# Improvement in Sleep Efficiency by an Amino Acid Based hGH-Secretagogue: A Pilot Study Heaton, AL, Kelly, C, and Greenway, FL, Pennington Biomedical Research Center, LSU System, Baton Rouge, LA

# Abstract

Human Growth Hormone (hGH) secretory activity peaks Background: A recent randomized, cross-over, double blind clinical trial showed the ability of an amino acid based at night within an hour of the onset of deep sleep, a key period of enhanced declarative memory consolidation. A functional compound (Protovale<sup>™</sup>) to increase serum growth hormone levels by 8-fold, equivalent to 682%, after a single relationship between reduced hGH peaks and reduced dose. While therapeutic interest in hGH physiology has efficiency of sleep patterns has been identified, with mainly been directed at benefits such as body fat reduction, particular note in cases of post traumatic stress disorder lean muscle mass increase, endurance, and skin benefits, (PTSD).<sup>1</sup> Importantly, poor sleep quality is also associated there is a paucity of data related to the effects of hGH on with obesity. In the present work, we investigated the sleep efficiency. Given the known connection between impact of Protovale<sup>™</sup> consumption, an oral amino acid impaired hGH levels and sleep fragmentation [van Liempt, S., based functional compound, on parameters of sleep et al. 2011 Psychoneuroendocrinology 36(9): 1361-1369], efficiency. we investigated the direct effect of repeated daily administration of the amino acid based supplement on Methods parameters of sleep efficiency.

Fifteen healthy subjects [10 males, 5 females; mean Methods: Fifteen healthy subjects [10 males, 5 females; age=33±7 years] determined to have baseline sleep mean age=33±7 years] determined to have baseline sleep parameters within a normal range (Epworth Sleepiness parameters within a normal range (Epworth Sleepiness Scale) consumed the amino acid based supplement Scale) consumed the amino acid based supplement on an on an empty stomach prior to bedtime every night for empty stomach prior to bedtime every night for twenty contwenty consecutive days. Sleep latency (estimated time secutive days. Sleep latency (estimated time to fall asleep) to fall asleep) and length of time awake during sleep were and length of time awake during sleep were reported daily by reported daily by the study subjects. the study subjects. These data were log-transformed and fit with a mixed-effects linear model with random subject inter-**Statistical Analysis** cept effects (to account for the repeated measures on each subject) and a fixed time effect.

**Results:** Both time to fall asleep and time awake in the night decreased according to the exponential model Ae-Bt. For sleep latency, the average intercept was A=18.8 and the common slope was  $B=-0.012\pm0.005$ . For time awake in the night, the average intercept was A=3.25 and the common slope was  $B=-0.032\pm0.013$ . Both slopes were significantly different from zero, (p=0.015 and p=0.012, respectively).

Conclusion: These results suggest progressively greater sleep efficiency by measurements of sleep latency and time awake during sleep. A larger multi-center study is being planned.



## Introduction

The results for sleep latency and time awake during sleep were logtransformed and fit with a mixed-effects linear model with random subject intercept effects (to account for the repeated measures on each subject) and a fixed time effect. This model allows the intercepts (A) to vary across subjects, but assumes a common slope (B) for all the subjects. Thus, each subject was assumed to start the study with a different expected time to fall asleep, but the effect of the supplement on the subjects was assumed to be the same. Statistical significance was set at p < 0.05.

# Results

Results showed overall decreases in values for both sleep latency and time awake during sleep over the course of the study. These data were well described according to the exponential model Ae-Bt. Figure 1 shows the logtransformed sleep latency data for each subject and the estimated population-level regression model. Figure 2 shows the log-transformed time awake during sleep data for each subject and the fitted population-level regression model. The mixed effects model allowed the population-level fitted regression line to be shifted upward or downward for each subject, and thus fit the data better than a fixed-effect model.

The model for sleep latency yielded an average intercept of A=18.8 and a common slope of B=-0.012 $\pm$ 0.005. The estimated slope was statistically different from zero, p=0.015. The model for time awake during sleep yielded an average intercept of A=3.25 and a common slope of B=- $0.032\pm0.013$ , with the estimated slope being statistically different from zero, p=0.012. Overall, these results show progressively greater sleep efficiency with exponential reductions over time for both sleep latency and time awake during sleep.

### FIGURE 1: LOG-TRANSFORMED SLEEP LATENCY (SL) IN MINUTES FOR EACH SUBJECT (BLUE POINTS) WITH THE POPULATION-LEVEL PREDICTED REGRESSION LINE (BLACK LINES)



FIGURE 2: LOG-TRANSFORMED TIME AWAKE DURING SLEEP (TA) IN MINUTES FOR EACH SUBJECT (BLUE POINTS) WITH THE **POPULATION-LEVEL PREDICTED REGRESSION LINE (BLACK LINES)** 



### **Discussion and Conclusions**

Therapeutic interest in hGH has mainly been directed at benefits such as body fat reduction, lean muscle mass increase, endurance, skin rejuvenation (wrinkle reduction), and its touted general anti-aging benefits. However, there is a paucity of data related to the effects of hGH on sleep quality, despite the known correlation. Our present findings establish a progressive benefit of daily supplementation with the amino acid based hGH secretagogue Protovale on key parameters of sleep quality. Notably, these improvements in sleep quality may have beneficial effects on obesity associated with short sleep cycles. A larger multi-center study is being planned.

### References

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- 2. Tam, CS, WD Johnson, et al. (2012) Obesity 2012, The 30th Annual Scientific Meeting of The Obesity Society, San Antonio, TX, Sept. 20-24.

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