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Minimally Invasive Spine Surgery Is a Smart Marketing Concept. But Does It Result in Quicker Recovery?

Minimally invasive spine surgery holds tremendous allure. "Patients like the idea of it. So do surgeons," says spinal technology consultant Terry Corbin of Corbin and Company in Minneapolis.

"They believe it shortens hospital stays, reduces scarring, speeds recovery, and leads to superior results in terms of pain, function, and need for pain medications," Corbin adds.

Hospitals, medical centers, and private clinics advertise the advantages of minimally invasive spine surgery aggressively on radio and television.

Anyone who doubts this need only listen to "sports talk radio" in Boston, where discussion of the performance of the Boston Red Sox pitching staff and the New England Patriots defensive backfield intermingles with ads from local hospitals for minimally invasive spine procedures. (See WEEI.com, 2009.)

However, Corbin suggests that neither surgeons nor patients should get carried away by the intuitive appeal of these procedures—or their marketing campaigns. "Thus far, rigorous scientific studies have not yet documented most of the advertised advantages of minimally invasive spine surgery," says Corbin.

Minimally Invasive Disc Surgery

A large new randomized trial evaluating a minimally invasive form of disc surgery illustrates this point.

The new study is also a superb example of comparative effectiveness research, i.e. a scientific investigation designed to directly compare the benefits and risks of popular treatment options—and allow patients, physicians, and other stakeholders to make better decisions regarding medical care.

It is the type of careful, independent research that should occur early in the research process for every new spinal technology—but rarely does, says Bradley K. Weiner, MD, Chief of Spinal Surgery at the Methodist Hospital in Houston, Texas. (See Weiner's full comments on page 105.) As a result, patients and other stakeholders often have to wait a decade or more to see how a new technology stacks up against other treatment choices.

Mark P. Arts, MD, and a group of spine surgeons from seven hospitals in the Netherlands decided to perform an independently financed randomized controlled trial (RCT) comparing a standard method of discectomy (microdiscectomy) with one of the most popular forms of minimally invasive disc surgery—the METRx tubular discectomy technique developed by Medtronic of Minneapolis. (See explanation of technique below.)

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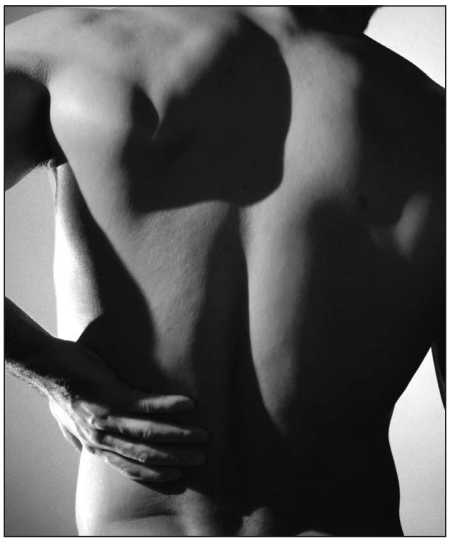

Opening Up Spine Research

Ever see a randomized controlled trial with results that appeared to be preordained? Or just incomplete, as if the researchers only wanted to report the outcomes that supported their collective viewpoints?

Everyone who reads medical journals has had this reaction. Without insulting anyone in particular, quite a few published trials in the spine field do not appear to be even-handed, objective evaluations of study hypotheses. And incomplete reporting of the results of randomized controlled trials appears to be common, suggesting that both randomized trials and systematic reviews of those trials may exaggerate the efficacy and underestimate the harms of treatments under study.

However, there may be some impending relief for those who would like to see this situation addressed with better science. It looks as if there is about to be a seismic shift in the way scientific studies are performed in the spine field—as in other areas of medicine.

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Black Holes in the Evidence on Medications for Radicular Pain

There are more than 1000 randomized trials on treatments for back pain, with additional trials being published every month. Yet there are still curiously large gaps in the evidence on treatments that could be studied easily.

Gaps in the Evidence On Neuropathic Pain

The drug treatment of neuropathic pain is a case in point. Neuropathic pain is generally defined as pain relating to disease of—or injury to—the nervous system.

The most common examples of pain with a strong neuropathic component in the spine would be various radicular syndromes, e.g. sciatica related to a disc herniation or radiculopathy/neurogenic claudication secondary to spinal stenosis.

Anticonvulsant medications have been used to address back problems since the 1960s. And they are regarded as particularly useful in the management of neuropathic pain.

However, a recent systematic review pointed out that there are major gaps in the evidence on anticonvulsants for specific neuropathic pain conditions.

Where Is the Evidence on Drug Treatments for Radicular Pain?

Felicity Goodyear-Smith, MB, and colleagues performed a systematic review on both the quantity and quality of evidence on anticonvulsants in the treatment of neuropathic pain. (See Goodyear-Smith et al., 2009.)

They found strong evidence in favor of anticonvulsants for several specific conditions: diabetic neuropathy, postherpetic neuralgia, trigeminal neuralgia, spinal cord injury pain, neuropathy related to HIV, and post-stroke pain.

However, they couldn't find any evidence on the use of anticonvulsants for some of the most common forms of neuropathic pain.

"What is clearly apparent is the huge number of gaps in the evidence—no drug has been trialed for all conditions ...," according to Smith et al.

And they found a gap that may undermine the care options of every patient with radicular back or neck pain. "There is no evidence at all (at least not where pain is the primary outcome) relating to the use of anticonvulsants for the most common type of neuropathic pain, that associated with the back or neck," according to the reviewers.

Scientific Evidence and Clinical Practice Diverging?

Many forms of neuropathic pain continue to be undertreated and/or poorly managed. This is an area where there is a growing discrepancy—in terms of off-label applications of anticonvulsants and experimental combination therapies involving these and other drugs—between clinical practice and the scientific evidence.

It is important to emphasize that this discrepancy needn't exist. There is ample scientific knowledge to run trials in all the areas where anticonvulsants are poorly studied. What is lacking is a rationally designed research system that can not only identify these gaps—but also quickly fill them with solid scientific research.

Reference:

Goodyear-Smith F et al., Anticonvulsants for neuropathic pain: Gaps in the evidence, *Clinical Journal of Pain,* 2009; 25:528–36.

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Treatment Options for Severe Back Pain in a War Zone

What would be some treatment options for soldiers in a war zone who suffer from chronic, intractable back and/or leg pain—but want to continue serving in combat operations? The list is surprisingly short.

In a recent case series on military personnel with severe pain complaints published in *Anesthesia and Analgesia,* Anthony Dragovich, MD, and colleagues discussed some of the possibilities. (See Dragovich et al., 2009.)

The use of nerve blocks isn't all that feasible in a war zone because of a shortage of trained medical providers to administer them, not to mention the need for recurrent treatment. These military physicians didn't mention it, but there is a also a lack of evidence from high-quality trials that nerve blocks can predictably deliver effective pain relief for chronic, intractable back or leg pain.

Pain-Relieving Medications Pose Problems

Oral medications and drug patches aren't exactly glittering possibilities either. "Pharmacotherapy has similar downsides in that all neuropathic pain medications have the potential to cause lethargy and cognitive dysfunction, which can endanger lives in combat zones," according to Dragovich et al.

What About Opioids?

Strong opioids in any form are problematic: side effects include "depression, lethargy, cognitive impairment, impaired wound healing, immunosuppression, and loss muscle mass," according to these authors. And opioids suffer from another major deficit: a lack of evidence from high-quality clinical trials that they are effective in the long-term treatment of chronic noncancer pain.

Intrathecal pain pumps also pose problems: lack of proven efficacy as well as potentially serious side effects related to device migration and dysfunction.

Is Spinal Cord Stimulation A Possibility?

Dragovich et al. propose spinal cord stimulation (SCS) as a possibility in a war zone. They make an interesting case for it, though this suggestion will certainly raise some eyebrows.

For those don't follow this area, SCS systems employ an implanted electrode and a battery to provide low-voltage electrical stimulation to the spinal cord and block the sensation of pain.

The exact mechanism of pain relief from SCS isn't clear. Some researchers believe that SCS blocks or partially blocks the transmission of pain signals by activating nerve fibers in the spinal cord. But there are other possible explanations, including placebo or nonspecific effects.

In their case series, Dragovich et al. describe the treatment of intractable chronic pain among four active-duty soldiers and two retired soldiers serving as military contractors in a combat area.

Three of the subjects suffered from a combination of back and bilateral leg pain after failed spine surgery, one had chronic ankle pain, and two others suffered from chronic forearm and head pain, respectively.

All had successful implantation of SCS devices, and all reported adequate pain relief without excessive complications. Five patients reported no complications or adverse side effects during their subsequent deployment. The sixth actually completed four tours of duty, but eventually had mechanical complications from the SCS system, requiring revision surgery.

Dragovich et al. offer an optimistic assessment of the potential of SCS among patients with demanding physical job tasks and a strong desire to return to normal activity. "Considering the risks and limitations of reoperation, nerve blocks, and pharmacotherapy in a forward-deployed area, spinal cord stimulation provides an appealing alternative in solders who desire to remain deployable on active duty," they said.

The Limitations of Small Case Series

Kudos to these authors for trying to help their patients continue physically active lives. And Dragovich et al. deserve congratulations for publishing their experiences in a peer-reviewed medical journal so other medical providers and patients can consider evidence on these options

However, this study has all the limitations of small case series. It shows that this treatment can be used effectively and safely by a small number of motivated individuals with radicular pain. It does not describe any individuals who failed to find adequate pain relief from SCS. Yet SCS has a reputation for providing effective pain relief to only 50% of patients who try it.

To what extent the experiences described in this case series generalize to other soldiers and other individuals with active lifestyles isn't clear. And one hopes there will be continued reporting about other active duty military personnel attempting these treatments.

Benefit for a Narrow Range of Back Problems?

According to recent reviews of the literature, SCS offers a proven benefit to a relatively narrow spectrum of patients with spinal pain, i.e. those with radicular pain after failed spine surgery.

The recent American Pain Society review of invasive, nonsurgical treatments for chronic back pain took a careful look at the evidence on SCS.

"We found fair evidence from two trials that spinal cord stimulation is more effective than either repeat surgery or continued conventional medical management for failed back surgery syndrome with persistent radiculopathy," according to the guidelines. (See Chou et al., 2009.)

The reviewers couldn't find any convincing evidence, however, that SCS was an effective treatment for axial back pain without a radicular component.

What About Complications?

The review by Roger Chou, MD, et al. also noted that these implanted systems are

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Opioids, Auto Accidents, and Fatalities

"Drugged driving, like drunk driving, is a matter of public safety and health. It puts us all at risk and must be prevented."

To what extent are the escalating epidemics of opioid utilization and misuse contributing to traffic accidents and fatalities?

This is a key question in the United States where opioids are being prescribed to unprecedented numbers of patients, particularly individuals with chronic low back symptoms.

Unfortunately, there is no clear answer regarding the influence of opioids on driving. (See adjoining article: How Strong Is the Evidence on Opioids and Driving?)

However, the incidence of driving under the influence of potentially impairing drugs in general is rising in the United States, according to a new report from the National Highway Traffic Safety Administration (NHTSA). (See Compton and Berning, 2009.)

"This troubling data shows us, for the first time, the scope of drugged driving in America, and reinforces the need to reduce drug abuse," said Gil Kerlikowske, director of the Office of National Drug Control Policy. "Drugged driving, like drunk driving, is a matter of public safety and health. It puts us all at risk and must be prevented."

Nationwide Survey of Alcohol and Drug Use by Drivers

The NHTSA recently published its first report on the 2007 National Roadside Survey of Alcohol and Drug Use by drivers. This survey—involving random stops of drivers at 300 locations across the United States during the day and at night—examined alcohol and drug use among a nationally representative sample of U.S. drivers.

One Less for the Road

The data on drinking and driving are encouraging. The survey found a dramatic decline in driving under the influence of alcohol. In 1973, a national survey concluded that 7.5% of drivers in the United States had blood alcohol levels above the current legal limit of 0.08 g/dL. That number fell to 2.2% of drivers in 2007. This is real progress.

However, for the first time, the 2007 survey included drug testing, employing both oral fluid samples (for drivers tested during the day and at night) and blood tests (only for drivers tested at night).

These tests assessed the presence of a group of potentially impairing drugs (illegal, prescription, and over-the-counter products), including stimulants, sedatives, antidepressants, marijuana, and narcotic analgesics.

Nearly One in Six Drivers Under the Influence of Drugs

The results are disturbing. During the day, 11% of the drivers tested positive for a potentially impairing drug—based on oral fluid samples. And at night, 16.3% of drivers had either a positive oral fluid or blood test for an impairing drug. In other words, nearly one out of six motor vehicles on the road at night had a driver under the influence of a potentially impairing medication.

One Toke Over the Line?

The agency reported that 8.6% of drivers tested positive for marijuana/ THC, 3.9% for cocaine, and 1.3% for methamphetamine. These may seem like small proportions, but given the number of drivers in the U.S., they translate into large numbers.

The NHTSA has not yet reported results on prescription medications, including narcotic analgesics. However, those data should be forthcoming.

Case-Control Study on Drug-Related Accidents

The agency is also performing a follow-up study to the 2007 survey—to see how drug use translates into actual accidents.

"The case-control study will include in-depth investigations of a large number of crashes of all severities. The proportion of drug use by crash-involved drivers will be compared to that of a similar sample of non-crash involved drivers to determine if drug use is associated with crash involvement," according to the NHTSA.

Is Driving Under the Influence of Opioids Dangerous?

A recent report suggested that 28% of visits for low back pain in the United States resulted in a prescription for opioids. (See Licciardone, 2008.) This suggests that large numbers of patients—as well as several million prescription opioid abusers—are operating motor vehicles under the influence of narcotics.

Some suspect that this constitutes a serious safety hazard. However, scientific studies—both in laboratory and in real-life settings—have yet to determine the degree to which opioid use leads to impaired driving.

As part of a recent guideline on the role of opioids in the management of chronic noncancer pain, a consensus panel from the American Pain Society (APS) offered the following recommendation on opioid use relative to driving and work safety (see Chou et al., 2009):

> *Clinicians should counsel patients on chronic opioid therapy about transient or lasting cognitive impairment that may affect driving and work safety. Patients should be counseled not to drive or engage in potentially dangerous activities when impaired or if they describe or demonstrate signs of impairment.*

The APS panel did not provide much practical guidance on how

patients or their health care providers should assess opioid-related impairment.

However, the panel did acknowledge that opioids may cause "somnolence, clouded mentation, decreased concentration, and slower reflexes or incoordination, especially when initiating therapy, increasing doses, or when opioids are taken with other drugs or substances." [*Editor's note:* "somnolence" means "sleepiness" or "drowsiness" and "mentation" means "mental activity."]

The panel offered rather optimistic advice for patients on chronic opioid therapy who don't show signs or symptoms of impairment:

> *In the absence of signs or symptoms of impairment, no evidence exists to suggest that patients maintained on chronic opioid therapy should be restricted from driving or engaging in most work activities.*

There is insufficient evidence to allow informed clinical decisions regarding the safety of driving under the influence of prescription opioids.

References:

Chou R et al., Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain, *Journal of Pain,* 2009; 10:113–30.

Compton R and Berning A, *Results of the National Roadside Survey of Alcohol and Drug Use by Drivers,* National Highway Traffic Safety Administration; www.nhtsa.gov/staticfiles/DOT/NHTSA/Traffic%20Injury%20Control/Articles/Associated%20Files/811175.pdf.

Licciardone JC, The epidemiology and medical management of low back pain during ambulatory medical care visits in the United States, *Osteopathic Medicine and Primary Care,* 2008; 2:11.

How Strong Is the Evidence on Opioids And Driving?

All the main evidence statements in the recent American Pain Society(APS) guidelines on chronic opioid therapy for chronic noncancer pain were the subject of a structured review to gauge the strength of the supporting evidence. (See Chou et al. [a], 2009.)

In addition, Roger Chou, MD, and colleagues published an article on major gaps in the evidence on opioids—a study that accompanied the guidelines. (See Chou et al. [b], 2009.)

The reviewers found meager evidence regarding the influence of opioids on driving and work safety. In their literature search, they identified two systematic reviews of nonrandomized trials and four case-control and/or cohort studies—in addition to a variety of epidemiological research.

"Evidence on driving and work safety is limited to epidemiologic studies and studies that evaluated the performance of patients on chronic opioid therapy [in] standardized driving tests," according to Chou et al.

The limitations in the data include: (1) reliance on cross-study comparisons to interpret epidemiologic studies (e.g. comparing rates of opioid use in persons involved in motor vehicle accidents compared with estimates of opioid use in the general population); (2) use of simulated and other controlled driving tests that may not reflect real-world conditions and circumstances; and (3) probable selection bias—because patients with significant opioid-related impairment may be less likely to drive and/or to participate in studies of driving abilities.

The main conclusion of this review won't be reassuring to patients or their health care providers: "There is ... insufficient evidence to reliably inform clinical decisions regarding driving and work-related risks in patients prescribed chronic opioid therapy ..." according to Chou et al.

That conclusion shouldn't come as a surprise, however. There is insufficient evidence regarding almost all aspects of opioid use in the long-term treatment of chronic pain. Only four of the 25 consensus statements in the APS guidelines on chronic opioid therapy for chronic noncancer pain were supported by strong evidence.

References:

Chou R et al. (a), Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain, *Journal of Pain,* 2009; 10:113–30.

Chou R et al. (b), Research gaps on use of opioids for noncancer pain: Findings from a review of the evidence for an American Pain Society and American Academy of Pain Medicine Clinical Practice Guideline, *Journal of Pain,* 2009; 10:147–59.

Clash Between Evidence-Based Medicine and Allegiance to Spinal Injections—With a Sad Outcome

Back pain experts who volunteer to take part in systematic reviews concerning the scientific evidence on low back pain usually do not have to look over their shoulders in fear of their professional societies.

Most participants understand that systematic reviews and related guideline development efforts follow a standardized method of identifying, analyzing, and rating the quality of randomized controlled trials (RCTs) and other studies.

Reviewers usually do not intend the final output to be a representation of their personal opinions but of the content of the underlying scientific evidence.

And most professional medical societies are supportive of the roles of their members in these evidence-vetting efforts even if these organizations don't agree with the conclusions of the systematic reviews.

British Pain Society Breaks With Tradition

The British Pain Society recently broke with this genial scientific tradition and decided to oust its president, Paul Watson, PhD, for taking part in a systematic review and guideline effort on the early management of persistent nonspecific low back pain—and for not protesting the conclusions of the guideline regarding spinal injections.

As a report in the *BMJ* noted, "The president was forced to resign on 21 July after a campaign from members who were unhappy with guidelines on the management of low back pain from the National Institute for Health and Clinical Excellence (NICE), which he helped develop." (See Kmietowicz, 2009.)

This is a sad punishment for a distinguished health care professional who was simply following the dictates of a standardized evidence-gathering process.

The NICE panel, chaired by Martin Underwood, MD, was investigating the evidence on the management of persistent low back pain lasting for more than six weeks but less than a year. Readers can find the complete evidence document and a summary of the main recommendations of the NICE panel at the reference below. (See NICE, 2009.)

Opponents of Health Care Reform Glom Onto the UK Injection Controversy—Employing the "R" Word

In an increasingly vicious debate, opponents of health care reform in the United States have latched onto the controversy in the UK—viewing the NICE recommendation (see adjacent article) against the use of spinal injections for persistent nonspecific low back pain as an example of "socialized medicine" and "rationing."

A headline at Spectator.org trumpets "Britain Balances Its Healthcare Budget on the Backs of the Sick—Literally." (See Vadum, 2009.)

The prosaically titled website HotAir.com offered this comment: "In order to save £33 million [$55.6 million U.S.], the British single-payer system will no longer give cortisone shots for nonspecific back pain despite the effectiveness of the treatment..."(See Morrissey, 2009.) The author alleged that the main goal of the NICE panel was to reduce National Health Service spending. "Its priority was to reduce its budget, not to ensure that patients have effective pain relief...they want to cut back by 95% on cortisone shots regardless of whether the shots are effective or the replacement treatments are not," according to Morrissey.

Not to be outdone, the National Center for Policy Analysis (NCPA) offered some purple prose in its headline: "British Patients Forced to Live in Agony." The article went on to speculate that steroid injections are effective. "Specialists say therapeutic injections using steroids can deaden nerve endings, can provide months or even years of respite from pain. Others fear that if funding is cut, tens of thousands of people, mainly the elderly and frail, will be left to suffer excruciating levels of pain or pay as much as £500 [about U.S. $847] each for private treatment..." according to the article. (See NCPA, 2009.)

All of these articles make some basic mistakes. They misunderstand the NICE evidence-review and guideline-development process. It was not primarily an effort to reduce costs. Rather, it took a cold, hard look at the scientific evidence to identify effective treatments in the early management of persistent back pain. None of the articles come to grips with the fact that spinal injections for persistent nonspecific low back pain don't appear to be effective, based on the current evidence. There is no compelling evidence that these injections do indeed provide respite from "agonizing" or "excruciating" or even run-of-the-mill "moderate" back pain.

And they don't come to the grips with the fact that health care systems with limited budgets simply can't pay for every single back pain treatment. And this is not an issue that applies solely to socialized health care systems. No health care system in the United States underwrites every form of treatment for low back pain. In fact, few health care systems cover treatments that don't find support in the scientific evidence.

When a health care system declines to pay for an ineffective or unproven treatment, does this constitute rationing—or is it intelligent use of finite financial resources?

References:

Morrissey E, Britain rations cortisone treatments for back pain, HotAir.com; 2009; http://hotair.com/archives/2009/08/03/britain-rations-cortisone-treatments-for-back-pain/.

National Center for Policy Analysis, British patients forced to live in agony, 2009; www.ncpa.org/sub/dpd/index.php?Article_ID=18282.

Vadum M, Britain balances its healthcare budget on the backs of the sick—Literally, spectator.org, 2009; http://spectator.org/blog/2009/08/02/britain-balances-its-healthcar.

The panel concluded, among many other things, that RCTs and systematic reviews do not provide evidence of the effectiveness of spinal injections for persistent nonspecific back pain. And the NICE panel recommended that the National Health Service not provide routine reimbursement for those injections.

Conclusions on Injections Not a Surprise

The NICE conclusions about the efficacy of spinal injections for persistent nonspecific low back pain do not come as a surprise. As readers of the *BackLetter* are aware, there is scant evidence that spinal injections are an effective treatment for nonspecific low back pain.

The American Pain Society guidelines on invasive treatments for low back pain by Roger Chou, MD, and colleagues recently concluded that there was moderate evidence that epidural steroid injections provide short-term pain relief for sciatica or radicular back pain but couldn't find any evidence that injections are an effective treatment for other forms of low back pain. (See Chou et al., 2009.) And even the evidence on steroid injections for sciatica is somewhat inconsistent.

The recent Cochrane Collaboration review didn't find any persuasive evidence of the benefit of spinal injections for subacute or chronic low back pain. (See Staal et al., 2009.)

NICE Decision Misguided?

However, despite the lack of evidence from RCTs, the British Pain Society protested the NICE decision. According to the *BMJ* article by Zosia Kmietowicz, "...the society said that NICE's guideline development group was 'misguided' for not considering evidence from cohort studies and clinical case series in deliberations on this and other treatments." Members of the British Pain Society expressed concern that this policy would deny pain-relieving treatment to a significant number of individuals with low back pain.

Outrage From NICE

The British Pain Society decision prompted a letter of protest from the chairman of NICE and its clinical director. "The British Pain Society has made its president a scapegoat because some of its members refuse to accept that there is not the scientific evidence to support their interventions. It is a sad day for the freedom of experts to express views, [and support] evidence-based medicine and the ideals of the medical profession," according to Michael Rawlins, MD, and Peter Littlejohns, MD. (See Rawlins and Littlejohns, 2009.)

What About Considering Cohorts Studies and Case Series?

The assertion by the British Pain Society that NICE should have considered the results of cohort studies and case series on spinal injections for nonspecific low back pain might sound reasonable to someone who is not familiar with the evidence on low back pain.

But if the NICE panel were to consider the results of cohort studies and case series for spinal injections, it would need to perform similar literature reviews for other back pain treatments. And the number of studies involved would challenge even the most ardent reviewer.

There are more than 200 treatments for chronic low back pain—and the number is rising almost by the day as new approaches wend their way into the medical literature. There are more than 1000 RCTs on treatments for back pain.

The number of cohort studies and case series cannot be easily estimated. However, a recent search at MEDLINE with the search term "back pain" produced 33,931 references. So the type of literature review that the British Pain Society recommends would likely keep an expert panel locked up for years.

And if NICE decided to accept evidence from cohort studies and case series regarding spinal injections on the basis of case series and cohort studies, it would have to make similar allowances for nearly every treatment for low back pain.

The net result would be a very liberal prescription of recommended treatments. And it would leave health care systems and payers with virtually no guidance on which of the 200-odd treatments and therapies they should underwrite.

Unfortunately, the British Pain Society's stance does not seem to be a practical response to the lack of evidence on spinal injections for persistent nonspecific low back pain.

A better approach would be for the members of the British Pain Society to design and conduct large, rigorous RCTs on injections for persistent, nonspecific low back pain and see if the society's faith in these injections is warranted.

There is scant evidence that spinal injections are an effective treatment for nonspecific low back pain.

References:

Chou R et al., Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society Clinical Practice Guideline, *Spine,* 2009; 34:1078–93.

Kmietowicz Z, President of British Pain Society is forced from office after refusing to denounce NICE guidance on low back pain, *BMJ,* 2009; www.bmj.com/cgi/content/extract/339/jul28_3/b3049.

NICE (National Institute for Health and Clinical Excellence), Early management of persistent, nonspecific low back pain; http://www.nice.org.uk/guidance/CG88.

Rawlins M and Littlejohns P, NICE outraged by ousting of pain society president, *BMJ,* 2009; 339: b3028.

Staal JB et al., Injection therapy for subacute and chronic low back pain: An updated Cochrane review, *Spine,* 2009; 34:49–59.

Spine Surgery

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Arts and colleagues performed this trial because many of the surgeons in the research group believed that minimally invasive tubular discectomy was superior to conventional disc surgery techniques. And they wanted to confirm this in a rigorous scientific trial.

However, the results confounded the researchers' expectations. "The study could not confirm that tubular discectomy led to quicker recovery," says senior author Wilco C. Peul, MD, PhD. Or that tubular discectomy had any significant advantage over the more conventional surgical procedure. (See Arts et al., 2009.)

The patients who underwent the minimally invasive procedure had slightly worse outcomes in terms of back and leg pain, function, and overall recovery. And they had more recurrent disc herniations requiring repeat surgery. The minimally invasive technique did not even have an advantage in terms of the length of the incision.

A Marginal Advantage

Peul emphasizes that the differences in outcomes between the two surgical techniques were somewhat marginal—and not clinically significant. In other words, the main point of the study is that the advertised advantages of the newer and slightly more expensive surgical procedure (under the Dutch insurance system) did not materialize.

Since tubular discectomy was not substantially inferior to standard microdiscectomy, surgeons will still be able to offer it to patients in the Netherlands, says Peul. "However, they will not be able to perform it on the premise that it leads to quicker recovery of leg pain," he observes.

A Change in Clinical Practice

At the inception of this study, Peul was enthusiastic about tubular discectomy and wasn't even sure that a randomized trial was necessary to demonstrate its advantages. And he said he was taken aback when he first looked at the study data.

But as Swedish spine research pioneer Alf L. Nachemson, MD, PhD, once observed, "High-quality randomized controlled trials often have surprising results." And this is the reason for performing them.

"We confirmed the wisdom of Alf Nachemson's statement," Peul remarked wryly.

The new RCT has altered Peul's own approach to the surgical treatment of painful disc herniations. "When we began this study, if patients came to me with a herniated disc and clear indications for surgery, I advised them to have tubular discectomy," Peul explains.

"Now I tell them, 'If you want to have surgical relief of your leg pain—and want to be sure in the long run that your complaints are resolved—I would opt for microdiscectomy.' So I have changed my clinical practice based on this study," he says.

RCT of 328 Patients

The new RCTs set out to discover whether the minimally invasive form of disc surgery leads to important treatment advantages over standard microdiscectomy. Three previous RCTs had compared the two surgical techniques—and concluded that both led to similar recovery in terms of pain. "However, these studies were only powered to detect large effect sizes and data on differences in time to recover," according to Arts and colleagues. (See Arts et al., 2009.)

So the Dutch researchers decided to perform a large study of 328 patients. To enter the trial comparing the two surgical techniques, all study subjects had to have painful sciatica of greater than eight weeks' duration. And the patients had to have clear-cut disc herniations with distinct nerve-root compression, as visualized on MRI.

Two hundred disc herniations occurred at L5-S1, 114 at L4-L5, with the remainder at L3-L4.

The study excluded all patients with small disc herniations (less than one-third of spinal canal diameter) and potential candidates with "doubtful nerve root compromise." (See study for the complete list of exclusion criteria.)

The 328 men and women (aged 18 to 70) were randomly allocated to one of two treatment approaches: (1) tubular discectomy with the METRx minimally invasive disc surgery system developed by Medtronic; or (2) conventional microdiscectomy (i.e. standard open discectomy with the aid of an operating microscope or headlight loupe). The surgeons were experienced in both techniques.

[*Editor's note:* readers can view both procedures on video at the *JAMA* website; see JAMA, 2009. They can also find an explanation of the minimally invasive disc surgery method at the Medtronic website; see Medtronic, 2009.]

What Is Tubular Discectomy?

During the minimally invasive procedure, a surgeon inserts a thin needle through skin and muscle to the affected area under fluoroscopic (x-ray) guidance. The needle is withdrawn, a small incision is made, and dilators are inserted, one around the other, to gradually split the paravertebral muscles until a narrow tunnel to the disc is created. A tubular retractor is inserted over the final dilator, and the dilators are removed.

The retractor holds the tunnel open, allowing the insertion of a microscope or endoscope, as well as surgical tools. Then, under microscopic visualization, the surgeon removes soft tissue and ligamentum flavum, and accesses the disc.

In both surgical techniques, the surgeons removed only the herniated portions of the disc. None of the surgeons attempted the more aggressive procedure of subtotal discectomy. There was minimal removal of laminar bone.

The mean operation time was 47 minutes for tubular discectomy and 36 minutes for standard microdiscectomy. Both involved the removal of a similar weight of disc material. And both involved similar duration of hospitalization (see study for details).

The study was performed on a double-blind basis. Both the patients and the outcome assessors were blind to treatment allocation. The primary outcome measure was functional assessment on the Roland-Morris Disability Questionnaire at eight weeks and one year after randomization. Secondary outcome measures included visual analog scales for leg pain and back pain and patients' self-report of recovery (on a seven-point Likert scale). There was more than 90% follow-up in both groups at eight weeks and one year.

Consistent Advantage for Conventional Microdiscectomy

Most of the outcome measures favored conventional microdiscectomy by a narrow margin. However, none of the differences would fall into the "clinically significant" category.

There was greater reduction in Roland-Morris Disability Questionnaire scores in the conventional microdiscectomy group.

The patients who underwent microdiscectomy had a similar advantage in pain scores. "On the visual analog scale, the 1-year between-group mean difference in improvement was 4.2 mm (95% CI, 0.9 to 7.5 mm) for leg pain and 3.5 mm (95% CI,

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Why Does It Take So Long to Compare Popular Treatment Options in Well-Designed Clinical Trials?

Comparative effectiveness research—i.e. research that documents the benefits and harms of alternative methods of diagnosing and treating various health conditions—is very much in the news these days. The U.S. Congress recently allocated $1.1 billion as a down payment on a massive new program of comparative effectiveness research in the United States. Many hope that this effort will lead routinely to the type of research that the current regulatory system rarely provides: high-quality, early, unbiased clinical trials comparing realistic treatment alternatives.

New treatments and technologies often receive FDA approval without evidence of their superiority over existing therapies. And they are often widely employed in clinical practice for years or even decades before they are put to the acid test of comparative clinical trials.

So one of the goals of the comparative effectiveness research movement is to document the relative merits of different treatments *early in their clinical history*—before they are widely disseminated.

The new randomized controlled trial (RCT) from the Netherlands discussed in this issue's lead article is an excellent example of comparative effectiveness research. It was an independently financed randomized trial of adequate size and methodology to detect important differences between two popular surgical methods.

However, the study from the Netherlands was published almost a decade after the METRx tubular discectomy system became available as an option in spine surgery. The predecessor of this system was introduced in 1997. And Medtronic received FDA approval to market the METRx arthroscopic system in the year 2000.

Why Is There a Time Lag?

So why does it take so long for new treatments and technologies to be investigated in rigorous, independently financed RCTs under the current research system?

Bradley K. Weiner, MD, is the Chief of Spinal Surgery at the Methodist Hospital in Houston, Texas. He is also Evidence and Methods editor for the *Spine Journal* (Elsevier). He explains that the current research system is not oriented toward early rigorous evaluation of new techniques.

Good RCTs Are Challenging And Expensive

"High-quality randomized controlled trials require lots of patients, lots of time, lots of money, meticulous methodologists and statisticians, ethics in application, and equipoise. All of these, unfortunately, are in short supply," said Weiner in a recent e-mail.

"Accordingly we often do the best we can with less. But settling for less often results in reliance upon flawed studies and inconclusive results; and many RCTs used to evaluate new techniques and technologies stand as examples," he added.

Scientific studies that support new technologies when they enter the clinical marketplace often have multiple flaws, said Weiner. These include inadequate description of study subjects and diagnostic categories; insufficiently defined treatments; and inappropriate control and comparison groups. There is sometimes a lack of blinding on the part of study subjects—leading to inflated expectations in favor of newer experimental treatments.

Studies are often underpowered, Weiner pointed out, and unable to document important differences between treatment approaches. And there is also the unfortunate habit in some research centers of "data dredging" and biased reporting of outcomes—in which the results of scientific studies are manipulated to present patient outcomes in the best possible light.

Devilish Details Often Lost in The Tide of Enthusiasm

"Unfortunately, these devilish details are often lost amidst the tide of enthusiasm and promotion which tends to accompany new spinal technologies. And it is only once the tide has receded—a decade later and after considerable profit has been captured—that independent assessors, via thoughtful, careful methodology, reveal the flaws in these technologies," according to Weiner.

And the new RCT from the Netherlands is a solid example of that type of careful independent research, Weiner added.

Weiner offered some suggestions for improving the quality of research on new techniques and technologies.

According to Weiner, "Four steps might make a positive impact: (1) More high-quality independent studies (such as the RCT from Holland) need to be undertaken—and at a time closer to, and perhaps prior to, the introduction of the technology; (2) Data from primary RCTs need to be made openly available to allow independent verification by other research groups; (3) The FDA needs to better assess RCTs conducted in support of new technologies to ensure that methodological flaws are filtered out a priori; and (4) We—the authors, reviewers, editors, and readers of the spinal literature—need to better recognize methodological flaws to calm misguided enthusiasm and implementation of the new procedures.

Spinal technology consultant Terry Corbin, of Corbin and Company in Minneapolis, and Wilco C. Peul, MD, PhD, senior author of the RCT from Holland, both agree with Weiner that there should be more rigorous research on new technologies early in the development process. Both were coauthors of a recent editorial commentary in *Spine* calling for more thorough FDA scrutiny of new technologies—and early comparative effectiveness research. (See Carragee et al., 2009.)

However, Peul commented that organizing early comparative effectiveness trials is always a challenge. It is particularly difficult convincing industry of the merits of this type of research.

Once their products secure FDA approval and reach the clinical marketplace, many companies are confident that their sales and marketing expertise can lead to widespread implementation and produce a strong flow of revenue. And some would rather not deal with the complications of additional clinical trials that might harm the product's reputation.

Peul and colleagues are very familiar with these issues. Their research group has five RCTs underway evaluating various spinal techniques and technologies.

Reference:

Carragee EJ et al., Clinical research: Is the spine field a mine field?, *Spine,* 2009; 34:423–30.

Spine Research

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Currently, most major studies on back or neck problems are performed only once. One set of researchers will design and perform a study, analyze the study data, and report the results in a scientific journal. At the present time, it is rare for investigators to then make their study methods and data available to other researchers who would like to perform the same study—to see if they can replicate the results.

That is all about to change. Major scientific organizations are calling on researchers to routinely make their research methods and study data public.

"The advance of knowledge is based on the open flow of information. Only when a researcher shares data and results with other researchers can the accuracy of the data, analyses, and conclusions be verified," according to a new report from the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. (See Kleppner et al., 2009.)

It makes perfect sense to allow open access to scientific data. Single groups of researchers may have distinctive beliefs, prejudices, and/or research methods that may compromise analysis and reporting of study data. Allowing secondary studies will make biases and outright research errors more transparent.

"Different researchers apply their own perspectives to the same body of information, which reduces the bias inherent in individual perspectives. Unrestricted access to the data used to derive conclusions also builds public confidence in the processes and outcomes of research," according to the new report.

An accompanying statement from the National Academy of Sciences news office suggests that open access to research data will become the norm in scientific research. There may be unusual cases in which this approach proves impractical—for example, when there are national security concerns or unusual patient privacy issues involved.

"But the default position should be that data will be shared—a practice that allows data and conclusions to be verified, contributes to further scientific advances, and allows the development of beneficial goods and services [related to the research]," according to the Academy. (See National Academy of Sciences, 2009.)

This sea change in scientific research has major implications for those currently planning scientific studies. According to the accompanying statement from the Academy, "Researchers should establish data-management plans at the beginning of each research project that provide for the stewardship of data, and research sponsors should recognize that financial support for data professionals is an appropriate part of supporting research." It will also be necessary for researchers to maintain the integrity of their study data and make sure they are not altered during the transfer process to other research groups—or during subsequent studies. "Maintaining the integrity of and accessibility of research data in a rapidly evolving digital age will take the collective efforts of universities and other research institutions, journals, agencies, and individual scientists," according to the Academy.

This entire transition is not going to happen instantly, suggests Richard A. Deyo, MD, of Oregon Health and Science University. There are still challenging logistical issues to address.

"Preparing data sets with complete documentation and removal of all protected health information (for HIPAA compliance), storage of the data, and providing personnel to facilitate formatting and transfer of information have real costs," Deyo points out. "These may extend well beyond the usual funding period of a grant." Right now, no one supports these costs, Deyo adds.

Institutional review boards are often very restrictive about sharing any data, even study results that have been cleansed of sensitive information. So they will need to alter their practices and standards if this new movement is to succeed.

"I think the ideal and the reality are still far apart," says Deyo.

References:

Kleppner D et al., *Ensuring the Integrity, Accessibility, and Stewardship of research Data in the Digital Age,* 2009; (free) prepublication PDF available at www.nap.edu/catalog.php?record_id=12615#orgs.

National Academy of Sciences, Office of News and Public Information, Report offers principles for maintaining the integrity and accessibility of research data, July 22, 2009; www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12615.

War Zone

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prone to complications, though most of them are not serious. Still, they certainly could pose problems in a combat environment.

"In the randomized trials, 26% to 32% of patients experienced a complication following spinal cord stimulator implantation, including electrode migration, infection or wound breakdown, generator pocket-related complications, and lead problems," according to Chou et al.

The evidence regarding the risks and benefits of SCS is equivocal enough that the American Pain Society guideline on invasive interventional treatments suggests that health care providers discuss this therapy only in a shared decision-making context.

And this is also what Dragovich and his military colleagues recommended as well: "In conclusion, this small series suggests that SCS should be considered in motivated patients who suffer from chronic pain and wish to return to physically strenuous occupations. Both the patient and treating physicians should be aware of the limitations and potential complications of dorsal column and peripheral nerve stimulators. However, with appropriate selection criteria, SCS can be a life-altering therapy that enables soldiers and other patients to achieve their professional goals."

References:

Chou R et al., Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society Clinical Practice Guideline, *Spine,* 2009; 34:1078–93.

Dragovich A et al., Neuromodulation in patients deployed to war zones, *Anesthesia and Analgesia,* 2009; 109:245–8.

MEETING CALENDAR

- **Annual Meeting, American College of Rheumatology**
  October 16–21, 2009
  Philadelphia, Pennsylvania
  Contact: American College of Rheumatology
  1800 Century Place, Suite 250
  Atlanta, GA 30345
  Tel: 404-633-3777
  Fax: 404-633-1870

- **Eurospine 2009**
  October 21–24, 2009
  Warsaw, Poland
  Contact: Medicongress
  Kloosterstraat 5
  9960 Assenede, Belgium
  Tel: +32 (0)9 344 39 59
  Fax: +32 (0)9 344 40 10
  E-mail: congresses@medicongress.com

- **Congress of Neurological Surgeons 2009 Annual Meeting**
  October 24–29, 2009
  New Orleans, Louisiana
  Contact: Congress of Neurological Surgeons
  10 North Martingale Road, Suite 190
  Schaumburg, IL 60173
  Tel: 847-240 2500
  Fax: 847-240 0804
  Toll Free: 877-517-1CNS

- **Annual Meeting, North American Spine Society**
  November 10–14, 2009
  San Francisco, California
  Contact: NASS
  7075 Veterans Blvd.
  Burr Ridge, IL 60527
  Tel: 630-230-3600
  Fax: 630-230-3700
  www.spine.org

- **Annual Meeting, Cervical Spine Research Society**
  December 3–5, 2009
  Salt Lake City, Utah
  Contact: Cervical Spine Research Society
  6300 N. River Road, Suite 727
  Rosemont, IL 60018-4226
  Tel: 847-698-1628
  Fax: 847-823-0536
  E-mail: csrs@aaos.org

- **Annual Meeting, International Society for The Study of the Lumbar Spine**
  April 13–17, 2010
  Auckland, New Zealand
  Contact: Shirley Fitzgerald
  2075 Bayview Road, Room MG301
  Toronto, Ontario, Canada M4N 3M5
  Tel: 416-480-4833
  Fax: 416-480-6055
  E-mail: shirley.fitzgerald@sunnybrook.ca

Spine Surgery

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0.1 to 6.9 mm) for back pain in favor of conventional microdiskectomy," according to Arts and colleagues.

At one-year follow-up, 69% of patients assigned to tubular discectomy reported a "good" recovery vs. 79% of those in the conventional discectomy group.

Subjects in the tubular discectomy group had slightly more intraoperative and postoperative complications. A slightly greater proportion of the minimally invasive surgery group had a recurrent disc herniation, and a greater proportion had repeat surgery within a year.

And the overall conclusion? "Although the minimally invasive technique of tubular discectomy seemed to be an attractive surgical method for treating sciatica, our data do not support a higher rate of recovery when compared with [conventional] microdiscectomy," according to Arts et al. "On the contrary, patients who underwent tubular discectomy fared worse with regard to back and leg pain, and fewer patients reported complete recovery at one year."

How Should Patients Decide On a Surgical Technique?

Although this study may have changed the clinical practice of senior author Peul, it will obviously not destroy the intuitive allure of minimally invasive disc surgery for patients. But how should patients decide which technique is preferable for the surgical treatment of a disc herniation—once they have made a decision to opt for surgery over nonoperative care?

Peul said he would advise patients to educate themselves and look at both methods. "I would recommend they ask their doctors about the results of scientific studies," he suggests.

Visual input may also be worthwhile. "They can go to the *JAMA* website and see videos of both operations," according to Peul. "They can see that there is not much difference between tubular discectomy and standard microdiscectomy. Tubular discectomy may look a little fancier but approximately the same thing is happening to your lumbar disc," he observes.

References:

Arts MP et al., Tubular discectomy vs. conventional microdiscectomy for sciatica: A randomized controlled trial, *JAMA,* 2009; 302:149–58.

JAMA, Video: Comparison of tubular discectomy and conventional microdiscectomy, 2009; http://jama.ama-assn.org/cgi/content/full/302/2/149/DC1?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=tubular+discectomy&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT.

Medtronic, Medtronic METRx Micro-Discectomy System Fact Sheet;/wwwp.medtronic.com/ Newsroom/LinkedItemDetails.do?itemId=110175539 7951&itemType=fact_sheet&lang=en_US.

WEEI Radio Network, Audio on demand, 2009; 850 am; http://audio.weei.com/weei/dale_and_holley.htm?resultType=media&media=audio.

THE BACK PAGE

Opioids a $72 Billion Problem?

As mentioned elsewhere in this issue, physicians in the United States have engaged in an unprecedented wave of opioid prescription over the past decade and a half—largely in the treatment of back and other forms of chronic noncancer pain.

The jury is still out as to whether this surge in medical opioid use has led to a net improvement in terms of pain relief and function among patients with pain conditions.

But it is increasingly clear that the diversion of opioids and other prescription drugs has become a hugely expensive drain on society. "Prescription drug diversion is one of the defining drug crimes in America today," noted a recent report from the Coalition Against Insurance Fraud. "It has few equals for sheer size, speed of growth, resistance to deterrence, harm to people from so many strata of society, and large costs to insurers."

The report pointed out that 7% of the U.S. population—or 20 million people—engaged in opioid abuse in 2007. And this has led to massive diversion of opioids through "doctor shopping" and other methods of obtaining opioids for illicit purposes.

"Drug diversion drains health insurers of up to $72.5 billion per year, including $24.5 billion annually for private insurers. The losses include insurance schemes, plus the larger hidden costs of treating patients who develop serious medical problems from abusing the addictive narcotics they obtained through the swindles," according to the report.

According to one analysis, the typical "doctor shopper" seeking opioids and other prescription medications costs insurers between $10,000 and $15,000 per year, with the excess costs related not only to the price of the opioids themselves, but also emergency room treatments, hospital stays, physician visits, diagnostic tests, and rehabilitation services. (See Coalition Against Insurance Fraud; www.insurancefraud.org/downloads/drugDiversion.pdf.)

Pain Is Inevitable. What About Suffering?

The words "pain" and "suffering" are often used together—as if pain automatically leads to suffering. There are actually no universally accepted definitions of either word. However, a fascinating editorial in the *Clinical Journal of Pain* points out that these concepts—and health states—are not inextricably linked.

"Pain by itself does not seem to be sufficient to cause suffering," according to Dennis C. Turk, PhD, and Hilary D. Wilson, PhD. "Rather, it seems that the person's interpretation of the symptoms, the perceived impact on physical and emotional suffering, meaning [of the symptoms], and coping resources are all crucial."

In other words, the degree and quality of suffering often depend on an individual's beliefs and attitudes about the nature and importance of a particular type of pain. "A person might experience significant pain related to suffering from a relatively low level of noxious stimulation if he or she believes the implications are ominous, interminable, and beyond his or her (or anyone's) control," according to the two pain researchers.

The editorial does not address back pain *per se*. However, common back pain would be a perfect illustration of this relationship. Much of the suffering related to low back pain is not an inevitable consequence of the initial symptoms. Rather, it often stems from a series of choices mediated by beliefs about the nature of back pain. For instance, the ill-advised injury model of low back pain has encouraged many to seek refuge from their symptoms in medical care-seeking, work absence, rest, and inactivity. And this has led all too many to loss of employment, leisure-time activities, socioeconomic status, and the ability to lead a satisfying, productive life.

Turk and Wilson point out that it is possible to relieve pain without alleviating suffering. And that it is also possible to reduce suffering without any impact on pain. And it is important to track both outcomes separately.

The differences between pain and suffering also speak to the need for responsible use of language in describing and linking these states. Unless there is direct knowledge regarding the impact of pain on an individual, according to Turk and Wilson, physicians should probably not routinely state that a patient is "suffering" from pain. It would be more accurate to say, "This person has a painful condition."

As the Dalai Lama and others have pointed out, in a variant on an ancient saying, "Pain is inevitable, suffering is optional." (See *Clinical Journal of Pain,* 2009; 25:353–5.)

Get a Life!

Health care providers often key on return-to-work as a marker for recovery from low back pain. And work is certainly a vital part of a healthy lifestyle for those of working age.

What about return to play? Pain blots out leisure-time activity even more often than it does work. But how often do health care providers query their patients on the number of times they gather with friends, go dancing, play soccer in the park, hike in the mountains, or double-over in laughter? And how often do they give them the profound therapeutic advice: "Get a life!"?

Recent studies and reviews suggest that diverse leisure-time activities have a strong association with good health. In a study of 1400 adults, Sarah Pressman, PhD, et al. found that subjects with the most diverse leisure-time activities exercised more and were less depressed. They had more satisfying lives, stronger social networks, and better sleep. They fared better in a variety of objective tests of good health.

"People who are engaged in multiple enjoyable activities are better off physically and psychologically," according to coauthor Karen Matthews, PhD. However, when people are overburdened by pain or stress, they often cut back on leisure pursuits. "But these data suggest that is the wrong thing to do...," says Matthews. (See *Psychosomatic Medicine,* 2009; epub before print: www.psychosomaticmedicine.org/cgi/content/abstract/PSY.0b013e3181ad7978v1.)

Coming Soon:

- **Vertebroplasty Ineffective in Two Placebo-Controlled RCTs**
- **Is This the End of the Vertebroplasty Era?**
- **Will There Now Be a Wave of Placebo-Controlled Trials In Spine Research?**
- **New National Data on Complementary/Alternative Therapies**
- **The Rising Prevalence of Chronic Back Pain: Are Opioid Abusers Affecting the Count?**