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Early PT May Be Effective as a Frontline Treatment for Sciatica—an Area Where There Are No *Proven* Therapies

A new study suggests that early referral for an active form of physical therapy—involving information, exercise, manual therapy, and other interventions—is modestly beneficial as a frontline treatment for acute back pain with sciatica (i.e. radicular leg pain) in primary care settings.

"This randomized clinical trial found that referral to early physical therapy from primary care was more effective in reducing disability than usual care alone for low back pain and sciatica of less than 90 days' duration. The early group showed greater improvement in disability and back pain intensity across all follow-up times. Differences between groups were robust across sensitivity analyses. Several secondary outcomes also favored early physical therapy," according to Julie M. Fritz, PT, PhD, of the University of Utah and colleagues.

Since this study took place in primary care settings, it may give primary care patients and their providers a viable early treatment option that does not require a referral to a surgical specialist.

"Modestly beneficial" is not a headline-grabbing descriptor for treatments in most areas of medicine. However, few therapies find strong evidence support as standalone treatments in the management of sciatica. These include the most common non-invasive treatments for sciatica in both primary care and specialty settings: analgesics, manual therapies, and various forms of exercise. None of these have demonstrated major benefits in randomized controlled trials and systematic reviews.

Because of uncertainty over nonsurgical care options many patients go on to invasive treatments prematurely, when they might have had a satisfactory recovery without injections or surgery.

Or, as Fritz et al. pointed out at clinicaltrials.gov, "Optimal primary care management is currently unclear and little data are available to assist clinicians and inform patients of the likely effects of common options. Practice guidelines agree that imaging, spinal injections, and surgery should be reserved for patients whose symptoms do not diminish within 4–8 weeks, yet utilization rates for these procedures are increasing rapidly, partly due to the uncertainty of what options may be offered to patients for initial treatment." (See Fritz, 2015.)

They performed their recent RCT to address this uncertainty. "We recruited patients who just had an initial visit with a primary care provider for back pain with sciatica. We asked them to either take a 'usual care' approach, which was to just wait and see. . . Or, we referred them to physical therapy for four weeks," said Fritz in a statement from the University of Utah.

The physical therapy option had multiple components: McKenzie-style mechanical evaluation and therapy, home exercise, manual treatments, and/or spinal traction.

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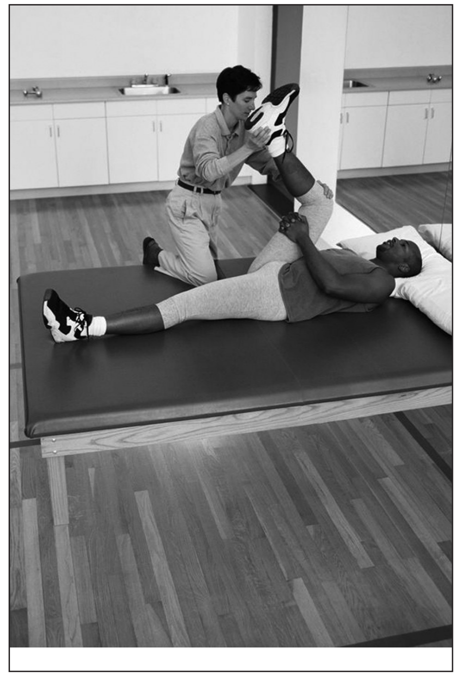

Ominous Article From 1937

A recent literature search on sciatica at the *BackLetter* serendipitously brought up an eye-opening and *ominous* article published in the *British Medical Journal* in 1937—entitled "The Intervertebral Disks and Back Pain." (See *British Medical Journal*, 1937.)

The early 1930s was a pivotal era in the cultural and medical history of low back pain. And this two-page, anonymously authored article hints at those dramatic developments. This was a period in which low back pain and sciatica began the transition from being largely "grin and bear it" illnesses to being compensable injuries and major public health problems.

Scientists and historians have argued that the current worldwide back pain disability epidemic had its roots early in the 1930s.

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COVID-19: Shocking Wave of Mental Health Problems

Everyone is aware by now that the COVID-19 pandemic has amplified psychological distress in many people. And some suspect that the increase in psychological distress will also lead to increased levels of pain, chronic pain, and related disability.

But what has been the magnitude of the surge in psychological distress? A recent study looked at one aspect of psychological distress—the prevalence of depression symptoms before and during the pandemic.

Comparison of Symptoms Before and During the Pandemic

Catherine K. Ettman and colleagues assessed depression symptoms before the pandemic by looking at the nationally representative National Health and Nutrition Survey (NHANES) of adults 18 years and older. They studied depression symptoms during the COVID-19 pandemic with data from the nationally representative COVID-19 and Life Stressors Impact on Mental Health and Well-being (CLIMB) study. Both surveys used the same depression symptom measure—the Patient Health Questionnaire-9. (See Ettman et al., 2020.)

The NHANES study assessed depression symptoms in the general population from 2017 to 2018. The CLIMB study looked at depression symptoms fairly early in the course of the pandemic in the United States—over the first two weeks of April 2020.

Three-Fold Increase in Depression Symptoms

This survey study found that prevalence of depression symptoms in the United States increased more than three-fold during the COVID-19 pandemic, from 8.5% before COVID-19 to 27.8% during COVID-19.

Greatest Impact on the Poor, the Disadvantaged, and the Socially Isolated

COVID-19 had its greatest impact on the poor, the disadvantaged, the unmarried, the socially isolated, and those with modest educational levels.

"Compared with married individuals, [those] who were widowed, divorced, or separated had 2.1-fold increased odds of depression symptoms (OR, 2.08 [95%CI, 1.29-3.36]) and individuals who had never married had 1.9-fold increased odds of depression symptoms (OR, 1.85 [95%CI, 1.17-2.94]). Compared with individuals with an annual household income of $75 000 or more, those with a household income of $19 999 or less had 2.4-fold increased odds of depression symptoms (OR, 2.37 [95%CI, 1.26-4.43]). Individuals with household savings less than $5000 had 1.5-fold increased odds of depression symptoms (OR, 1.52 [95%CI, 1.02-2.26]). Experiencing more COVID-19 stressors was also associated with greater odds of depression symptoms compared with people with low stressor exposure (medium: OR, 1.77 [95%CI, 1.16-2.71]); high: OR, 3.05 [95%CI, 1.95-4.77])," according to the study.

Traumatic Events Have Often Led to a Wave of Health Problems

This study is the latest in a long line of scientific studies suggesting that traumatic events lead to an increase in mental health problems. However, the magnitude of the increase relative to COVID in the United States is far higher than that reported in previous studies conducted elsewhere.

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Elevated Levels of Opioid Use—and Treatment Costs—Following Surgery for Spinal Stenosis

Patient and provider impressions of the benefits of various spine treatments often come from carefully conducted studies—which are frequently carried out in highly selected populations under the supervision of expert clinicians and supportive staff members.

It is important to balance out those impressions by also taking a look at the results of various treatments in real-world settings, where patients may not be as carefully selected and may undergo less skillful treatment with less supervision.

Two Retrospective Studies of a National Surgery Database

Observational studies have suggested that properly selected patients who undergo surgery for spinal stenosis have favorable outcomes in terms of pain and functional abilities—and do not require extensive ongoing treatment and pain medication.

However, two studies presented at the recent virtual annual meeting of the North American Spine Society painted a different picture.

Study of More Than 17,000 Patients Who Underwent Stenosis Surgery

In the first study, Tanmaya Sambare and colleagues from Stanford University performed a retrospective study of national claims data (Marketscan 2011–2015) on patients who underwent surgery for spinal stenosis. They wanted to characterize patterns of medication usage, including opioids, before and after surgery. (See Sambare et al., 2020.)

They confined their analysis to surgery patients who had continuous enrollment in a health plan that provided pharmacy data for two years before and two years after surgery.

There were 17,466 study subjects with a mean age of 58 years and an even male/female split.

Median annual drug treatment costs for this cohort were $1810 two years before surgery, climbing slightly to $2125 in the year before surgery. Median annual drug costs were similar in the year after surgery ($2021) and then fell to $1656 in the second year after surgery.

Disturbing Patterns of Opioid Use

The patterns of opioid use before and after surgery were disturbing.

"The percentage of patients taking opioids prior to surgery increased dramatically leading up to surgery and remained elevated 2 years postsurgery. To a lesser degree, the percentage of patients taking anxiolytics, muscle relaxants, and anticonvulsants also increased prior to surgery and remained elevated 2 years post-surgery. 84.3% of patients used opioids in the two years preoperatively, while 95.2% used opioids in the 2 years postoperatively," according to the authors.

Although opioid use grew dramatically before surgery and continued at an elevated level after surgery, the median dose remained fairly stable.

It is not clear what these patterns reflect. The study period from 2011 to 2015 occurred at the height of the opioid overtreatment epidemic in the United States—and at a time of growing use of antianxiety medications, anticonvulsants, and muscle relaxants. All these drugs can be habit-forming and addictive. This was also a period in which surgeons were liberal in their prescription of narcotic painkillers after surgery. So these results could have reflected these factors or inferior treatment outcomes.

What About Overall Healthcare Utilization?

In a second study from Stanford presented at the NASS virtual conference, Jayme Koltsov and colleagues retrospectively studied healthcare resource utilization before and after single-level stenosis surgery—among patients in the Marketscan database from 2007 through 2015. (See Koltsov et al., 2020.)

The majority of patients—67%—had gradually decreasing costs after surgery, with costs of medications, physical therapy, home health services, and radiology declining and then plateauing 16 months after surgery. In this group median monthly healthcare utilization costs fell from $1626 per month two years before surgery to $592 per month two years after surgery.

However, a sizeable minority of patients had high healthcare utilization costs before and after surgery.

The greatest predictor of high costs before surgery was a diagnosis of depression. "High preoperative cost patients were also more likely to be female, older, and have chronic pain, other psychiatric disorders, and comorbid conditions such as diabetes, congestive heart failure, hypertension, and congestive obstructive pulmonary disease," according to Koltsov et al.

The strongest predictor of high postoperative utilization costs was preoperative utilization costs. Over 70% of the group with high preoperative costs went on to have high postoperative costs.

And a disappointing 19% of those with low preoperative costs went on to have high postoperative costs. Preoperative factors associated with being in this group were depression and other psychiatric disorders, chronic pain, diabetes, having a neurologic deficit, chronic obstructive pulmonary disease, hypertension, and high cholesterol levels. Having a surgical complication was also a risk factor for transitioning to the high-cost group post-surgery.

Both these studies were presented as abstracts at the North American Spine Society (NASS) virtual meeting—so there is limited information available about them. Readers should wait until they are published before drawing any firm conclusions.

At a normal prepandemic spine conference, study abstracts are usually presented by one or more authors—so conferees and the mass media can access further information and details about the study fairly easily. This appears to be a major shortcoming of virtual meetings.

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Michigan Legislation Reined in Opioid Use Among Surgery Patients

A new study suggests that a 2018 Michigan law has restrained both preoperative and postoperative opioid use for degenerative spine problems—without impairing patient pain control or postoperative outcomes.

In 2018, in reaction to the opioid overuse and overdose crisis, the State of Michigan enacted legislation to reduce excessive opioid use—and limit adverse events related to it.

The legislation mandated that healthcare providers had to educate patients on the potential risks of opioid use in the treatment of pain and how to dispose of expired, unused, and unwanted opioids. In addition, they were required to let patients know that the inappropriate use or diversion of an opioid in the State of Michigan is a felony. Patients were required to sign an informed consent document that would become part of their permanent medical record.

In a recent study presented as an abstract at the annual (virtual) meeting of the North American Spine Society, Paul Park, MD, and colleagues assessed the impact of the legislation by studying patients enrolled in the Michigan Spine Surgery Improvement Collaborative (MSSIC) Registry. They examined patient data collected at two time points: a year before the initiation of the new opioid laws and a year after. (See Park et al., 2020.)

This registry, supported by Blue Cross Blue Shield and the Blue Care Network (See MSSIC, 2020.), is a group effort to improve spine surgery outcomes in Michigan.

"A key element of MSSIC is a comprehensive data registry that includes pre-surgical clinical and demographic data, information on the surgical procedure(s) done for each patient and aspects of peri-operative care, and then outcomes of surgery, including any complications or adverse events and a set of patient-reported outcomes. With this registry and an associated real-time interactive 'dashboard' showing variations in performance by hospital and surgeon on key quality measures, MSSIC participants can identify best-performing hospitals and best practices, and do site visits to top performers to identify methods that can be replicated to improve outcomes statewide."

Park et al. found 12,325 patients who had undergone surgery for degenerative spine disease before the new law and 11,988 who had surgery afterward. The demographic and surgical characteristics of the two groups were broadly similar.

There was a statistically significant reduction in the number of patients taking opioids after the law was enacted. A total of 3783 subjects were taking opioids before the legislation (48.7%) and 2698 afterward (39.7%).

Patients did not seem to be adversely affected by the new regulation, according to the Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) outcome measure.

"At 3 months postoperatively, there were no differences in PROMIS PF (41.5 vs 41.8, P = .0789), minimum clinically important difference (56.0% vs 58.0%, P = .060), numeric rating scale (NRS) of back pain (3.5 vs 3.4, P = .1745, NRS of leg pain (2.7 vs 2.7, P = .6909), satisfaction (83.8% vs 84.0%, P = .763), or 90-day readmission rate (6.7% vs 6.4%, P = .3688) between groups," according to Park et al.

It would be useful to assess longer term outcomes among these cohorts of patients—and see how many surgical patients went on to long-term opioid use and/or abuse.

Disclosures: None declared.

References:

Michigan Spine Surgery Improvement Collaborative, 2020; https://mssic.org.

Park P et al., The impact of Michigan's new opioid prescribing laws on spine surgery patients: Analysis of the Michigan Spine Surgery Improvement Collaborative (MSSIC), presented at the annual (virtual) meeting of the North American Spine Society, October, 2020.

New International Task Force Statement on the Prevention of Opioid Abuse After Surgery

There is now overwhelming documentation that surgery is a major vector for the development of opioid overuse, abuse, addiction, and overdose deaths. And broad recognition in surgical, anesthesiology, and pain medicine fields that better prevention of opioid misuse and abuse is imperative.

An international expert task force recently published a statement in the journal *Anaesthesia* on the prevention of opioid-related harm among adult surgical patients. (See Levy et al., 2020.)

"Opioids are effective medicines that form an integral component of balanced multimodal painkilling strategies for the management of acute pain in postoperative patients," explained senior author Dileep Lobo, MD, of the University of Nottingham in the UK. "However, over the past decade it has been increasingly appreciated that, in efforts to improve pain relief after surgery, doctors prescribing these drugs to help pain relief during and after surgery have unwittingly contributed to persistent postoperative opioid use, abuse and harm in some patients."

"In addition to the social and economic costs of opioid misuse, there are personal costs, with many people dying from opioid overdose, or in accidents caused, for example, by driving under the influence of opioids."

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Pregabalin Ineffective for Sciatica—Like Opioids, NSAIDs, and Other Common Analgesics

A recent randomized controlled trial (RCT) from Karachi, Pakistan, is a reminder that anticonvulsant medications such as pregabalin have no proven role in the treatment of symptomatic disc herniations. Nor do any other common medications.

In an open-label RCT, Deepak Kataria, MD, and colleagues randomly allocated consecutive patients with symptomatic disc herniations to one of two treatment regimens: (1) the anticonvulsant pregabalin plus an nonsteroidal anti-inflammatory drug (NSAID) or (2) an NSAID alone. They assessed pain levels at baseline and at 12 weeks with a visual analog pain scale. (See Kataria et al., 2020.)

"The results showed a significant reduction in pain over time in both the groups: pregabalin (p-value < 0.0001) and placebo (p-value < 0.0001). However, the difference in pain reduction between pregabalin and placebo was not significant (p-value = 0.57)," according to the authors.

They called for further large-scale studies to determine whether pregabalin should play any role in the treatment of disc herniation-related radicular pain.

Proponents of anticonvulsants might quibble with the size and methodology of this study. However, the results are consistent with a larger and more sophisticated RCT published in the *New England Journal of Medicine* in 2017.

In that study, Stephanie Mathieson, PhD, and colleagues randomly allocated 209 patients with acute or chronic sciatica to either (1) pregabalin or (2) a placebo for up to eight weeks. The primary outcome measure was pain intensity on a 10-point pain scale at eight weeks. Secondary outcome measures included pain at one year, disability, and quality measures at various junctures in the trial. (See Mathieson et al., 2017.)

"Treatment with pregabalin did not significantly reduce the intensity of leg pain associated with sciatica and did not significantly improve other outcomes, as compared with placebo, over the course of eight weeks," according to Mathieson et al.

So treatment with pregabalin did not offer any clear benefits. It did, however, increase risks. The pregabalin group had twice the level of adverse effects as the placebo group.

What does the larger body of evidence say about the benefit/risk profile of anticonvulsants such as pregabalin in the management of radicular pain?

Raphael Zambelli Pinto, PhD, and colleagues published a review of drug therapies for sciatica (radicular leg pain) in *BMJ* in 2017. They found four RCTs with low-to-moderate risk of bias comparing anticonvulsants (pregabalin, gabapentin, or topiramate) against placebo. (See Pinto et al., 2017.)

One small RCT of only 50 subjects found an advantage of gabapentin over placebo. The other three found no advantage for anticonvulsants at all. The only major take-home message from this body of evidence is that there is a dire need for further research.

Anticonvulsants are not alone in having no proven role in the treatment of sciatica. The review by Pinto et al. found no evidence that *any* medication— including opioids, NSAIDs, anti-depressants, and anticonvulsants—is a panacea against sciatica.

Nonsteroidal anti-inflammatory drugs are arguably the most widely employed analgesic in the treatment of sciatica. Yet the review by Pinto et al. found no evidence that NSAIDs are superior to a placebo in terms of pain or disability.

So this area poses multiple challenges. There is a need for further rigorous research. And there is also a need for carefully crafted dialogues with patients explaining the limited and inconclusive evidence regarding medications for sciatica.

Disclosures: None declared.

References:

Kataria D et al., Comparison of pregabalin versus placebo in reduction of pain due to lumber disc herniation, *Cureus*, 2020; 12(8):e9985.

Mathieson S et al., Trial of pregabalin for acute and chronic sciatica, *New England Journal of Medicine*, 2017; 359: 1111–20. doi:10.1056/NEJMoa1614292 pmid:28328324.

Pinto RF et al., Which pain medications are effective for sciatica (radicular leg pain)?, *BMJ*, 2017; 359:j4248. doi: 10.1136/bmj.j4248.

Recommendations on Opioids

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The task force made several main points:

- All patients undergoing surgery should be assumed to be at risk of developing persistent postoperative opioid use/addiction and may need interventions to mitigate those risks.
- Healthcare teams must consider optimizing management of preoperative pain and psychological risk factors before surgery, including weaning patients off opioids they are already taking, where possible. In addition, patients need to have a realistic attitude about postoperative pain.
- The provision of opioids after surgery should be guided by functional as well as pain measures.
- "Multiple methods of pain management should be optimized, and patients educated about the use of non-pharmacological and non-opioid painkilling strategies to reduce the amount and duration of opioids required to restore function."
- Providers should not prescribe long-acting opioids for acute postoperative pain.
- Postdischarge prescriptions of opioids, if necessary, should be limited to less than a week's duration. A small number of patients may need repeat prescriptions, but these should not be automatic.
- "Automated post-discharge repeat prescriptions for opioids should be avoided. Doctors, including those in outpatient clinics and general practice, should perform a patient review if more opioids are requested. Research has shown each additional repeat prescription has

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Prognosis for Sciatica Not as Positive as Many Believe

There is a consensus across spinal medicine that the prognosis of sciatica—particularly sciatica stemming from a disc herniation—is generally positive. And that symptoms and signs of sciatica will wane for many people over days, weeks or months.

So a common approach to the management of sciatica is to engage in stepped care over a period of several weeks to let patients take advantage of the generally positive course of this condition.

Unfortunately, the evidence on sciatica is all over the board. And there is major variability in estimates of the course of sciatica.

"While the majority of patients with sciatica experience early improvement in symptoms, usually in the first 2–3 months, either with or without treatment; a minority will experience more persistent symptoms or disability, and for some this continues beyond 12 months. Some patients will experience intermittent or recurrent sciatic symptoms over time. There is, however, inconsistency in the literature about the proportion of patients affected by ongoing symptoms," according to Clare Ryan and colleagues in *BMJ* Open. (See Ryan et al., 2020.)

Raymond Ostelo, PhD made similar points in a recent review in the *Journal of Physiotherapy*.

"Although the general consensus is that the prognosis is usually favorable because most cases of sciatica are self-limiting with pain decreasing over time, the evidence is less straightforward. The course of sciatica in primary care is often not studied in isolation, as most studies of low back pain include patients with and without leg symptoms/sciatica. A recently published UK-based study of patients seeking primary care for back-related leg pain, including sciatica, of any duration and severity, showed that only 55% of the patients with sciatica met the criterion for improvement in disability (ie, ≥ 30% reduction in disability 1 year later). Because all of these studies included some type of (conservative) treatment the real (untreated) prognosis is, as yet, unknown," Ostelo asserted.

The UK-based study Ostelo referred to is the ground-breaking ATLAS cohort study, the largest study to look at prognosis and prognostic factors among sciatica patients in a primary care setting.

In that study, Kika Konstantinou, PhD, and colleagues studied 609 patients seeking care for sciatica from a general practitioner in the UK. As mentioned above, almost half of patients did not achieve a successful outcome at one year.

So what factors were associated with a better recovery? According to the study, shorter pain duration, lower leg pain intensity, fewer other symptoms associated with the back and leg pain, patient belief that the problem will be short-lived, and initially having myotomal weakness.

"These prognostic factors can be used to inform and direct management decisions about timing and intensity of available therapeutic options for symptom relief, especially in sciatica patients with corroborative MRI findings, for whom there are potentially appropriate therapeutic interventions that are not applicable for patients with nonspecific low back and leg symptoms," they concluded.

Early PT May Be Effective

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"What we found was that the physical therapy option helped speed their recovery and reduce their disability to a greater extent [than usual care] over the one-year follow-up period that we included in our project," according to Fritz.

Although few individual treatments for sciatica have found more than marginal support in rigorous clinical trials, Fritz said she was not surprised by the results. (See Fritz et al., 2020.)

"Keeping patients at work and helping them to remain physically active is something that we know helps across a broad range of musculoskeletal conditions. It hadn't been demonstrated sufficiently in this patient population. But what we found is very consistent with a lot of other recommendations for patients with various musculoskeletal pain conditions. That activity and exercise can be beneficial and [early physical therapy] can help provide that care," she explained in a video presentation.

"We think it is important for primary care providers and their patients to understand that PT can help them accelerate their recovery, assist them in regaining their activity levels, and help provide assistance in regaining their quality of life when physical therapy is provided early in the episode of care."

However, the new trial also documented some lingering uncertainties. The early referral group had no advantage in terms of further healthcare use. For example, 8.3% of the early referral group went on to have surgery vs 6.4% of the usual care group. Similar proportions of both groups (13.9% and 12.8%, respectively) had a lumbar epidural injection or injections. And there were no differences in work loss between the two groups.

And although the early referral group reported less back pain at follow-up, the patients in this group had no statistically significant advantage in terms of leg pain—often the dominant symptom of sciatica.

Well-Designed and Executed Clinical Trial

Raymond Ostelo, PhD, is a professor of evidence-based physical therapy at the Vrije University in Amsterdam and the Amsterdam University Medical Center—and the author of a recent comprehensive review on physical therapy management of sciatica. (See Ostelo, 2020.)

He is impressed with the study, although he has some questions about it. "First of all, I think this is a well-designed and well executed trial. However, to me, the results are somewhat ambiguous," said Ostelo in a recent email.

He noted that the study results are just above the threshold for a minimum clinically important treatment difference—as predefined in the randomized controlled trial. He also noted that the lower bounds of the 95% confidence interval are close to the line of "no effect."

"But the results are rather consistent over all outcomes, lending support for the conclusion of the authors that the treatment has modest, but nevertheless beneficial, effects," Ostelo observed.

Is Exercise Effective?

Ostelo's recent review of physical therapy for sciatica did not find strong evidence supporting exercise for sciatica or evidence that one form of exercise is superior to another. And this study did not provide that evidence, either.

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Early PT May Be Effective

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"It's difficult to draw strong conclusions for (or against) exercise therapy on its own, as this was just one component of the treatment package," Ostelo noted. The same holds true for the other elements of the active treatment program.

Ostelo said he would be interested in learning more about how patients responded to the McKenzie-style mechanical evaluation and therapy in this RCT.

"As the exercise regime focused on mechanical diagnosis and therapy [in combination with other interventions], I would be interested to learn if the treatment is more effective in patients who have a clear response to the repeated movement tests at baseline, as these patients might be more likely to respond to mechanical diagnosis and therapy.

"That would be informative regarding the question as to which patients are more likely to benefit from this treatment. But I do understand that the authors did not use a 'clear response to the repeated movement tests' as an inclusion criterion for this study, because it was not really an effectiveness study of mechanical diagnosis and therapy," Ostelo said.

What About Nonspecific Effects?

Ostelo also pointed out that it is not possible to determine which aspects of this treatment approach contributed most to the positive results. The exercise, the manual therapy, or nonspecific effects stemming from reassurance and the provision of information about sciatica?

He suggested that nonspecific treatment effects might have played a key role in the results.

"The main reason why I think these components might be very important is that we know that many LBP-patients are frustrated about their consultation and many patients don't feel validated in their complaints. So, from the perspective of really taking care of patients, listening to them, validating their complaints, reassuring them, and explaining in detail what sciatica is and what the best treatment options are might be very important components," Ostelo explained. "This is not a situation where a friendly hand on the shoulder from a health care provider and the comment that 'all will be over within in a couple weeks,' is sufficient," he added.

"In sum, I think further research into these so-called 'non-specific effects' is needed, as these might be much more important than the specific type of exercise regime used in the treatment for these patients," said Ostelo.

An accompanying editorial in *Annals of Internal Medicine* by Nadine Foster, DPhil and Michael Reddington, PhD, agreed that nonspecific effects might be responsible for some of the advantages in the early referral group. (See Foster and Reddington, 2020)

"We cannot rule out that the average, modest, but nevertheless, beneficial effects seen in this trial may be attributed to the increased attention and interaction with a caring health professional (a physical therapist) who provided legitimization of the patients' symptoms rather than the specifics of the intervention program itself (the exercise, manual therapy, or traction)."

Study Not Designed to Identify the Impact of Individual Treatments

However, this RCT was not designed to distinguish specific from nonspecific effects. It was designed to assess the benefit of the whole package of interventions.

A *BackLetter* editor asked Fritz whether she has a working hypothesis as to which treatment components might be responsible for the positive results.

She suggested that untangling the components which led to the positive results would be difficult.

"Nearly any treatment, particularly a behavioral intervention like PT, will have both specific and non-specific effects. These effects are inherently interconnected and disentangling them to assign some sort of proportion to each would be speculative and not likely very productive," according to Fritz.

The study was also not designed to assess the cost-effectiveness of the early referral intervention. Given the cost constraints in many healthcare systems around the world, that is something that would have to be documented in studies down the road.

Need for Further Research

"Although disability was, on average, better in the group referred early to physical therapy, the lack of effect on further health care use or days lost from work could mean that the additional cost of referring all patients with acute or subacute sciatica for early physical therapy would still be difficult to justify in many resource-constrained health care systems. We need to determine which patients need a course of physical therapy, what that should consist of, and when to instigate it, if we are to use health care resources wisely," according to Foster and Reddington.

And they suggested that the modest treatment benefits in this RCT emphasize the need for further research and more effective treatments in this area.

What Types of Research Might Be Most Useful?

Fritz was asked what types of further research she would be most interested in seeing: replication studies, cost-effectiveness analyses, studies that might pin down more exact treatment mechanisms?

"Each of the research efforts mentioned are important (replication, cost-effectiveness analyses, mechanistic evaluations). However, I believe the efforts that would be of greatest impact for the largest number of patients would be implementation efforts with respect to a care pathway that focuses on provision of evidence-based, non-invasive, non-pharmacological care for patients with acute back pain and sciatica without red flags before advancing to more intensive efforts."

What About Applying the Results in Clinical Practice?

And how would Fritz like to see healthcare providers use the results of the study? Should they employ the early PT intervention exactly as described in the study? Or should they experiment with other forms of exercise, manual therapy, and ancillary interventions?

Fritz recommended flexibility in applying the study results. "In our project, we tried to allow individualized patient decision-making within an evidence-based framework. We would encourage this approach with respect to PT and medical management of the condition. There is not strong evidence to say that the particular exercises or manual techniques used are superior to other forms of providing these interventions. Our study wasn't designed to answer that question."

The study cited four different sets of evidence-based guidelines addressing the treatment of sciatica in primary care settings—from Denmark, Australia, the UK, and the United States. (See Stochkendahl et al., Traeger et al., Bernstein et al., Qaseem et al.) The Danish and Australian guidelines

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A Barebones Description of the Study Methods

Julie Fritz, PT, PhD, and colleagues from Utah performed a randomized controlled trial (RCT) in an attempt to identify an optimal approach for patients with acute back pain and sciatica seeking treatment in primary care settings. The study took place in two healthcare systems in Salt Lake City.

They recruited 220 adults aged 18 to 60 with sciatica of less than 90 days' duration who were making an initial primary care consultation for this condition.

Inclusion Criteria

Inclusion criteria included the following:

- Symptoms of pain and/or numbness in the low back and/or buttocks;
- Symptoms of pain and/or numbness primarily into one leg, extending below the knee over the previous 72 hours, corresponding to a lower lumbar nerve root distribution (L4, L5, and/or S1);
- Current symptom duration of 90 days or less;
- Oswestry Disability Index score greater than 20%; and
- One of more of the following:

  Positive straight-leg raising test
  Reflex, sensory, or strength deficits consistent with lower lumbar nerve root involvement.

Exclusion Criteria

Patients were excluded from the study if they met any of the following criteria:

- Any prior fusion surgery and any lumbosacral spine surgery within the past year;
- Current pregnancy;
- Currently receiving care for low back pain from any other provider or any low back pain treatment in the previous six months; or
- Primary care provider identification of potential "red flags" signaling serious conditions such as cauda equina syndrome, major or rapidly progressing neurological deficits, fracture, cancer, infection, or systemic disease.

Two Treatment Approaches

The study subjects were recruited after an initial primary care visit. All study recruits were given a copy of the *Back Book*—which has "evidence-based messages about the favorable prognosis of low back pain and the importance of remaining active and avoiding bed rest." A research assistant reinforced these educational messages and advised all participants to follow up with their primary care provider if they grew dissatisfied with their progress.

The sciatica patients were randomly allocated to one of two treatment approaches:

Usual care: patients in this group underwent education, reassurance, and watchful waiting for four weeks, with no routine provision of treatments during that time period. They were advised to consult with the primary care provider if they weren't making adequate progress at the end of four weeks. At that time, the provider and patient could opt for further evaluation and/or treatment consistent with usual, stepped care.

Referral for early physical therapy: The patients in the early PT group received the same educational approach. They then underwent four weeks of multimodal physical therapy. This revolved around McKenzie-style mechanical evaluation and therapy. "On the basis of mechanical diagnosis and therapy principles, each session began with an assessment of symptom response to repeated or sustained movements of the lumbar spine. Movements or positions that centralize or move symptoms toward the spinal midline form the basis for exercise recommendations."

The therapists encouraged a general progression of extension exercises designed to maximize symptom centralization. "Participants were provided written directions and instructed to do assigned exercises at home every 4 to 5 hours on days between sessions," according to Fritz et al. Patients also underwent manual therapy, including mobilization or high-velocity thrust manipulation intended to facilitate symptom centralization. The PTs were free to choose the content and dosage of these therapies based on treatment response. Traction could be used at the physical therapist's discretion to facilitate centralization

Outcome Measures

The primary outcome measure was the Oswestry Disability Index score after six months. Secondary outcomes included intensity of back and leg pain, patient-reported treatment success, healthcare use, and missed workdays.

Patients in the early referral group had a statistically significant though modest advantage in the primary outcome measure and several secondary outcomes. Roughly 45% of the early referral subjects self-reported "treatment success" compared to 27.6% in the usual care group. There were no significant differences in healthcare use or missed workdays over the course of the study. (See study for further details.)

The overall conclusion? "Our results found that early physical therapy referral after an initial primary care visit for recent-onset low back pain and sciatica resulted in greater improvement in disability and secondary outcomes than usual care across the 1-year follow-up. Health care use did not differ by treatment group assignment," according to Fritz et al. (See Fritz et al., 2020 for further details.)

COVID-19 and Mental Health

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As alluded to earlier, depression can be viewed as a risk factor for pain, chronic pain, and disability—as well as other health problems. However, rigorous studies have not yet documented the impact of COVID-19 on pain levels in general population samples around the world.

Disclosures: None declared.

Reference:

Ettman CK et al., Prevalence of depression symptoms in US adults before and during the COVID-19 pandemic, *JAMA Network Open*, 2020; 3(9): e2019686. doi:10.1001/jamanetworkopen.2020.19686.

Ominous Article from 1937

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In the article, the author noted quite accurately that doctors in the early 1930s had only recently recognized disc herniation as a potentially pathologic condition.

"Alajouanine and Petit-Dutaillis drew attention to the condition in 1930. In 1934 W. J. Mixter and J. S. Barr of Boston, Massachusetts, gave an account of nineteen cases of herniation of the nucleus pulposus into the spinal canal with compression of the cord or cauda equina. In the same year M. M. Peet and D. H. Echols reported two further cases, and more recently W. J. Mixter and J. B. Ayer have collected a series of thirty-three examples of the condition. Further accounts are also given this year by J. S. Barr and P. C. Williams," the unnamed author noted.

According to this article, physicians had previously visualized fragments protruding from discs and migrating into neural canals—but had mischaracterized them as chondromas, fibromas, loose cartilage, fibrochondromas, and myxochrondromas.

The article described the clinical syndrome associated with symptomatic disc herniations. "There may be complaint of pain radiating into the buttock and down the leg suggestive of sciatica, and sensory and motor signs so slight as to be overlooked, with little more than some loss of sensation and a depression of the ankle-jerk."

And the author noted that the symptoms and signs, curiously, were not constant and consistent and that "remissions" occur. It would be decades, however, before scientists documented that most disc herniations are asymptomatic and do not have any obvious relation to low back pain or sciatica—or any negative impact on human health.

This article suggested that disc herniations might explain conditions previously described as radiculitis, sciatica, fibrositis, myalgia, and backache of "gynecological origin."

The author observed that back and leg symptoms were the "bane" of physicians and that this new speculative explanation for them might relieve some of the physician's burden regarding garden-variety low back pain.

So why would this article be "ominous"? And the answer is that the line of research it described led to the unfortunate conclusion that many low back and leg symptoms are the result of traumatic injury and are therefore covered by workers' compensation insurance.

The misguided management of these putatively traumatic injuries over the years has included extensive medical interventions, work absence, protracted bed rest, inactivity, and withdrawal from normal social activities and key aspects of daily living. The generally minor illness of low back pain morphed into a major worldwide epidemic of back pain disability and work loss.

The word "rupture" as applied to "ruptured" discs came to be an important steppingstone in this sad story of growing disability. And it drew the attention of workers' compensation authorities across industrialized countries.

As Nortin Hadler, MD, noted in *Stabbed in the Back*, "If the outcome is a 'rupture,' even if precipitated by an activity that is customary and customarily comfortable, the worker has suffered a compensable back 'injury.'" (See Hadler, 2009.)

And for more than 75 years, "the idea of back 'injury" has troubled the lives of workers with disabling backache for whom workers' compensation insurance is designed to provide a remedy. Over the past few decades, the construct, the diagnosis, and many of its ramifications have been put to the test. We have learned why discal 'rupture' is a flawed pathogenetic theory and compensable back 'injury a sophism that can make people sicker," according to Hadler.

Disclosures: None declared.

References:

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Early PT May Be Effective

Continued from page 139

appear closest to the "evidence-based, non-invasive, non-pharmacological care" Fritz is recommending.

Disclosures: None declared.

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Nonsurgical Management of Symptomatic Disc Herniations Broadly Successful in the US Military

The following might seem to be a paradox. Few, if any, nonsurgical treatments have been proven to speed healing and resolve symptoms in the treatment of symptomatic disc herniations (i.e. disc herniations accompanied by sciatica/radicular pain). Yet overall outcomes in this area are generally positive.

In other words, the symptoms of sciatica resolve fairly quickly in the majority of patients with symptomatic disc herniations, even if they do not disappear completely. And this relates to the generally positive natural history of this form of sciatica. (See the article on page 138 for further discussion of this question.)

A recent study presented at the annual (virtual) meeting of the North American Spine Society provided an example of this positive history.

Ashley Anderson, MD, and colleagues recently performed a retrospective study of the incidence of surgical intervention among soldiers and other members of the US Military Health System. (See Anderson et al., 2020.)

"The Military Health System Data Repository (MDR) contains patient-specific detail on all healthcare beneficiaries including active duty service members, dependents, and retirees. In this set of patients, we then identified patients who failed conservative management, finding the time to the first postdiagnosis encounter for lumbar microdiscectomy or lumbar decompression."

The researchers queried this registry to identify all patients who had a diagnosis of lumbar disc herniation from 2011 through 2018.

A total of 84,985 Military Health System beneficiaries were diagnosed with a symptomatic lumbar disc herniation over that time frame. Almost 63,000 were active duty service members.

A total of 10,532 Military Health System members (12.4%)—including 7650 active-duty soldiers (10.9%)—ended up having a microdiscectomy or decompression surgery. So almost 90% of active-duty soldiers avoided having surgery for their disc herniation and sciatica.

"Multivariable Cox regression among all health care beneficiaries revealed that younger age, male sex, and history of smoking were each associated with higher risk of surgical intervention independent of diagnosing facility characteristics," according to Anderson et al.

Disclosures: None declared.

Reference:

Anderson A et al., The timing and incidence of surgical intervention following diagnosis of lumbar disc herniation at military treatment facilities, presented at the annual (virtual) meeting of the North American Spine Society, *The Spine Journal*, 2020; 20(9):S85–6.

Recommendations on Opioids

Continued from page 137

been found to increase the risk of opioid misuse (encompassing diagnoses of opioid dependence; abuse; or overdose) by 40%, with each additional week of opioids taken raising the risk of misuse by 20%. GPs should assess patients before re-prescribing opioids."

- Patients should be advised on safe storage and disposal of unused opioids and directed to avoid opioid diversion to other individuals (e.g. sharing with friends and family).

Here is the task force's overall conclusion:

"While the use of opioids during and after surgery has the capacity to promote recovery after life-saving or life-enhancing surgery, their use can be associated with harm from persistent postoperative opioid use; opioid-induced respiratory impairment; opioid diversion to people they were not originally prescribed for; and driving under the influence of prescription opioids. Strict control of opioid use within hospitals (stewardship) is required to minimize the risk of opioid-related harm. This will require the multidisciplinary involvement of anaesthetists; surgeons; pain specialists; pharmacists; nursing staff; physiotherapists; primary care clinicians; hospital management; and patients to adopt the recommendations from this consensus statement to local practice."

Disclosures: None declared.

Reference:

Levy N et al., An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients [published online ahead of print October 7, 2020], *Anaesthesia*. doi:10.1111/anae.15262.

Spinal Stenosis Outcomes

Continued from page 135

Unfortunately, many studies presented as abstracts at spine conferences end up morphing into quite different studies, with different conclusions, when they finally pass through peer review and are published. So when it comes to consumption of spine conference abstracts, *caveat emptor* (buyer beware!) is a sensible attitude.

Disclosures: None declared.

References:

Koltsov J et al., Health care resource utilization in lumbar spine surgery for stenosis: A national claims data analysis, *The Spine Journal*, 2020; 20(9 suppl): S95.

Sambare T et al., Patterns of opioid and other prescription medication use in lumbar surgery for spinal stenosis: A national claims database analysis, *The Spine Journal*, 2020; 20(9 suppl):S133.

MEETING CALENDAR

Cervical Spine Research Society
December 10-12, 2020
Las Vegas, Nevada
Contact: Cervical Spine Research Society
9400 W. Higgins Road, Suite 500
Rosemont, IL 60018-4976
Tel: 847-698-1628
Fax: 847-268-9699
E-mail: csrs@aaos.org

International Association for the Study of Pain 2021 World Congress on Pain
June 27-July 1, 2021
Amsterdam, The Netherlands
Contact: IASP
1510 H Street NW, Suite 600
Washington, DC 20005
Tel: 202-856-7400
Fax: 202-856-7401
www.iaspworldcongress.org

Annual Meeting, International Society for the Study of the Lumbar Spine
May 31-June 4, 2021
Milan, Italy
Contact: Katarina Olinder@gu.se
Institute of Clinical Sciences
Sahlgrenska Academy
PO Box 426
SE-405 30 Gothenburg, Sweden
Tel: 46-31-786-44-36
E-mail: katarina.olinder@gu.se

68th Annual Meeting, American College of Sports Medicine
June 1-5, 2021
Washington DC
Contact: American College of Sports Medicine
401 West Michigan Street
Indianapolis, IN 46202-3233
Tel: 317-637-9200
Fax: 317-634-7817
www.acsm.org

American Academy of Orthopedic Surgeons Annual Meeting
August 31-September 4, 2021
San Diego, California
Contact: AAOS
9400 West Higgins Road
Rosemont, Illinois 60018
Tel: 847-823-7186
www.AAOS.org

Scoliosis Research Society 53rd Annual Meeting
September 22-25, 2021
Online
Contact: Scoliosis Research Society
555 East Wells Street, Suite 1100 Milwaukee, WI 53202
Tel: 414-289-9107
E-mail: meetings@srs.org

North American Spine Society Annual Meeting
September 29-October 2, 2021
Boston, Massachusetts
Contact: North American Spine Society
7075 Veterans Boulevard Burr Ridge, IL 60527
Tel: 630-230-3600
Fax: 630-230-3700
www.spine.org

Eurospine 2021
October 13-15, 2021
Gothenburg, Sweden
Contact: Eurospine, Spine Society of Europe
Attn: Judith Reichert Schild
Seefeldstrasse 16
Uster-Zurich, Switzerland
Tel: 41-44-994-1404
www.eurospinemeeting.org

Cervical Spine Research Society
December 2-4, 2021
Atlanta, Georgia
Contact: Cervical Spine Research Society
9400 W. Higgins Road, Suite 500
Rosemont, IL 60018-4976
Tel: 847-698-1628
Fax: 847-268-9699
E-mail: csrs@aaos.org

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- **No Fixes for Back Pain: So Where Should the Field Go from Here?**
- **Should Back Pain Patients Focus on their Ability to Function Rather Than Pain?**
- **Does *Wisdom* Enhance Recovery?**
- **Posttraumatic Stress Disorder and Its Influence on Chronic Pain**

THE BACKPAGE

Unshackling Physicians from Their Computers

When people go to medical school—or other healthcare educational institutions—they never aspire to spending their future professional days handcuffed to a computer, recording information for the electronic medical record. Several spine care providers have commented to *BackLetter* editors that they spend a third or more of patient visits typing into a computer rather than addressing their patients' complex spine and pain issues.

There is a solution to this and that is the use of medical scribes. Scribes can be employed creatively to free up a healthcare provider's time at reasonable cost. And the scribes don't need to be in the physician's office to do their work. Here is a link to an article by Sarah Kwon from *Kaiser Health News* on this rapidly expanding profession—and the increasing use of scribes working remotely from low- and middle-income countries.

At the current time, this is an unregulated profession, so healthcare professionals and their employers need to approach hiring scribes with eyes wide open. They need to check that the scribes do accurate work and also have adequate pay and working conditions. (See https://khn.org/news/remote-scribes-taking-notes-for-doctors-electronic-health-records/.)

Steep Reduction in Face-to-Face Medical Visits

It is no surprise that COVID-19 has led to a steep reduction in face-to-face medical visits. Caleb Alexander, MD, and colleagues recently tallied the utilization and content of primary care visits in the United States from the first quarter of 2018 through the second quarter of 2020.

"The pandemic has been associated with a more than 25% decrease in primary care volume, which has been offset in part by increases in the delivery of telemedicine, which accounted for 35.28% of encounters during the second quarter of 2020," they reported.

There is a general consensus that back and spine care ground to a halt in the early stages of the pandemic in the United States, for better or for worse.

Some have suggested the COVID-19 pandemic has brought the greatest reduction in back pain visits in the history of modern medicine. However, at this point, accurate data in this area are scant. And it is not clear whether the reduction in back pain services had a positive or negative impact on patients seeking care—or on the overall prevalence of back problems.

Some might express surprise that there was only a 25% decrease in primary care visits through the second quarter of 2020. However, COVID-19 affected the United States unevenly, imposing a heavy early burden on certain urban areas on the east and west coasts (Seattle, New York, and Boston, for example). However, COVID-19 did not have a major impact on several regions of the United States until the third quarter of 2020. And the impact of the pandemic is still growing. (See *JAMA Network Open*, 2020; 3(10):e2021476. doi:10.1001/jamanetworkopen.2020.21476.)

Older Patients Opting for Topical Cannabis

A small study from the University of California at San Diego found surprisingly high use of cannabis among older adults—and a surprising mode of cannabis delivery

Christopher Kaufmann, PhD, and colleagues surveyed 568 patients attending a "Medicine for Seniors Clinic" at UC San Diego. Overall, 15% of the patients had used cannabis over the past three years. Interestingly, these were not aging hippies who had first tried cannabis in their Grateful Dead days years before. The researchers found that 61% had initiated cannabis use after the age of 60.

"Pain, insomnia and anxiety were the most common reasons for cannabis use and, for the most part, patients reported that cannabis was helping to address these issues, especially with insomnia and pain," according to colead author Kaufmann.

Co-lead author Kevin Lang said new users of cannabis fell into a distinctive pattern. "New users were more likely to use cannabis for medical reasons than for recreation. The route of cannabis use also differed, with new users more likely to use it topically as a lotion rather than by smoking or ingesting it as edibles. Also, they were more likely to inform their doctor about their cannabis use, which reflects that cannabis use is no longer as stigmatized as it was previously."

In some ways, it makes sense for older patients to experiment with cannabis in the treatment of pain, insomnia, and psychological issues. In the management of pain, for example, most available drug therapies have benefit/risk profiles that don't favor extended use by older patients. Opioids bring risks in multiple dimensions as do oral NSAIDs, gabapentinoids, steroids, and even acetaminophen." However, the benefit/risk ratio for cannabis also remains questionable.

"There seems to be potential with cannabis, but we need more evidence-based research. We want to find out how cannabis compares to current medications available. Could cannabis be a safer alternative to treatments such as opioids and benzodiazepines? Could cannabis help reduce the simultaneous use of multiple medications in older persons? We want to find out which conditions cannabis is most effective in treating. Only then can we better counsel older adults on cannabis use," said Kaufmann. (See *Journal of the American Geriatrics Society* [published online ahead of print October 7, 2020]. doi:10.1111/jgs.16833.)

The Back*Page* Online

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