

Interview

Interview With Michael Schneider, DC, PhD, On A Non-surgical Approach to Spinal Stenosis

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Abstract

Michael Schneider, DC, PhD, is an Associate Professor at the School of Health and Rehabilitation Sciences at the University of Pittsburgh.

Schneider was the only chiropractor to receive a grant as part of the Patient Centered Outcomes Research Institute's (PCORI) first wave of 25 grants, in late 2012. PCORI was created as an independent entity by the Patient Protection and Affordable Care Act, with a mission to fund high-quality comparative effectiveness research. The topic of Dr. Schneider's research is *A Comparison of Nonsurgical Treatment Methods for Patients with Lumbar Spinal Stenosis*.

Dr. Schneider serves on the postgraduate faculty of several chiropractic colleges, is program chair Chiropractic Health Care Section of American Public Health Association, and is a past chair of the Soft Tissue Committee of the Council on Chiropractic Guidelines and Practice Parameters. He has had numerous articles published in peer-reviewed research journals.

A graduate of the State University of New York at Binghamton who later received his PhD in Rehabilitation Science at the University of Pittsburgh, Schneider is among a growing cadre of chiropractic researchers who form a crucial bridge between chiropractic and other health professions.

You recently received a grant from the Patient Centered Outcomes Research Institute (PCORI) to study the comparative effectiveness of several different treatment options for spinal stenosis. What criteria did you have to meet to have your proposal selected? I understand that the competition was quite rigorous.

The grant mechanism is different than for a typical NIH [National Institutes of Health] grant. Probably the biggest difference, which worked to my advantage, was that as its name indicates, the Patient Centered Outcomes Research Institute is supposed to be about patient-centered outcomes. This means that they're interested in very pragmatic types of studies, not necessarily studies on mechanisms of action.

Also, PCORI is very big on effectiveness studies rather than efficacy studies. An example of an efficacy study would be one that compares two pills, where one is an active treatment and the other is a placebo. In efficacy studies, the research design is fastidiously controlled to analyze the effect of just one active treatment in isolation. A challenge with research on chiropractic is that most chiropractors don't just do one active treatment in the real-life clinical setting. They may perform spinal manipulation but also recommend exercises or use other methods. So efficacy studies are not considered the ideal design for the "packages" of treatments typically used by chiropractors in private practice.

And so an effectiveness study, a pragmatic study, more accurately reflects the sort of care that someone would receive at a chiropractor's office, or at some other practitioner's office.

Correct. Pragmatic studies compare "packages" of treatments within different general approaches, rather than individual treatments in isolation. For example, we have a community-based group exercise arm in the study. Patients randomized to this arm of the study will go to a 45 minute group exercise class that consists of about 15-20 different exercises. An efficacy trial would focus on analyzing the treatment response of each individual exercise. In our trial, we just want to look at the whole group of exercises as a unit; because that's what's being done in real-life.

In my trial, the usual medical care and manual therapy/individualized exercise arms are also pragmatically designed. In a pragmatic design, you're not focused on "how or why it works" but "whether it works better than something else". What PCORI wants to know is, "Does treatment "package A" work better than treatment "package B", or are they comparable?" The goal is to compare their effectiveness. Rather than, "How does treatment A work in isolation and how does treatment B work in isolation?"

Spinal Stenosis: Top Reason for Medicare Spine Surgery

Your study is on nonsurgical approaches to spinal stenosis. Please tell us what spinal stenosis is and why it's important to study?

We know that back pain is one of the most common causes of pain in the United States and the second most common reason to see a primary care physician. *Spinal stenosis is the number one reason for spine surgery in the Medicare population.* Recent studies document a 629% increase in Medicare expenditures for epidural steroid injections; a 423% increase in expenditures for opioids for back pain; a 307% increase in the number of lumbar magnetic resonance images among Medicare beneficiaries; and a 220% increase in spinal fusion surgery rates.

Those are some pretty powerful statistics.

Yes. That's according to Rick Deyo's published study.¹ Surgery rates for stenosis are escalating and this is especially true in the Medicare population. Worse yet, the rate of complex fusion surgery seems to be on the rise. The trend may be leveling off a bit for spine surgeries in the Medicare population, but when they do one, it's more likely to be a complex fusion surgery rather than a laminectomy without fusion. The cost of the complex surgeries is incredible; the average cost of a fusion surgery is over \$50,000. In comparison, the cost for a simple laminectomy without fusion is more like \$12,000-15,000, depending on what part of the country you're in.

The complex fusion surgeries are more expensive. They're also far more risky. There's a much higher risk of mortality. There really hasn't yet been a good comparative effectiveness trial for nonsurgical treatments for stenosis.

Have there been comparative effectiveness studies on the surgeries themselves, comparing the complex fusion to the laminectomy?

Yes, but it's a work in progress. Most have looked at the complication^{2,3} rates and re-hospitalization rates, as well as the mortality rates. The complex fusion surgeries are much riskier. As far as their effectiveness with regard to symptoms down the road, there doesn't appear to be much difference.

So we have a surgical approach that is three or four times more expensive, has a higher death rate and higher rate of patients needing to return to the hospital, and it has not been shown to be more effective in terms of long-term outcomes. Yet that is the method whose frequency has skyrocketed. And Medicare picks up the bill. Have I summarized that correctly?

There is a slightly greater improvement in symptoms with complex fusion surgery, but this minimal benefit, which is really negligible, is greatly outweighed by the readmission and complication rates.

I also want to emphasize that stenosis is a huge public health issue in the United States. Not only is it the number one reason for spine surgery in the Medicare population, but the incidence of stenosis is rising as baby boomers are hitting Medicare age. The projection line for cases of stenosis is going up, up, up. So from a public health point, we should really have some nonsurgical options.

Nonsurgical Approaches, Including Chiropractic and Exercise, Offer Possibility of Avoiding Risks and Costs of Surgery

And, in fact, PCORI has funded you to study just that, nonsurgical alternatives for stenosis treatment. Methods that could potentially eliminate the need for either type of surgery for at least some stenosis patients.

Yes. Right now, patients with stenosis are told to have surgery. When they ask, "What should I do in the meantime?" they're told, "Well, it doesn't matter." That's the question I want to answer. Does it matter?

What methods will you be comparing in this trial of nonsurgical approaches to stenosis?

It's a three-arm randomized trial. There will be 180 patients, with 60 per group. The first group will receive usual medical care, which will be treatment with a physical medicine and rehab doc, who will examine the patient and at his discretion determine whether that patient needs oral medication or an epidural injection, or both. That doctor can prescribe anything he wants; it could be a prescription med

or a nonprescription med, depending on the patient's severity. There would be no formal exercise in that group but the patients will be advised to stay active. The pragmatic nature of this approach is that the physical medicine doc can customize the treatment to that particular patient.

To practice as he or she normally would.

Right. The next group is community-based exercise. Some people may be familiar with the Silver Sneakers program, which is a proprietary product. In our study, we are using a generic equivalent of Silver Sneakers, which is basically a general calisthenics class for older adults. It's a 45-minute group exercise class, where people come in and do arm circles, march in place and so on. It's general conditioning. The people in these classes aren't there for their stenosis but for general exercise.

This is pragmatic because there are many older people who decide that they don't want to go to a rehabilitation clinic, or physical therapist or chiropractor. They're feeling aches and pains and they want to go to a class with other people their age and exercise at their own pace. So community exercise is the second group.

The third group is called the "individualized clinic-based approach," where patient will come into a clinic and get a combination of manual therapy and exercise. There are some things that everyone will get and some that are at the discretion of the treating clinician. We're going to have both physical therapists and chiropractors deliver the treatment.

Is it determined in advance what specific modalities the chiropractor or physical therapist will administer?

We're going to have an algorithm for treating the patient. For example, all of these patients will get some form of exercise, including some light aerobic exercise, like on a stationary bike. They'll all get some flexion-distraction treatment to mobilize the lumbar spine and they'll all get neural mobilizations to stretch their nerve roots, presumably.

So, for example, the discretionary treatment would involve an algorithm where, if they have significant hip osteoarthritis, they can be treated with hip mobilization technique and soft tissue technique around the hip joint. If the lumbar spine is still stiff after the flexion-distraction, then there could be manual manipulation or mobilization of the lumbar spine or sacroiliac joints. So they'll have discretion to individualize the care to each patient. There's a basic protocol and they can improvise off that as necessary.

How long will you follow the progress of the patients in the study?

The intervention period is six weeks for all groups. The medical group, the community exercise group and the clinic-based exercise plus manual therapy group, all are treated for six weeks. In the community class they go twice a week; if they come in to the clinic for the manual therapy and exercise, it's twice a week, for a total of 12 treatment sessions. With the medical doc, there will be three visits — an initial exam, a follow-up at three weeks, and a final visit at six weeks. The main outcome is how they do at baseline as opposed to six weeks. We'll also follow them at three months and six months.

During the period between the end of the six-week treatment phase and the end of the six-month follow-up phase, are there any limitations placed on what treatments or self-care methods the subjects can or cannot use?

That's almost impossible to control. We're going to track them over time. Part of the pragmatic design is that when they're done, we ask them not to go for further treatment. But if they decide to do it, we can't stop that. We'll just track that as a variable. That's why the primary outcome has to be how they're doing at the end of the six-week mark. But we will see how they did between six weeks and six months and we'll see whether they got additional treatment during that time.

It's hard to predict such things but what's your goal as to how soon the results of this study might be made public through publication in a journal or presentation at a conference?

The whole study is a three-year project. I probably will start recruiting people in Spring 2013 and I anticipate that it will take two years to get the 180 people through the treatment. It will probably be two-and-a-half years before we have any results.

Schneider's Study Will Define Stenosis to Include Narrowed Cord Space Plus Walking Impairment

In a 1985 study on low back pain by Cassidy and Kirkaldy-Willis, which was first study with a chiropractor as an author to be published in a medical journal, one of the most striking findings was that among the subset of chronic low back pain patients who had stenosis (all of whom had unsuccessfully been treated with conventional medical care), chiropractic adjustments of the low back were successful for a majority of patients, with 20% becoming pain-free. Did this study help lead you in the direction you're now pursuing?

Let's go back to a question I didn't answer before, which is, "What is lumbar spinal stenosis?" That's probably the most important question. There's a radiographic diagnosis of spinal stenosis, which is made with MRI, CT or x-ray. You just measure the size of the opening of the central canal and neural foramen. [Narrowing indicates possible pressure on the spinal cord, which is located within the central canal]. There are certain measurements below which someone is said to have stenosis of the spine. But in our study, that's not good enough. As a requirement for inclusion, there has to be that anatomical narrowing but there also has to be the hallmark symptom of neurogenic claudication. That is, the patient has to have a walking impairment related to the anatomical imaging findings. We're looking for people who don't just have back pain but also an impairment such that when they walk, their legs start to bother them and they have to sit. That's the clinical syndrome of stenosis. In the Cassidy study, did they look at the clinical syndrome or just the radiologic findings?

To the best of my knowledge, it did not have to include the walking impairment.

So, I see a different key finding in that study; that manipulating older people's spines is safe. And they also showed that some people with radiographic stenosis improve with spinal manipulation. Our study will look at walking impairment as an independent variable. In other words, if you have some people with severe walking impairment from stenosis, how did they do in comparison to people with mild walking impairment? That might turn out to be a prognostic indicator of treatment success. With 180 patients, we have a pretty good sample size to see if there's some association between walking impairment and response to treatment in all three arms of the study.

Have there been other studies that have explored that question in depth?

We did a systematic review of the literature in chiropractic, physical therapy and physical medicine. We found one randomized trial in the physical therapy literature that looked at two different approaches for

lumbar spinal stenosis. The best chiropractic study to date is a case series by Don Murphy [a DC at Brown University], using flexion-distraction, neural mobilizations and other non-surgical treatments. There are a couple of studies not yet published — one pilot RCT by Jerrilyn Cambron from the National University of Health Sciences on flexion distraction, that will hopefully be published later this year.

Don Murphy is a co-investigator on my PCORI grant and his protocol greatly influenced the protocol we're using in the PCORI study. My other co-investigator is from Canada, Carlo Ammendolia, a DC-PhD from the University of Toronto. He was their Researcher of the Year last year. He's developed a spinal stenosis treatment program that's similar to the one Don Murphy uses, and he's doing a pilot study on that right now, a small randomized trial. Drs. Murphy and Ammendolia are going to train the chiropractors and physical therapists in their procedures.

Do you want to know what I expect to find?

Working Hypothesis

Sure, what's your working hypothesis?

I think that we're likely to find that not all stenosis patients are going to respond to the same types of treatment. There might be a sub-group of people who do better with epidurals and medical care, but I don't know what predicts that. So hopefully we might find some baseline variables that predict which people will do well with epidurals, because some people do really well with them. But others have no response.

My guess is that both of the active care groups — the community-based exercise and the clinically-based care — will do better than usual medical care. And that individualized care will do a little better than community-based care. I also expect that there will be some exceptions. We are very interested in gaining greater understanding about those exceptions.

NIH Grant: Distance Learning on Evidence-Based Practice

In what other research projects are you currently involved?

The other big one is an NIH grant. The acronym is DELIVER, which is a distance education grant on evidence-based practice beliefs and attitudes in chiropractors.

There are two phases. The first (which we're in right now) is to do an online survey of the chiropractic profession using a validated questionnaire about attitudes, skills and use of evidence in chiropractic practice. That information will give us a cross-sectional view of where the chiropractic profession is at with respect to evidence-based practice. Then, we're going to take a sample of 250 of the people who took the survey, and randomize them to exposure to getting a 10-hour distance learning program that was developed at Northwestern Health Sciences University. It is called the Foundations of Evidence Informed Practice.

After they're done with the distance learning, there are a few exercises they'll practice their skills on. And then we'll retest them with the original survey to see if they've changed in their attitudes, skills and use of evidence in practice. The other 125 people will have been on a wait-list and at six months, they'll be given access to these online modules and we'll see if that second cohort has had the kinds of changes I just mentioned.

University of Pittsburgh Medical Center Now Requires Three Months of Chiropractic or PT Before

Approving Back Surgery

You are the chiropractic consultant for the University of Pittsburgh Medical Center, which has pioneered new protocols for managing musculoskeletal pain. Please tell us about those.

This first started about five years ago at the UPMC Health Plan. The health plan is similar to Kaiser Permanente; it's basically a physician-owned insurance medical plan. So about five years ago, the health plan recognized what everybody else does, that back pain is a huge problem. Within the health plan, they identified it as the third most costly health condition they treat. Numbers one and two are cancer and heart disease.

That's a powerful statement.

Low back pain is the third most costly condition. They found that it was important to educate their providers — not just patients — about nonsurgical treatments that are available, like physical therapy and chiropractic. They started a low back pain initiative five years ago to educate doctors about using less medication, doing less imaging and less surgery, and trying to increase their referral rates for chiropractic and physical therapy services. As often happens, after five years this wasn't making a big impact, especially on the surgical rates, which continued to be extremely high. So the health plan finally decided that they would mandate something that's pretty provocative — that for patients with chronic (not acute) back pain, before any spine surgery is approved, the patient has to have tried a minimum of a three-month course that would include both chiropractic and physical therapy.

Primary Spine Care Practitioner: An Emerging Model

I know you've written (as have others, including myself) about the concept of the primary spine care practitioner. It sounds to me like there is a good deal of conceptual overlap between that idea and this UPMC protocol. Could you address that?

Yes, I think the UPMC health plan recognized that, when they looked at their internal data on utilization, for most patients with back pain the first provider they see is a primary care physician. They also tracked where those patients go and found that it's most common for a primary care physician to send the patient for an MRI and then to a surgeon, before they'll send them to a physical therapist or a chiropractor.

In terms of outcomes, that is quite problematic.

It's problematic because low back pain is the third most costly condition in the health plan, and the two things that are driving those costs up the most are diagnostic imaging and prescription drugs. So inappropriate MRI and inappropriate prescription drugs are driving the costs up and the health plan recognizes that maybe the primary care physician is not the best person to be first to see these patients with back pain. And so they're encouraging more utilization of chiropractors and physical therapists, which is very interesting. To your point, they're recognizing that the triage at the front end — primary spine care, if you will — is probably best performed by a physical therapist or a chiropractor. And not a primary care physician.

Why are PCPs not well suited to being the initial provider to see these musculoskeletal pain cases?

I think it's a matter of training. Primary care physicians do not have adequate training in musculoskeletal diagnosis during their medical school education. They don't get it in their residency either, so they're really not qualified musculoskeletal differential diagnosis. In contrast, physical therapists and chiropractors get a great deal of musculoskeletal triage in their training.

There's one other issue, something that really surprised me. The utilization rates of physical therapy are just as low as they are for chiropractic!

Really? That is surprising.

Chiropractors think that patients with an acute episode of low back pain go to their primary care doc and then get referred right away to the physical therapist. That's *not* the case. They go to their primary care doc, who gives them drugs and mucks around for three or four weeks. And when the patient is no better, they send them out for an MRI. And if they're still no better, they then send them to a surgeon or physical medicine specialist. Then, if the surgeon says they're not a surgical case, it's only at that point that they might send them to the physical therapist.

What you're describing doesn't exactly sound like a streamlined and efficient modern health care system.

Absolutely not. My point is that chiropractors think these acute patients are being sent to physical therapy. And that's not true. And the physical therapists think the chiropractors are seeing the acute cases, and that's not true either. The limiting step here is the primary care physician, who tries to manage back pain without referring the acute patients to either PT or DCs.

Thanks. You've given us a great deal of food for thought.

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