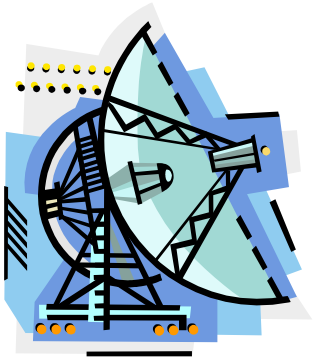
KENTUCKY SLEEP SOCIETY

September 2011

Quarterly Newsletter

President's Message—Robert Pope, MD



Special points of interest:

- President's report provides a recap of the KYSS Activities
- Video conferencing available for Annual Meeting
- Annual Meeting Program at a Glance
- Assess the Impact of PAP Therapy Mode and Titration
- Treatment for Insomnia

I have the honor of representing the Kentucky Sleep Society at the inaugural AAST State Sleep Society Leadership Conference on September 17-18, 2011 in Darien, IL. The AAST has underwritten the expense of conducting this conference which has been developed to provide key information about managing a successful state sleep society. I hope to share the KYSS experience from the past 13 years and bring back information to strengthen our organization.

A valuable tool in guiding our way has been the *Strategic Retreat* that takes place every two years. All KYSS members are invited to gather at this day-long event to discuss the current state of affairs and plan a course of action. The most recent retreat took place in Bardstown on August 6. Thanks to Kathy Ohlmann and Kathryn Hansen for organizing the event and to all who attended.

These are tumultuous times for all us in the sleep medicine. A strong KYSS is essential to safeguard our profession and promote the welfare of our patients. Don't hesitate to share your thoughts and questions with any of the board members. Consider volunteering for a committee.

I'm looking forward to seeing you at the annual meeting in Louisville.

New technology to be used at the Annual meeting:

We will be developing video and audio recordings of most of the lectures at the Annual meeting. These will be available for CEs following the meeting.

If you are interested in completing your registration by phone, please call the office at 859-312-8880.

13th Annual Sleep Medicine Conference: Program At A Glance

The Kentucky Sleep Society is dedicated to providing our health care providers innovative education. This year is no different.

Plan to attend a comprehensive three days of technical and professional development education.

Take time to talk with our exhibitors to learn about the latest in technical advances and clinical monitoring opportunities.

New **Online registration available at www.kyss.org**

Friday: October 14, 2011

- Coronary Artery Disease
- Family dynamics and sleep deprivation
- Gender and sleep problems
- Seizures/Parasomnias
- Teenage sleep deprivation
- Childhood sleep problems
- Personality types and the polysomnogram
- Working with the Special Needs Patient

Saturday: October 15, 2011

- Interactive Scoring of PSGs
- Diabetes and Kids
- ASV/PAP Compliance
- Challenging Case Studies
- Cardiac Emergencies
- Death in the Sleep Center
- Using Technology to Increase Efficiency in Your Practice
- Cloud Computing
- Use of Social Media to Market Your Center
- Using Your Motivation to Grow Professionally
- Sleep and Transportation

Sunday, October 16, 2011

- Narcolepsy vs Idiopathic Insomnia
- Examining Fatigue Factors in Transportation Accidents
- Regulatory Compliance to Increase Revenues
- Creating a Relationship Between the Sleep Center and Primary Care
- Out of Center Testing Updates

Kentucky Sleep Society September 2011

Positive Airway Pressure Initiation: A Randomized Controlled Trial to Assess the Impact of Therapy Mode and Titration Process on Efficacy, Adherence, and Outcomes;

Kushida et al. SLEEP 2011;34(8):1083-1092.

Article Review

Reviewed by Alexander Tzouanakis, MD, Central Baptist Hospital Sleep Diagnostic Center; Lexington, KY

Auto-CPAP (APAP) is increasingly used as an initial or long term therapy for obstructive sleep apnea (OSA). By some recent estimates, approximately 30 percent of CPAP prescriptions are APAP. Given the higher cost of APAP systems, it would be reasonable to assume some data exists that would link APAP therapy to better outcomes or, at least, to better patient acceptance or compliance. It is intuitive to assume that a system, such as APAP, which dynamically adjusts to a patient's breathing pattern, would be intrinsically superior. Unfortunately, even after years of APAP use in clinical practice and multiple studies examining its effects, evidence that APAP is superior has not been forthcoming.

In the August issue of SLEEP, Kushida et al. presented a study re-examining this question. It is a multicenter, randomized study involving 150 patients in 3 arms. Analysis was on an intention-to-treat basis. An additional aim of the study was to determine the effect of A-Flex, Respironic's proprietary form of exhalation pressure reduction, added to standard APAP. Inclusion criteria were age 21 to 75 and an AHI $\geq$ 15.

Participants were randomized to one of 3 study groups:

A-Flex group: APAP with A-Flex for the duration of the study (180 days).

CPAP-APAP group: Standard APAP for 14 days then switching to standard CPAP at a fixed pressure corresponding to the 90% pressure obtained during the APAP period.

CPAP group: Standard CPAP at a fixed pressure throughout the study period (CPAP pressure determined from an overnight titration study at the time of randomization).

Results were categorized based on the 3 primary aims of the study: efficacy, adherence, and outcomes, and are as follows:

Aim 1 (Efficacy): There was no difference in residual apneas, oxygen saturations, or other key PSG variables between the groups at 180 days though the AHI was significantly higher in the A-Flex group at the time of the initial PSG.

Aim 2 (Adherence): There were no significant differences found between the treatment groups at 90 or 180 days.

Aim 3 (Outcomes): There were no significant differences between the groups in the results of the Epworth Sleepiness Scale, the FOSQ, or the Psychomotor Vigilance Task reaction time. There were no significant differences across treatment groups in systolic or diastolic blood pressure. Attitudes toward use and subjective ratings for sleep quality, mask comfort, treatment satisfaction and benefit were also measured. Minor differences were noted. Surprisingly, treatment satisfaction trended higher in the CPAP alone group.

There are some limitations to this study that bear notation. As in any study, one needs to look at those patients that were excluded from the study but are seen commonly in clinical practice. Patients with unspecified "major" medical problems, chronic respiratory failure, a need for more than one titration, or need for acute or chronic sedative/hypnotic use were excluded. These are patients most of us see with great regularity. Might these sub-groups benefit more significantly from APAP or A-Flex?

What about the more morbidly obese? These are valid questions that can't be definitively answered by this study.

Given the results of the numerable studies comparing similar aspects of APAP and CPAP, I was not surprised by these general conclusions. However, the significance of this "negative" study is several-fold.

First, the statistical power of this systematic multi-center randomized study makes the results important. Secondly, the very systematic nature of this study's clinical design may well be its most important feature. The authors themselves note that "this study does not necessarily reflect routine clinical practice due to the close monitoring and comprehensive nature of the follow-up of participants in this study". Might it be that it is this careful clinical attention to detail and follow-up that renders small differences in efficacy between APAP/A-Flex and routine CPAP less important?

In summary, APAP with A-Flex did not demonstrate superiority over regular CPAP in regards to efficacy, adherence, or functional outcome at 180 days in this particular study. Interestingly, the indices of sleep disordered breathing (AHI and oxygen saturations) were significantly worse in the A-Flex group compared to CPAP at baseline. These differences disappeared during subsequent follow-up. There were no significant differences in subjective sleepiness, objective vigilance, quality of life, or blood pressure between the groups. One caveat was that participants using CPAP had significantly more positive attitudes toward their treatment compared to A-Flex at baseline and at 30 days, but these differences disappeared subsequently. The authors did not offer an explanation for this anomaly, however.

It is compelling but not unprecedented to assume that the hidden gem of a study may be its comprehensive clinical approach to the patient and not the hardware this very approach was designed to isolate. In a small way, this study warms the cockles of my clinician's heart. As much as I'd like to see the mechanics of PAP machines improved, the message here may be, at least at this juncture, that careful, competent clinical management may trump the "ghost in the machine".

CRANIAL ELECTROTHERAPY STIMULATION : A TRENDING TECHNOLOGY FOR TREATING INSOMNIA

Kelly Roman, Vice President, Fisher Wallace Laboratories
515 Madison Avenue, New York, NY 10022

"I've had great success using the device to treat severe, chronic insomnia in patients who are resistant to pharmacotherapy," states Dr. Andres San Martin, Assistant Professor of Psychiatry at Columbia University's College of Physicians and Surgeons. "Also, patients who seek a drug-free alternative to treat insomnia have used the Cranial Stimulator to reduce or eliminate their dependence on prescription drugs."

Check the facts: Trending Technology for treatment of Insomnia

What, exactly, is a Cranial Stimulator?

The popular TV show The Doctors recently featured the technology as an effective treatment for insomnia. With an audience of 3 million viewers, the show resulted in many sleep doctors fielding questions from their patients about the technology.

Is there research proving its safety and effectiveness?

The following article will examine Cranial Electrotherapy Stimulation in more depth – called "CES" by the doctors who prescribe it – and how it may become a new tool for sleep doctors seeking non-drug treatment alternatives for their patients. In 1991, the device received Food and Drug Administration (FDA) clearance to be marketed in the United States for the treatment of depression, anxiety and insomnia.

There are only a handful of manufacturers of CES devices. The Fisher Wallace Stimulator is the device featured in The Doctors and prescribed by Dr. San Martin and his colleague,

Dr. Richard Brown, at Columbia University who together prescribed it to over 500 patients in the past 18 months and report a 75% success rate with patients.
Currently, over 350 psychiatrists nationwide prescribe the Fisher Wallace device to treat insomnia and depression.

Used 20 minutes at a time, once or twice a day, the handheld device – smaller than a TV remote control - delivers patented micro-electrical currents to the brain via sponge electrodes applied to the head. This stimulates the brain to produce serotonin, GABA and endorphins – as evidenced in blood and CSF results in clinical trials.

The device is contraindicated for use in patients who have demand or sensing type cardiac pacemakers or conductive or other metals implanted in their head. Examples include implanted stimulators, shrapnel, stents, and active or inactive implants such as deep brain stimulators and vagus nerve stimulators. There are no known contraindications with medication, and the device is routinely used with patients who are simultaneously taking antidepressant and sleep medication.

There are several mild side effects associated with using the FW-100. These side effects are comprised of the rare occurrence of a mild headache (9 cases reported in the 8,792 persons receiving CES in clinical research, 0.1%), dizziness (also 9 cases reported in the 8,792 persons receiving CES in clinical research, 0.1%) and/or skin irritation at the sponge electrode contact site (6 cases reported in the 8,792 persons receiving CES in clinical research, 0.07%). These side effects, which are temporary and cease after discontinuation of using the device, do not outweigh the benefit the device provides in treating depression and anxiety.

There is no evidence that extremely low amperage electrical stimulation (1-4 mA) causes or increases the risk of seizure, even in patients with a history of seizure. Seizure prone, head injured patients have been treated with CES in research projects designed to permit seizures, and no seizures occurred during treatment. Charity Hospital in New Orleans successfully used CES on withdrawing alcoholics to prevent withdrawal seizures.

Throughout the 1970's, 1980's, 1990's and 2000's, many well-controlled investigations were conducted that demonstrate safety and effectiveness in treating insomnia, anxiety and depression, particularly in the substance abuse population. Click on the study below to read the abstract or full article. This research section is followed by a description of how to prescribe and use the device:

DATA SUPPORTING EFFECTIVENESS

Drug Alcohol Depend. 1991 Jan;27(1):1-6.
The administration of transcranial electric treatment for affective disturbances therapy in alcoholic patients.

Alcohol Clin Exp Res. 1986 Mar-Apr;10(2):158-60.
Cranial electrotherapy stimulation as a treatment for anxiety in chemically dependent persons.

Biological Psychiatry, Volume 29, Issue 5, 1 March 1991, Pages 451-456
Efficiency of transcranial electrostimulation on anxiety and insomnia symptoms during a washout period in depressed patients a double-blind study

Br J Psychiatry. 1979 Jan;134:111-3.
Treatment of methadone withdrawal with cerebral electrotherapy (electrosleep).

Alcohol Clin Exp Res. 1995 Aug;19(4):1004-10.
Effects of cerebral electrical stimulation on alcoholism: a pilot study.

J Altern Complement Med. 1996 Winter;2(4):485-91.
Electrostimulation: addiction treatment for the coming millennium.

J Clin Psychiatry. 1984 Feb;45(2):60-1, 62-3.
Cranial electrotherapy stimulation treatment of cognitive brain dysfunction in chemical dependence.

Journal of Altered States of Consciousness, Vol 2(2), 1975-1976, 185-196.
Electrosleep (electrical transcranial stimulation) in the treatment of anxiety, depression and sleep disturbance in chronic alcoholics.

Dokl Biol Sci. 2001 Nov-Dec;381:516-8.
Opiate abstinent syndrome is rapidly blocked by electrostimulation.

Biol Psychiatry. 1990 Oct 15;28(8):650-6.
Transcutaneous electrical stimulation with Limoge current potentiates morphine analgesia and attenuates opiate abstinence syndrome.

Neuroelectric Therapy (NET) in Addiction Detoxification.
Meg Patterson, M.D., F.R.C.S.E., Noel V. Flood, R.M.N. & Lorne Patterson, R.M.N.

Biol Psychiatry. 1975 Dec;10(6):675-80.
Electrosleep in the management of alcoholism.

Ph.D. dissertation, The University of Tulsa, 1994.
The effectiveness of cranial electrotherapy stimulation (CES) for the relief of anxiety and depression among polysubstance abusers in chemical dependency treatment.

Phoenix House Foundation, New York, NY
A retrospective chart review of cranial electrotherapy stimulation for clients newly admitted to residential drug treatment

DATA SUPPORTING SAFETY

A reasonable assurance of safety has been long established since the 1974 CES safety study commissioned by FDA ("An Evaluation of Electroanesthesia and Electrosleep,'' National Research Council, National Technical Information Service, PB-241-305, 1974, FDA Contract 70-22, Task Order No. 20. NTIS PB 241305 pp. 1-54) and the 30+ years in which no significant adverse event reports have been filed in regards to CES.

J Neuro Rehab 1998; 12:65-72
Is Transcranial Electrical Stimulation (TCES) a Safe Intervention for Children with Cerebral Palsy?

Journal of Neurotherapy, Vol. 9(2) 2005
Cranial Electrotherapy Stimulation Review: A Safer Alternative to Psychopharmaceuticals in the Treatment of Depression

Southern Medical Journal: December 2004 - Volume 97 - Issue 12 - pp 1269-1270
Special Sections: Letters to the Editor
Cranial Electrotherapy Stimulation: A Safe Neuromedical Treatment for Anxiety, Depression, or Insomnia

Brain Inj. 1994 May-Jun;8(4):357-61.
The use of cranial electrotherapy stimulation in the treatment of closed-head-injured patients.