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# SPS NEWS

The Official Publication of The Southern Pain Society

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## Critical reading of the Pain Literature

Ike Eriator, MD, MPH, Damon Dozier, MD, Vincent Mendy, B. Sc.

### Introduction:

When we see the result of a study on an interesting topic, we often ask if we can apply it to our patients. To make correct decisions based on the data, we must not only know how the data was obtained, but also whether the conclusions are statistically appropriate. If there are statistical errors, the conclusions may be incorrect. Our knowledge of statistics helps us to make that judgment. Multiple studies have demonstrated that practicing physicians, especially those without formal education in epidemiology and biostatistics, have poor understanding of common statistical tests and limited ability in interpreting study results (Windish et al, 2007). Such practitioners are able to understand the analysis and interpretation of results in only 21% of research articles (Horton and Switzer, 2005). Several steps have been taken to try to address this situation. In fact the Accreditation Council for Graduate Medical Education (ACGME) currently requires that trainees “demonstrate ability in locating, appraising and assimilating evidence from scientific studies related to their patients’ problem and apply knowledge of study designs and statistical methods to the appraisal of clinical studies”. The literature in the field of pain management is made more complex by the facts that pain is a subjective sensation, with no appropriate objective measure and that the most commonly used measures – the numerical and visual analogue scales- are oversimplified measures of a complex sensation that involves sensory, emotional and cognitive aspects. The pain practitioners are therefore required to employ an adequate knowledge base in addition to commonsense and a critical intuition in extrapolating evidence from the literature to the care of their patients.

Some of the most pressing problems include the lack of understanding of the importance of the methodology and study designs in assessing the validity of the results of a study and the appropriate interpretation of p-values.

### Methodology & Study Designs:

Study designs constitute the fundamental basis of the conduct and interpretation of research. The method section is the most important part of any research paper (Altman, 1991). When trying to decide whether a paper is worth reading, you should do so based on the design of the study, and not on the interest value of the hypothesis or the potential impact of the results (Greenhalgh, 2001). The justification for data analysis lies not in the data collected, but in the manner in which the data were collected (Schoolman et al., 1968). Assessing methodological quality of articles has been described in many places (Oxman et al., 1993, Giacomini and Cook, 2000, Sackett et al., 2000, Greenhalgh, 2001). Four preliminary questions that can help are; why was the study done? What hypothesis were they testing? What type of study design did they use? Was this study design appropriate for the intended research?

Understanding the common types of study design used in pain research as well as their pros and cons will help you to judge the value of articles, the applicability of the findings and the integration of such findings into your practice. Different study types carry different weights and are allocated different positions in the hierarchy of levels of evidence. Systematic reviews and large randomized control trials (RCT) carry the highest weight. Cohort studies are less than RCTs, but higher than case-control studies. Cross-sectional surveys are ranked next, and come before case reports. However, not everything that counts can be counted. And not everything that can be counted, counts. A sloppy RCT usually carries less weight than a large well designed cohort study. Reasoning is needed in conducting studies, evaluating them and in applying them to your practice (Eriator, 1998).

### Power:

One of the commonly overlooked parameters in the interpretation of study results is the statistical power. Power is very important in statistics. By convention, a study power of 0.8 or above is usually sufficient for a study. When the power of a study is small, it can lead us to falsely assume that there was no difference between the treatment and control groups. So we walk away thinking that the treatment did not make a real difference. Power is usually stated as a probability and is related to type II error. The greater the power, the less the likelihood of a type II error. You should always look at the power before interpreting the result of the significance difference. The p-value may not reach the level of statistical significance if the study power is small. **See pg 6**

**Mission Statement**

The Southern Pain Society is a regional section of the American Pain Society and endorses and supports the mission and goals of the American Pain Society. The Southern Pain Society's missions are to serve people with pain by advancing research and treatment and to increase the knowledge and skill of the regional professional community.

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SPS News is the official publication of the SPS, provided quarterly to its members. SPS may publish material dealing with controversial issues. The views expressed are those of the authors and may not reflect those of the SPS. No endorsement of those views should be inferred unless specifically identified as the official policy of the SPS. Submissions are welcomed. Publication is based on editorial judgment as to quality of material, timeliness, and potential interest to members.

# Editor's Desk

Ike Eriator, MD, MPH



**The Future of Pain Management:**

To know where we are going, we need to know whither we have come. The world of pain management has come a long way. The result of this long journey can be measured by the current status of pain. Today, the burden of pain in the community has been recognized, or is being recognized -thanks to the efforts several pain organizations, pain practitioners and the lay public. Opioids (formerly called "narcotics") – the gold standard for managing severe pain- can be used in the open, following some criteria. The place of physical and occupational modalities for managing pain has been better defined. The impetus and use of complementary modalities is gaining ground. Nerve blocks are being done using fluoroscopy to guide and improve accuracy. Neuropathic pain and its burden have been recognized and clinical and basic science research efforts are geared towards attenuating its burden. Basic science research is illuminating the genetic basis of pain and the variation in responses. Today, JACHO requires that pain be appropriately assessed and managed in our patients. Many states have established practice standards for pain management. Pain management as a subspecialty is strong and still gaining momentum. We live in the Decade of pain control and research.

And we must not forget to give credit where it is due. Several clinicians, scientists and philosophers pioneered and piloted the ship that has brought us thus far. Whether we are talking about the original conception of pain transmission envisaged by Rene Descartes around 1660, or the discovery of anesthesia, or the war observations of Henry Beecher that introduced the concepts of the placebo and the need for controls in pain experiments, or similar observations by John Bonica that engendered the concept of the multidisciplinary approach to pain care, or the Puzzle of pain and the gate control theory by Melzack and Wall, several individuals contributed in no small measure to the pillar of the modern pain status. Isaac Newton wrote that if he had seen further than most men, it was by standing on the shoulder of giants. We must take care to venerate our giants as they pass on. There are giants at the local, national and international scenes. In this issue of your Newsletter, we pay tribute to Dr. Hubert Rosomoff, a giant for the Southern pain society and the pain world at large.

As we venerate our giants, we must take good care to carry on the torch. That would be the best way to remember them. The pain world is still plagued by a lot of unknowns. Today, as we discussed pain in the conference room in the pain clinic, I put a question to a collection of medical students, anesthesiology residents and pain fellow; what would they like to see improved with regards to pain concepts in the future? The answers came

**Research Presentation:**

- Transcranial Magnetic Stimulation as a Promising Treatment for Migraine Pain Relief
- Presented at the June, 2008 50<sup>th</sup> Annual Scientific Meeting of the American Headache Society in Boston

In a multi-center, randomized, double-blind clinical trial, the use of a portable, hand-held transcranial magnetic stimulation (TMS) device was deemed safe and effective in eliminating migraine headaches when administered during the aura phase preceding a migraine. The portable, single-pulse TMS device is made by the medical technology company Neuralieve. Researchers recruited 201 patients suffering from migraine with aura, then randomly assigned them to use the TMS device or a "sham" control device. Patients were instructed to apply the device over the site of the migraine at its onset. Two hours after treatment, 39% of the TMS patients were pain-free, versus 22% of patients using the sham device. There were no differences reported for

adverse reactions between the two groups. In some study patients, the treatment also eased migraine-related symptoms of nausea and sensitivity to light and sound. The TMS device sends a strong electric current through a metal coil, which creates an intense magnetic field for about one millisecond. Dr. Richard Lipton, lead investigator, posited that TMS pre-empts headache or reduces the duration or severity of the migraine episode by disrupting the cortical spreading depression that precedes migraine with aura.

**Selected Open Clinical Trials Around the South:**

All studies below were excerpted from listings on the ClinicalTrials.gov website. All are currently open and recruiting participants. For inclusion and exclusion criteria for these studies and for more information on open studies in your local area, please visit the registry of federally and privately supported clinical trials: [ClinicalTrials.gov](http://ClinicalTrials.gov), a service of the U.S. National Institutes of Health.

ClinicalTrials.gov Identifier	Location	Sponsor	Contact/Principal Investigator and Phone	Title of Interventional Study	Notes:
NCT00678717	Nashville, TN	Vanderbilt University Clinical Research Center	Laura Diedrich, MD (615) 936-0041	Autonomic Function Testing and Spinal Cord Stimulation: Implication for successful therapy in chronic visceral pain	Recruiting patients with chronic visceral pain; Conditions: "Sham" vs. Medtronic or ANS spinal cord stimulator implant
NCT00385671	FL, AL, NC, TX, Others	Eli Lilly and Company	1-877-CTLILLY (1-877-285-4559)	An Open-Label Comparison of Duloxetine to Other Alternatives for the Management of Diabetic Peripheral Neuropathic Pain	Recruiting patients with DPNP currently treated with gabapentin
NCT00323609	25 study locations including FL, GA, LA, VA, WV	Medtronic Spine, LLC	Van Weiss (408) 548-5494; Dan Jolivet, MD (408) 658-6523	KAVIAR Study – Kyphoplasty and Vertebroplasty in the Augmentation and Restoration of Vertebral Body Compression Fractures	

## Continued from Page 1

### p-values:

Many clinicians look to the p-value in deciding whether the treatment made a significant difference or not, and whether to apply the results to the care of their patients. Unfortunately, statistical significance and clinical significance are not the same thing. An inherent limitation in using p values is that they simultaneously reflect the sample size and the effect size (or treatment difference or magnitude of association). When we make decisions based on the p value of a study, the relative contribution of the sample size and the measure of association is unclear (Houle, 2007). In any study, the p value may be large because the sample size is too small or the difference in effects between the treatment and control groups is small. If either the sample size or the effect size is very large, the p value will be much smaller. Consider the situation where the effect of a medication is not much different from placebo, but the study used a very large sample of patients; the p value will be small and the result will be interpreted as statistically significant. However, for the clinician, a drug that produces little or no difference from a placebo is not worth administering to our patient, irrespective of what the p-value says. Supposing in a study, the patients on one treatment have five times less pain than the patients on another treatment, you will expect to find a significant difference, but if the sample size is small, the p value will be large, and may not reach the cut off level. The astute clinician will consider using the drug that made such a huge difference, even if the p-level did not reach the statistically significant cut off point – until bigger studies are done. The Number Needed to Treat (NNT) in such cases, can help in evaluating the reduction in pain or other symptoms provided by the treatment.

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### Editor's note:

Damon Dozier, MD is a Pain fellow at the University of Mississippi medical Center, Jackson, Mississippi.

Vincent Mendy is an MPH student at Jackson State University, Jackson Mississippi.

## Selected Pain Science News Tidbits

Leanne Cianfrini, PhD

### Article Review:

Ditre, J.W., & Brandon, T.H. (2008). Pain as a Motivator of Smoking: Effects of Pain Induction on Smoking Urge and Behavior. *Journal of Abnormal Psychology, 117(2)*, 467-472.

It has been noted that the prevalence of smoking among individuals with chronically painful conditions is approximately double that of the general population. The goal of this experimental study was to determine whether situational pain was sufficient to increase smoking motivation. The study was conducted by researchers from the University of South Florida and the H. Lee Moffitt Cancer Center and Research Institute. Researchers tested whether laboratory-induced cold pressor pain would increase self-reported urge to smoke as well as observation of immediate smoking behavior. One hundred thirty two smokers who smoke at least 20 cigarettes a day were randomly assigned to either pain or no pain conditions.

Participants who underwent cold pressor pain induction (i.e., immersed non-dominant hands in a circulating cold-water bath until the pain became intolerable) reported significantly greater smoking urges as measured by a single-item visual analog scale and demonstrated shorter latency to smoke than participants in the control/no-pain condition. The causal relationship between pain and enhanced smoking motivation was only partially mediated by pain-induced negative affective (mood) state, which suggests that pain may be a potent motivator of smoking above and beyond simple mood effects. Although this research is not necessarily generalizable to individuals with chronic pain conditions, it is the first to demonstrate that acute, or situational, pain is a potent motivator of smoking. In contrast, other studies have examined and determined smoking as a possible contributing cause of chronic pain conditions. If pain stimulates the desire to smoke, and smoking exacerbates painful conditions, smokers with chronic pain may get caught in a devastating cycle that can worsen their pain while maintaining and even increasing their dependency on cigarettes.

pouring in very quickly; Objective measurement of pain, development of non addictive medications for severe pain, cure for addiction, preemptive analgesia and prevention of chronic pain, behavioral modifications, improved physical and occupational modalities for treating the recently injured patients, development of longer acting medications for interventional options...

Despite the considerable progress that has been made, it seems that the same problems that are rampant today, bedeviled many of our giants. Morphine, the gold standard for treating severe pain today was known to the ancient Egyptians and Mesopotamians as part of their plant extracts. It seems like the more things change, the more they remain the same. Perhaps T. S. Elliot was right when he wrote that the end of your journey would be to get back to the beginning and to rediscover it for the first time. But then, we are richer because (thanks to the giants before us), we can see from a few more perspectives compared to when we started the quest. We must venerate our pain pioneers as we stand on their shoulders and look to the future.

## Newsletter Submissions

All submissions to SPS News should be typewritten and double spaced with title and name of author(s). The article should be copy-ready. Please include short biographical information.

### Submission Deadlines

Winter edition-November 1; Spring edition-February 1; Summer edition-May 1; Fall edition-August 1. Please submit your articles to [lpostal@southernpainsociety.org](mailto:lpostal@southernpainsociety.org) or to our editor [ieriator@anesthesia.umsmed.edu](mailto:ieriator@anesthesia.umsmed.edu)

## New Members

Welcome to the following new Southern Pain Society Members:

**Amy Michelle Smith, RN, APN** from Brookhaven, MS. Ms. Smith is interested in working on the membership, professional education, newsletter and e communications committees.

**Carol Cox Pursley, PhD** from Alpharetta Georgia who has rejoined.

**M. Waynen Bosserman, MD** from Hampton Cove, AL

**Jumar B. Apolinario, MD** from McAllen, TX

**Andy C. Austin, RN, APN** from Monroe, LA

Please let us know how we can serve you!

# President's Message

Daniel M. Doleys, PhD

## Dr. Hubert L. Rosomoff: A Passion for Pain



It is with great sadness and a profound sense of loss that I note the passing of Dr. Herbert (Hu) L. Rosomoff on June 5, 2008. As many of you know, Hu was a neurosurgeon by training but a passionate pain physician at heart. His remarkable career spanned a half century. His distinguished academic career began with publications in 1963 on edema and the evaluation of nerve root compression. As recently 2007 he contributed to an article examin-

ing the medicolegal issues of patients taking opioids and operating vehicles. The number of articles and chapters generated by the Rosomoff Comprehensive Pain Center, under Hu's directorship, exceeds 200. He contributed to the development of neurosurgical procedures and created one of the first, if not the first, truly interdisciplinary pain clinics. His emphasis on rehabilitation born of a comprehensive evaluation and specific diagnosis, attracted patients from around the world and became the gold standard by which many of us judge our own programs. Untold numbers of patients have been spared potentially unsuccessful and painful surgery by Dr. Rosomoff's continued enlightenment as to the role of myofascial components of pain and ergonomics. In addition to all of his administrative, clinical and academic activities, he was actively involved in the American Pain Society (APS) and served as APS president in 1992-93. He was a founding member and the first president of the Southern Pain Society (SPS). We at SPS virtually owe our very existence to him. The details of Dr. Rosomoff's training and remarkable career are further highlighted in the biography appearing in this newsletter.

On a more personal note, I came to regard both Hu and Renee as more than colleagues. I looked forward each year to sitting down with them at the annual SPS meeting to gain from their insight and experience. His persistent and challenging attitude was always stimulating and infectious. Hu directed me to two early neurosurgery books on pain by White and Sweet, unique by virtue of their emphasis on detailed case studies. These books have become treasured possessions reminding me of Hu's interest and commitment each individual patient.

Dr. Hubert Rosomoff is a true icon the field of pain. He has been a mentor, colleague and friend to so many. In his memory, and with grateful appreciation to both Hu and Renee for all their many contributions to SPS, the SPS Board of Directors unanimously voted to name the award for excel-

lence in pain the "Dr Hubert L. and Renee S. Rosomoff Excellence in Pain Award". We are very pleased and honored, that Renee has agreed to present the award to its first recipient at our annual meeting in New Orleans. I have no doubt that Hu's indomitable spirit will be present.

With deepest appreciation, thoughts and prayers to Dr. Hubert and Renee Rosomoff, my friends in pain.

#### BIOGRAPHY

**Hubert L. Rosomoff, M.D., D.Med.Sc.,** world-respected neurological surgeon and researcher, who pioneered the multidisciplinary treatment of chronic pain, died at 81.

He was the son of Moms Rosomoff of Kiev, Russia and the former Caroline Green of Philadelphia. Born in Philadelphia, He attended the University of Pennsylvania where he obtained a B.A. in Chemistry in 1948.

Dr. Rosomoff entered Hahnemann Medical College in 1948, obtaining his M.D. degree in 1952. From 1954-1959 he completed a Neurological Surgery Residency at both the Columbia Presbyterian Medical Center and the Neurological Institute of New York. At the Neurological Institute of New York, Dr. Rosomoff began his groundbreaking research into hypothermia which earned him the American Academy of Neurological Surgery Award in 1956. He was a consultant from the United States to the Institute for Artificial Hibernation and Resuscitation in Moscow, U.S.S.R. Dr. Rosomoff returned to the Neurological Institute in 1957 to complete training and in 1960, obtained a D.Med.Sc. Degree in Physiology from Columbia University College of Physicians and Surgeons. During this time, he helped introduce hypothermia clinically as an adjunct to the neurosurgery of vascular lesions, and the treatment of brain injuries. While still a resident, Dr. Rosomoff was a guest lecturer at the Royal Society of Medicine, London. Further recognition was accorded, by Yugoslavia, for his work in hypothermia and the Soviet Union where he was asked to participate in an exchange educational program with the Institute of Resuscitation.

He was invited to present his research in hypothermia at the opening plenary session of the First International Congress of Neurological Surgeons in Brussels in 1956 at the tender age of 29. Hypothermia (lowering of body temperature) has become an important adjunct to Neurological Surgery, treatment of braidspinal cord injuries, brain hemorrhage, cardiac arrest, attacks (infarction) and surgery.

In 1954, Dr. Rosomoff was commissioned a lieutenant in the U.S.Navy. He served as a Surgeon and Research Physiologist, eventually rising to the rank of Lt. Commander. Stationed at the Naval Medical Research Institute in Bethesda, Dr. Rosomoff continued his research in hypothermia along with hospital duties in Neurology. He served on active duty until 1957, and remained in a reserve capacity until 1963.

In 1959, Dr. Rosomoff joined the faculty of the University of Pittsburgh School Of Medicine as Clinical Assistant Professor, and Chief of Neurological Surgery at the Veterans Administration Hospital. He remained at the University of Pittsburgh until 1966, when he became Professor and the youngest Chairman in history at the prestigious Albert Einstein College of Medicine in New York. His initial efforts were in the field of head injury, and the lowering of body temperature in the management of head injuries, as well as an adjunct to the surgery of vascular lesions of the brain, particularly, aneurysms. He developed the prototype for the cryoprobe now used for cryosurgery in a large number of medical fields. Dr. Rosomoff also became involved in tissue transplantation and developed the method for preparing ethylene oxide sterilized, freeze-dried dura mater for repair of dural defects. He developed a technique for cranial reconstruction using chemically treated bone which could provide indefinite shelf life and transplantation from one individual to another. In the 1960s, Dr. Rosomoff became involved in research on pain and developed the technique of percutaneous radiofrequency cordotomy for intractable pain. This immediately gained recognition and replaced the open surgical method which had been used up to this point. Dr. Rosomoff was the first to investigate the effects of LASER on the brain and the use of LASERS for treatment of tumors in man; he performed the first brain surgeries with the LASER in 1965. The 1970's brought investigations of low back disorders, effect of lumbar disc nerve root compression on the function of the bladder, the neurogenic bladder Transaxial tomography, which looked at the spine in a cross-sectional plane, was developed to demonstrate intrusions into the spine by either bone or soft tissue, a prologue to CAT scanning of the spine, then the MRI. This led to a new operation, neural arch resection for bony encroachment into the lumbar spine, which was abandoned for the management of pain by non-invasive techniques and rehabilitation of low back disorders

Over his many years of practice and research, Dr. Roso-

moff became recognized as a world authority on pain and its treatment. He pioneered investigation of hypothermia for intracranial vascular surgery and developed techniques of cryosurgery. The first to use lasers in brain surgery, he also introduced several innovative surgical procedures for the spine, including the technique of radiofrequency percutaneous cordotomy. Dr. Rosomoff also helped to develop the radiological criteria which led to the present day interpretations of CAT-scans and MRIs.

In 1971, Dr. Rosomoff was recruited to become Professor and the first Chairman of the newly autonomous Department of Neurological Surgery at the University Of Miami School Of Medicine. During his long tenure, the Department became nationally recognized for its innovative techniques and the outstanding quality of its faculty. He also served as Professor of Orthopedics and Rehabilitation and Anesthesiology at the UM. Under his leadership, Dr. Rosomoff helped bring together the team and resources that advanced to become the Miami Project to Cure Paralysis, which has gone on to become an Institute of Neuroscience at the UM.

In 1974, Dr. Rosomoff founded the University of Miami's first Comprehensive Pain and Rehabilitation Center. He served as its Medical Director, and his wife Renee Rosomoff served as first Programs Director. This Center is now the largest of its kind in the world, employing some 70 professionals in an integrated, cohesive program for the management of painful disorders. The hypothesis and techniques developed in this program are causing review and re-evaluation of the heretofore traditional methods. This approach has a high rate of success, 85% for return of function and decrease and/or relief of pain. The clinical research conducted in the Center not only has produced new techniques for management, but has brought forth new theories on the etiology of pain in low back disorders, with attention to the symptoms and signs that originate from associated soft tissue injuries. In fact, this work has demonstrated that herniated discs or stenosis are not the most common cause of low back syndromes, but rather soft tissue injury and secondary changes which mimic and produce neurologic findings which heretofore have led to surgical intervention.

In 1994, Dr. Rosomoff stepped aside to become Professor and Chairman Emeritus of the Department of Neurological Surgery to devote fulltime effort to the Pain Center, which was then established as a Center of Excellence by

the University of Miami. In 2003, the Center was renamed the Rosomoff Comprehensive Pain Center (RCPC) in their honor. In 2004, the Center moved to its present location at the Miami Jewish Home and Hospital. The Center has become the world model for multidisciplinary Pain Treatment Programs, successfully evaluating and treating over 34,000 patients. In 2007, the American Pain Society honored the RCPC as one of its first national "Centers of Excellence."

During his stellar career, Dr. Rosomoff guided many professional organizations. He helped found the International Association for the Study of Pain, the American Pain Society, and the Eastern Pain Society. He served as President of the American Pain Society, American Academy of Pain Medicine, and the Southern Pain Society. Dr. Rosomoff was prominent in the effort to develop the specialty of Pain Medicine, which has been recognized by the American Board of Medical Specialties. He was selected by the governor to serve as Vice-Chairman of the Florida Pain Commission. Along with his wife and Co-director, Renee Steele Rosomoff, he helped to develop pain rehabilitation centers and hospitals in Colombia, Peru, India, Israel, and Egypt. A pain treatment center in Cali, Colombia bears his name.

Dr. Rosomoff treated high-profile patients-Robert Goulet, Bob Hope, two sons of Egyptian President Hosni Mubamk, and Colombian soccer star Willington Ortiz.

Among the many prestigious awards Dr. Rosomoff received were the American Pain Society's "Distinguished Service Award," the Jeremiah J. Fix Award in Rehabilitation, the Philipp M. Lippe Award from the American Academy of Pain Medicine and the Claude Pepper Award for development of the Rosomoff Comprehensive Pain Center. Dr. Rosomoff was honored with a "Life Achievement Award" from the Greater Miami Chamber of Commerce, and in 1997 he was named "Alumnus of the Year" by his medical school at Hahnemann University. He was the author of over 350 books and articles, and editor of several journals. Dr. Rosomoff was a member of numerous professional organizations an international guest lecturer, and consultant.

Dr. Rosomoff was a giant in the academic, medical and surgical world. Many patients benefitted from his knowledge and caring and were given back their lives. He will be missed by all of those who knew and loved him.