2 of 7 or 29%) seemed to be significantly affected (see results of video observations).

5.2 ACTIGRAPHY

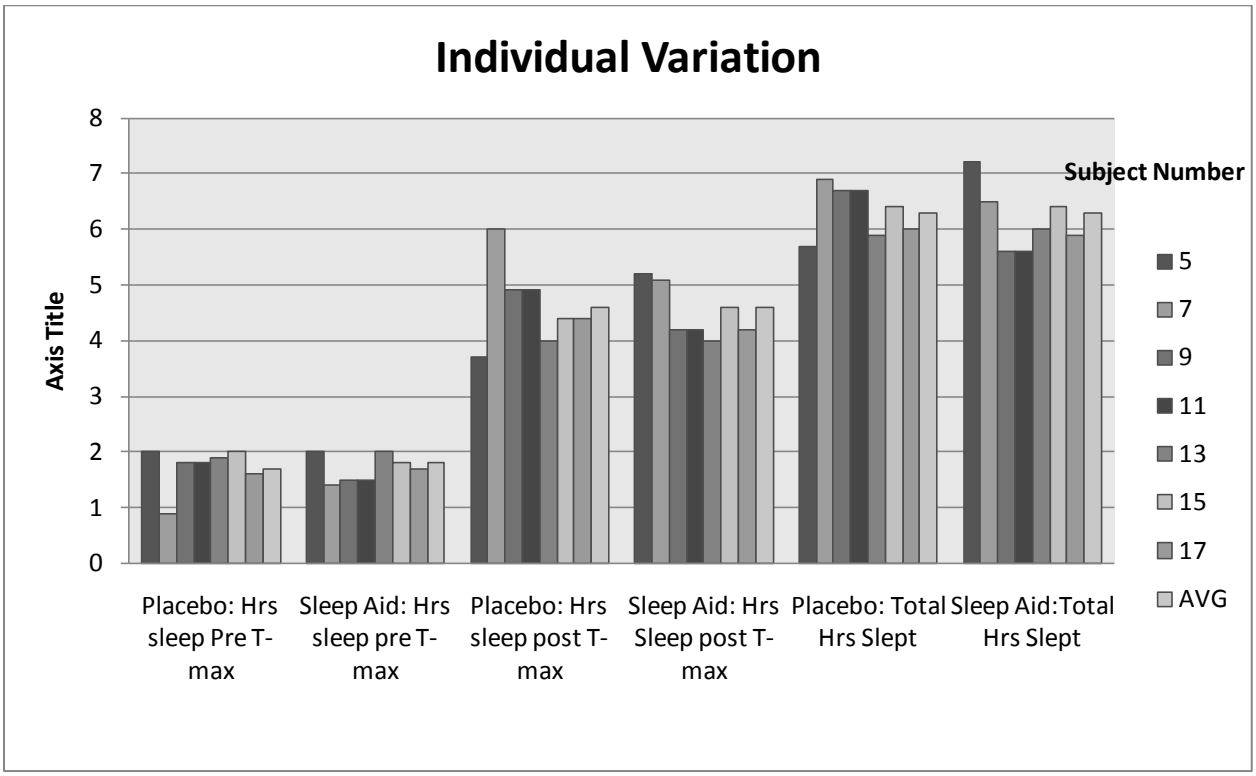
Actigraphy data showed that subjects had essentially the same average amounts of sleep when medicated compared to placebo. The same amount of sleep was observed before abrupt wake up for both medicated and placebo control nights. Also the same amount of sleep was observed for both medicated and placebo controlled night in terms of post wake up sleep and total amount of sleep observed (see table 5.1). Some variation was observed however, with more variation in hours slept post T-max seen with placebo when compared to the hypnotic (see figure 5.1).

TABLE 5.1 ACTIGRAPHY

Subject #	AQF Placebo Night: Avg Hrs sleep Pre T-max	AQF Placebo Night: Avg Hrs sleep post T-max	AQF Placebo Night: Total Avg Hrs Slept	AQF Night Sleep Aid: Avg Hrs sleep pre T-max	AQF Night Sleep Aid: Avg Hrs Sleep post T-max	AQF Night Sleep Aid: Total Avg Hrs Slept
5	2	3.7	5.7	2	5.2	7.2
7	0.9	6	6.9	1.4	5.1	6.5
9	1.8	4.9	6.7	1.5	4.2	5.6
11	1.7	4.8	6.5	1.9	4.8	6.7
13	1.9	4	5.9	2	4	6
15	2	4.4	6.4	1.8	4.6	6.4
17	1.6	4.4	6	1.7	4.2	5.9
AVG	1.7	4.6	6.3	1.8	4.6	6.3
STDEV	0.38	0.75	0.44	0.24	0.47	0.54

This table shows results from the actigraphy data. Subjects had similar average amounts of sleep before T-max. Subjects also had the same average amount of sleep after abrupt awakening and total sleep for both placebo and medication.

FIGURE 5.1 Individual Variation from Actigraphy data



This figure shows individual variation from actigraphy data.

5.3 VIDEO OBSERVATIONS

The video observer was blinded to the subject's medication status. This gave the observer the opportunity to make an unbiased estimate, based on video evidence, of whether medication or placebo was given to a subject. These observations proved to be correct in six out of the seven cases (85.7%), with one case where it was incorrectly guessed (14.3%).

The first observation that became clear after observing the video data for all subjects is that there was a wide variety of responses to abrupt awakening. There were some subjects where there were obvious differences in response on medication compared to placebo. These subjects appeared more distracted, with more difficulty concentrating on tasks and more grogginess on medication compared to placebo. Other subjects had similar reactions on both nights. After abrupt awakening, all subjects appeared slower in responses compared to the beginning of the night.

When comparing the video observations to results from the objective testing, similarity was seen. For example, one of the subjects had differences in responses between medication and placebo nights. It became obvious which night the hypnotic was used because on abrupt awakening, the observed reactions were considerably slower with the subject getting distracted more often compared to placebo. On the night when the hypnotic was given, the subject fell asleep while taking one of the computer-based tests and was awoken by monitoring personnel. This correlates well with the results from the computer-based testing for this subject- with a much slower time to alarm shut off, more lapses in attention by PVT, and much less correct responses on the DST and DSST when given the hypnotic.

Another subject, who had similar results both nights from the computer based test, had only minor observable differences on video. While the observation on whether medication or placebo was given on each night was correct, very few observable clues were seen. On the night with medication, some yawning was observed while on the night with placebo, no yawning was observed. The video observation again correlates well with the results from the PVT, DST, and DSST where very little difference was seen between hypnotic and placebo.

Overall, on the nights where medication was given, there were some observable clues to impairment when compared to placebo. Subjects given hypnotic sleep medication moved much slower to complete tasks after abrupt awakening when compared to placebo. There were also more signs of fatigue on abrupt awakening with the hypnotic. These signs included head drooping, yawning, and fidgeting actions to remain awake.

There was also considerable variation between subjects in terms of behavior. Two subjects awoke before the morning alarm. Two subjects fell asleep in between the middle of the night testing bouts and had to be awoken by observing personnel. On nights with placebo, there were less episodes of dozing off after abrupt awakening and the appearance of more focus when compared to nights with medication.

5.4 QUESTIONNAIRE DATA

A qualitative questionnaire was administered in the morning prior to the subject's departure from the AQF after each test night. The subjects were asked about the alarm, and what was remembered about the testing (see Table 5.2). On both nights, all subjects remembered alarm awakening and completing the testing bouts. On the night with medication, two subjects out of seven did not remember turning off the alarm (all subjects were able to turn off the alarm on both testing nights).

TABLE 5.2 QUESTIONNAIRE DATA

NASA Sleep Med Protocol – Pilot data (N=7)

Sleep medication changes awareness and recall of alarm during the first awakening

	Medication			Placebo		
	Yes	No	Uncertain	Yes	No	Uncertain
Did you sleep?	86%	14%	0%	100%	0%	0%
Were you awake when the alarm sounded?	**29%**	**71%**	**0%**	**0%**	**86%**	**14%**
Did you remember being awakened by the alarm?	100%	0%	0%	100%	0%	0%
Do you remember turning off the alarm?	**71%**	**29%**	0%	**100%**	**0%**	0%
Do you remember doing the RT task?	100%	0%	0%	100%	0%	0%
Do you remember doing the symbol task?	100%	0%	0%	100%	0%	0%
Do you remember doing the subtraction task?	100%	0%	0%	100%	0%	0%

This table shows the results of the questionnaire data that was asked of all the test subjects after completing the testing protocol on both nights. Questions were asked about their recall of sleep, the alarm, and completion of tasks.

CHAPTER 6

DISCUSSION

This study was not a traditional sleep study with polysomnogram information (includes EEG, EOG, EMG, ECG, and pulse oximetry). It was an experimental, observational study using computer-based testing, video evidence, actigraphy and questionnaire data. It could be considered an operational ground testing study with the main goal of finding practical medical recommendations. While a polysomnogram sleep study may yield considerably more information, it would be too time consuming and costly.

Another consideration is whether the performance effects seen between subjects can be attributed to stable individual differences or to differences in stage of sleep. This remains unknown with this study because the stages of sleep was not determined or tested. Determining the stage of sleep may be useful, but may not be necessary for operational testing of sleep medication in healthy individuals with no known sleep pathology.

What is clear from this study is that there was considerable variation in results between individuals. The same medication dosage and parameters were used for each subject, but there was a large amount of variation between subjects. There was no correlation between dosage and body weight. This highlights the need for customizing the choice of hypnotic medications and the dosage for subjects and educating subjects of their effect. Ground testing using this protocol with individualized medication choices and dosages can be used before travel, training, and space flight missions to help predict performance in abrupt awakening situations.

The results can help form the basis of a recommendation for hypnotic sleep medication in subjects with minimal change when comparing performance measures with placebo and

hypnotic. In this case, a 10 mg. dosage of zolpidem might be the ideal choice of hypnotic sleep medication. Other hypnotics can be tested for these subjects in a similar fashion and compared to the results with zolpidem.

There are a number of recommended options available for subjects with considerable differences in performance between placebo and sleep medication. One option may be to ground test another hypnotic. Zaleplon is a hypnotic with a shorter half life and T max that can be considered for testing. With the shorter half life of zaleplon, cognitive performance testing for these subjects may be improved compared to zolpidem at 10mg. Another option may be to test zolpidem at a lower dosage, specifically at a 5 mg dose. The final option could involve using this hypnotic medication at this dosage, but keeping the performance problems in mind. These recommendations need to be considered in the context of operations and the best interest of the subject.

Video recordings can be used to observe objective and subjective measure of performance when used in conjunction with objective computer based testing. When compared to the objective computer based data, a considerable amount of correlation was observed. This video can help to inform flight surgeons and subjects of behaviors that were observed due to the effects of sleep inertia and medication. The video evidence also serves as an educational tool for showing subjects undergoing ground testing exactly how they behaved under the influence of a hypnotic. This is another way to help the flight surgeon make individualized recommendations and for the subject to understand the basis for those recommendations.

Data from actigraphy and questionnaires can also be used to help guide individual recommendations. When considered along with computer based testing and video, this

information will help to individualize medical recommendations for hypnotics. Knowing how much sleep an individual subject gets at night and their overall awareness can also help to educate the subject as to best choices in fatigue avoidance.

There are numerous other areas besides spaceflight where the results of this study and the next phase of this study can be applied. Almost any field where sleep and fatigue are an issue could benefit from this data. These fields include military operations, fire fighters, medical personnel and anyone who uses hypnotic sleep medication.

Similar protocols could be used to test for medications that promote wakefulness. These medications include modafinil, dextro-amphetamine, and caffeine. These medications could be ground tested with comparison to placebo using computer based testing, actigraphy, and video evidence. This could help to inform subjects and flight surgeons about performance and behaviors associated with these medications as well.

It should be noted that no astronaut is required to take medication in space flight. Ground- based testing is used as means to assure medication safely in an operational environment. The protocol presented here helps because it informs subjects and flight surgeons about the performance decrement and the risks of using this type of medication. Knowing the effects of sleep medication prior to operational use will help with risk assessments for each individual. In case an abrupt awakening is needed in space flight, an astronaut and their flight surgeons will know the effects of the medications they are using.

This study showed the effects of a sleep medication (zolpidem) compared to placebo in regards to abrupt awakening. With large variation in performance, the need for individualized recommendations is important. Using this protocol, it is possible to determine those effects in a

ground-based testing environment before a space flight. By testing and individualizing a medication recommendation before a flight, risks can be minimized. Also, flight surgeons and astronauts will better understand those risks. If the unexpected happens and an abrupt awakening is needed to prevent catastrophe, we would be able to better predict the effects that sleep medication and sleep inertia will have on an individual.

GLOSSARY

NASA = National Aeronautics and Space Administration

JSC= Johnson Space Center

AQF= Astronaut Quarantine Facility

PVT = Presistant Vigilence Test

DST = Desccending Subtraction Test

DSST= Digital Symbol Substitution Test

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Vita

Dr. Kalpesh K. Purohit was born November 21, 1974 in Tarrytown, New York to Dr. Kirit N. Purohit and Mrs. Kumud Purohit. Dr. Purohit moved to Brielle, New Jersey when he was four years old. He graduated from Manasquan High School in June of 1992. He attended college at Richard Stockton College in Pomona, New Jersey where he graduated in 1996 with a Bachelor of Science in Biology. He attended graduate school at Drexel University in Philadelphia, Pennsylvania where he graduated with a Masters in Medical Science in 1999. In 1999, he began medical school at the New York College of Osteopathic Medicine where he graduated with a Doctor of Osteopathic medicine degree in 2003. Before he began medical school, he was awarded a scholarship through the Army Health Professions Scholarship Program. He completed a transitional internship at Union Hospital in Union, New Jersey. He then came on active duty and served in Korea as a brigade surgeon for the 1st Heavy Brigade Combat Team at Camp Casey in Tongduchon, South Korea from 2004-2006. In June of 2006, he began an Internal Medicine internship at Eisenhower Army Medical Center at Fort Gordon in Augusta, Georgia. After completion of this internship, he attended the Army flight surgeon course and was assigned as a flight surgeon to 3-4 Aviation Regiment at Fort Hood, Texas in 2007. While serving as their flight surgeon, he deployed with the unit to Taji, Iraq from 2008-2009 in support of Operation Iraqi Freedom. He is currently a resident in the combined Army/Navy Aerospace Medicine residency in Pensacola, Florida.

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