



SPS NEWS

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Compliance Monitoring

Peter D. Wright, M.D.

Scheduled medications such as opioids continue to play a significant role in most pain physicians' treatment of chronic pain patients. Although there is clearly a role for these medications in alleviating pain, they also play a role in substance abuse and addiction, as well as diversion.

Therefore, any clinician involved in the prescribing of scheduled medications needs to actively monitor his/her patients for compliance with the treatment plan. Also, the clinician should be aware of state and federal regulations regarding these medications, as well as guidelines for prescribing scheduled medications. Vigilance is critical.

When considering a patient for opioid medications, several rules should be followed:

- Consider only after adjuvant therapies have failed.
- A history of substance abuse is a relative contraindication.
- A single practitioner should take primary responsibility.
- Patients should sign an Informed Consent / Controlled Substance Agreement.
- Long acting opioids are preferred.
- Pain control should be in conjunction with physical and psychological rehabilitation.
- Rescue meds can be utilized for breakthrough pain.
- Patient should be seen on a regularly scheduled basis.
- Discontinue meds if evidence of aberrant behavior.

- Portenoy, J Pain Symptom Management, 1990

An integral part of controlled substance prescribing involves compliance monitoring. Two critical tools in compliance monitoring are the use of the Random Urine Drug Screen and the Random Pill Count. In the Commonwealth of Kentucky, we also are fortunate to have a third tool: The KASPER report, which I discussed in my last contribution to the Southern Pain Society newsletter. In addition, the use of psychologic testing can aid in identifying persons who could be at increased risk for abuse or misuse of their medications. None of these methods are foolproof, however when used in conjunction, they aid the clinician in reducing the likelihood of diversion and abuse in his/her practice.

Unfortunately, Medicaid of Kentucky has recently decided to no longer cover the expense for urine drug testing, stating that its use is not medically indicated. I could not disagree more strongly. The urine drug screen is critical in our monitoring methods, and although only part of the overall approach, is nonetheless vital. Since we believe that urine drug screening is crucial to our safe prescribing practices, we do still require that these be obtained on the Medicaid population. We have been able to work out a reduced pricing schedule for our Medicaid patients, and have informed them that it is their responsibility to have \$25 available at each visit in case a urine drug screen might be required of them. This no doubt places additional burden on an already disadvantaged population, but we maintain it is critical in ensuring that all of our patients are appropriately monitored. We are currently attempting to reverse Medicaid's decision, arguing this is no different than refusing to pay for an INR for patients on coumadin, or a glycohemoglobin level for diabetics. However, Medicaid is interested in reducing costs wherever possible. Be vigilant for similar policy changes in your state.

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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Editor's Desk

Jonathan D. Cole, Ph.D.

With the demands of our busy schedules, a different pain meeting seems to come up almost every week. Why should you take the time to attend yet another pain meeting? After being involved with the Southern Pain Society, as well as other pain groups and having previously lived in Biloxi, MS for 5 years I have a unique perspective on that question.

I present you with 7 reasons to attend the annual Southern Pain Society Meeting in July at the Beau Rivage Casino and Resort in Biloxi, MS.

1. Program events – There is a wide variety of speakers from neurology to chiropractic specialties. There should be something for everyone in pain management.
2. Accessibility of Speakers – Unlike larger national conventions, the SPS meetings are more manageable and it is easier to talk to most speakers directly. Also, you will get a chance to see how other disciplines treat pain.
3. Beau Rivage Casino and Resort – A first class casino and hotel on the beach with accessibility to excellent fishing and golf.
4. Networking – Talking to others around the country gives you a different perspective on how to treat pain.
5. Ideas – Attending lectures and talking with colleagues helps stimulate thinking and gives you ideas on research and treatment.
6. Food – Fresh seafood; I would recommend the marinated crab claws at Mary Mahoney's and the red velvet cake at Chappy's.
7. Rejuvenation – Pain Management is a high burn out specialty. Attending conferences allow you to understand you are not alone in your problems and may give you different ways to solve them.

I hope to see you in Biloxi.

President's Column

Angela J. Koestler, Ph.D.



Family and internal medicine physicians are on the frontline in waging war against pain. They frequently provide ongoing care to patients with painful disorders and serve as gatekeepers to other pain specialists. Their patient pain population is diverse and not limited to specific diagnostic categories as is

found in rheumatology, neurology, and other specialty areas. Care is provided to patients with painful neuropathies and sickle cell to lumbar sprains and other musculoskeletal problems. Yet, the number of family and internal medicine physicians involved in pain organizations is quite low.

Understanding the complexities of pain disorders is difficult given the spectrum of factors that can affect the patient's pain experience (i.e., perception, coping response, etc.). For example, symptom magnification and symptom exaggeration are often misinterpreted as a clear indication of malingering. Additionally, several journal articles have appeared over the last five years attempting to clarify the intended meaning of Waddell Signs. Positive Waddell Signs have sometimes been interpreted to signify malingering when, in fact, this is not the case, nor the intent of the authors.

Education and networking are cornerstones of pain organizations and offer healthcare providers many opportunities to participate and learn about practice guidelines, the latest research, and interdisciplinary approaches to pain management. The Southern Pain Society will hold its 2004 Annual Scientific Meeting with the Mississippi Pain Society at the Beau Rivage Resort in Biloxi, Mississippi, July 30- August 1, 2004. A special invitation will be extended to family practice and internal medicine physicians to attend. Dr. Bert Ray,

Program Chair, and his committee have done an outstanding job in planning and organizing the meeting. Program topics include diagnosis and treatment of headaches, pharmacotherapies, interdisciplinary pain treatment, and ethics in pain treatment. The brochure is in the mail! Mark your calendars and join us on the Mississippi Gulf Coast!

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 biographical information.

Submission Deadlines

Winter edition-November 1; Spring edition-February 1; Summer edition-May 1; Fall edition-August 1.

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OUTCOMES

Daniel M. Doleys, Ph.D.
Director, Pain and Rehabilitation Institute
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“When the right thing can only be measured poorly, it tends to cause the wrong thing to be measured well. And, it is often much worse to have a good measurement of the wrong thing, especially when it is so often the case that the wrong thing will, in fact, be used as a indicator of the right thing, than to have a poor measure of the right thing”

John Tukey, Ph.D.

“Evidence-based medicine refers to the conscientious, explicit, and judicious use of the best evidence in making decisions about the care of individual patients” (p. 330; Sackett & Rosenberg, 1995). It requires the deliberate and thoughtful use of the most systematic and contemporary information in determining a treatment algorithm. Indeed, one fundamental purpose of continuing education requirements is to provide a mechanism for disseminating this information. Outcomes research should generally form the basis of the data presented as opposed to personal bias, speculation, conjecture, anecdote, or blatant assertion. Presumably, the FDA, insurance companies and other health care agencies rely on these outcomes to form the foundation for their decision making; though clearly there appear to be other political, financial, and/or practical considerations. Community standards often form the basis for “off label” applications.

Treatment goals and, therefore outcome measures, may be very different for acute vs chronic conditions. Outcomes involving acute conditions often rely on measures of symptom resolution, return to baseline health and/or mortality data. Chronic conditions are often more complex as treatments are oriented toward management vs resolution, improved quality of life, decreased distress, increased functioning and, especially in the case of “pain”, alteration in a subjective

symptom. Chronic pain poses the additional problem of not falling into a distinct organ system, pathophysiological process or discipline. The “source” of the pain may range from a minor musculo-skeletal problem to a major nerve injury. The pain may be limited to a single body part or generalized exceeding usual dermatomal and/or nerve distribution patterns.

There are many types of outcomes measures. Some are “disease specific” others more “generic”. These measures may be collected longitudinally i.e. on a regular basis over time, or crosssectionally i.e. at a specific time for all patients. Some of the more disease specific measures might include numerical pain rating (NPR), visual analogue scale (VAS), pain affect, depression, and medication utilization. Health related quality of life and overall health status represent typical generic measures. The more specific the measure i.e. swelling or skin temperature in a CRPS I patient, the less generalizable it will be to other conditions. However, the less specific measures may not be sensitive enough to detect meaningful changes. Oftentimes, some measures, such numerical pain rating, identify changes which are sufficient to produce a statistically significant change without evidence of any noteworthy functional or clinical change (Todd, 1996).

Different measures of a particular factor or dependent variable may constitute a “domain”. Several domains may then be assessed. For example, in evaluating pain, Deyo, Battie et al (1998) have suggested measuring pain, mood and function as primary domains. Bombardier (2000) recommended the use of five domains in evaluating outcomes related to low back pain including (a) back specific function (Roland-Morris; Oswestry), (b) generic health status (SF 36), (c) Pain (Numerical rating scale), (d) Work disability (Work status), and (e) Patient satisfaction. This was felt to represent a “core set” of measures that would be sensitive and specific enough to uncover meaningful

changes. Similarly, De C. Williams (2001) suggested pain experience, affect, cognition and coping, behavior and activity, social role interference, biological and fitness measures, and use of health care system as outcome domains.

Turk and Dworkin et al (2003) made up a panel of 27 experts convened for the purpose of recommending outcome domains to be used when conducting clinical trials. The six "core" domains included (1) Pain, (2) Physical functioning, (3) Emotional functioning, (4) Participant rating of global improvement, (5) Symptoms and adverse events, and (6) Participant disposition ie adherence to treatment regimen and reason for premature withdrawal from the trial. They also recommended eight "supplemental" domains; (1) Role function (ie work and educational activity), (2) Interpersonal functioning (relationship with family and activities with others), (3) Pharmacoeconomic measures and health care utilization, (4) Biological markers (quantitative sensory testing, imaging, genetic markers), (5) Coping, (6) Clinician or surrogate ratings of global improvement, (7) Neuropsychological assessment, and (8) Suffering and other end-of-life issues.

There has been considerable recent work as to the degree of pain reduction required for there to be a clinically meaningful change. Acute, cancer and chronic pain patients were studied (Cepeda et al 2003; Farrar et al, 2000,2001,2003; Price et al 1985,1986). Outcomes were be grouped as "minimal improvement", "much improved", and "very much improved". A reduction in units on a NPR scale (0-10) and percent reduction in pain (0-100%) were calculated for the "moderate" pain (4-6/10) and "severe" pain (6+/10) groups. In the moderate group, reductions of 1.3 units or 20%, 2.5 units or 35%, or 3.5 units or 45% were required for minimal, much and very much improved respectively. Changes of 1.8 units or 20%, 4.0 units or 44%, 5.2 units or 56% were noted for the three levels of improvement in the severe group. No data is available regarding the correlation of these changes with functional status. Todd and Funk (1996) found a reduction of 18mm or 23% decrease from baseline on a VAS to be required for an outcome to be of "minimal" clinical importance. Wells et al (1993) reported patients considered their pain "somewhat

worse" when the VAS score was 14.5mm higher and "somewhat better" when it was 6.2mm lower than another patient's pain.

Studies by Doleys et al(1998) examined pain reduction in patients undergoing intrathecal therapy for chronic pain. On average, patients reported a 3.9 units or about 43% reduction in NPR pre-post. However, when asked to rate their "percent improvement" the average was about 63%. When asked to rate their improvement in functioning, patient estimates tended to be nearly twice as high as their significant other. This led the authors to conclude that patients tended to pay more attention to how they "feel" and significant others to what patients "do". This relative lack of improvement in function, in spite of reporting an apparent significant decrease in pain, was also noted by Jamison et al (1998). In addition, the degree of perceived disability and distress appears to be greater for patients with a similar level of NPR taking oral opioids compared to those not taking opioids (Fillingim, Doleys et al, 2003). Ironically, males taking oral opioids showed greater affective distress than those not; however, the reverse was true for females. Thus, neither the NPR, nor the degree of decrease in NPR, necessarily correlate with increased function or degree of functional/emotional "disability".

Cleeland (1998) determined that patients could be grouped as having mild, moderate or severe pain according to their NPR; 1-4 = mild, 4-6 = moderate, 6+ severe. An unpublished report by Haddox and Doleys (2003) noted similar groupings when subjective reports of the impact of pain were considered. In this regard, it may be as, or perhaps more, important to consider whether or not a patient has changed from one group to another. For example, a patient's whose NPR has decreased from 9.5/10 to 7.0/10 may show less overall improvement as compared to one that goes from 7.5/10 to 6.0/10. In the latter case, the decrease in NPR and the percent reduction from baseline is less, but the patient has moved from the "severe" to "moderate" group.

Establishing goals and expectations is a major part of many, especially functional restoration ori-

ented, treatments. However, the goals must be considered in the context of what is rational and realistic for a given patient. Those for a patient with musculoskeletal problems may be very different from one with severe CRPS. Likewise, as demonstrated by Anderson et al (2001), not all patients value the same goal equally. That is, some find improvement in walking tolerance much more important than others. In fact, in their monograph discussing trailing mechanisms for intrathecal therapy, Follette and Doleys (2002) suggested evaluating outcomes based on percent and degree of goal achievement, thus allowing for this individual variation in goals among patients.

The role of patient satisfaction continues to be of interest. There has been some indication that overall satisfaction may be linked to (a) the patient's "perception" as to the degree the practitioner has attempted to help, and (b) the correlation between the "expected" and achieved outcome and not the actual outcome per se. That is, a patient expecting 80% improvement is not likely to be as "satisfied" with 60%, whereas one expecting 60% would. This observation leads to the logical question as to "satisfied with WHAT?"; practitioner's manner, education process, pain relief, functional outcome, etc. Hudak and Wright (2000) have outlined several of these dimensions and proposed a questionnaire to evaluate patient satisfaction which included questions relating to satisfaction with care and with treatment outcome.

The appropriate comparison pre-post treatment is another consideration. Our emphasis on "statistical" significance within or between groups of patients has led us away from examining the individual patient, N=1 design (Doleys, 2000). This statistical approach may camouflage important individual differences. It is noteworthy how often the more basic science research, upon which we tend to build our clinical theories and treatments, utilize rather small number of cells, neurons, tracts, animals, etc. Likewise, there is a tendency to adopt a "predictive" approach, based on outcomes data, to determine the likelihood that a given patient "fits the mold". In so doing we deem those falling outside some hypothesized and often imaginary range, incapable of, or at the very least, a poor candidate for, the proposed treatment. I wonder if we are really this sure? In this scenario, the practi-

tioner may ignore the nuances of the procedure, concerned only about the outcome data, as the model has already predicted a good outcome. If the outcome is other than "predicted" or expected, the patient, of course, is usually held responsible, i.e. "... treatment was successful, but the patient did not respond".

As noted above, there appears to be disconnect between pain severity/relief, functioning, and patient's ratings of improvement/satisfaction. In addition, there is reason to believe that "focusing on the pain", as would be the case with repeated request for a NPR or VAS score, might actually increase the perception of pain and/or reinforce certain ratings. With this in mind, perhaps we should attend to those areas more related to patient well-being, such as increase in reinforcing activities, improvement in mood, "acceptance"/coping with residual capacities, etc. which, when they occur, seem to be associated with a more content, satisfied, and productive patient, independent of their pain rating or degree of pain reduction. We have certainly encountered patients that report remarkable increase in satisfaction with life and functioning following treatment despite little or no change in NPR or VAS score. This observation would seem consistent with our understanding of the multidimensional aspect of the pain "experience", i.e. sensory, affective, evaluative/cognitive, and behavioral, and the somewhat segregated yet interconnected cortical areas (i.e. somatosensory cortex, thalamic/limbic system, and frontal cortex,) involved in "pain processing". Perhaps the affective, cognitive and behavioral are more amenable to change. A hypothetical parallel might be the diabetic patient, wherein the treatment is focused on weight control, diet, and exercise, realizing that these are primary factors in controlling blood sugar levels.

Clearly, the above is not a comprehensive or critical review of the literature on outcomes. Rather, the intent was to highlight a few areas of interest to the author and, hopefully, stimulate some provocative thinking. Even as the search for a biomarker of pain continues (Mannes et al, 2003), Kalso(2004) reminds us "pain needs the brain to be perceived" (p200). The patient's sub-

jective response has a long history of importance (Beecher, 1952). However, it behooves us to remain mindful of those variables which make up and influence that response.

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