

Do Modic Changes, Disc Degeneration, and Facet Abnormalities Predict Chronic Pain and Disability?

One of the persistent uncertainties in spinal medicine is to what extent individual MRI abnormalities predict long-term pain and disability among patients with low back pain.

The evidence is inconsistent and unclear. Degenerative changes are remarkably common both in patients with low back pain—and members of the general population who are asymptomatic. Basing clinical decisions on MRI scans is an exercise fraught with hazard. Yet, it is standard practice in many areas of spinal medicine.

Recently, an international group of researchers performed a longitudinal observational study of 204 back pain patients from Denmark with baseline MRI scans and 13-year follow-up. They expected to find that degenerative changes visualized on MRI—including disc degeneration, facet degeneration, and Modic changes (disruption/degeneration of the nerve-rich vertebral endplates)—would be associated with increased long-term pain and disability. However, the results confounded their expectations.

“MRI is often used as a diagnostic and prognostic modality in low back pain patients. This study found baseline degenerative MRI changes to be very common. Disc degeneration, defined as Pfirrmann scores greater than 3, and facet joint degeneration, defined as Fujiwara scores > 2, were present on at least one lumbar level in 52% and 82% of all patients at baseline,” according to lead author Peter Udby, MD, who presented the study at the annual meeting of the North American Spine Society (NASS) in Chicago. (See Udby, 2019.) Almost 40% of study subjects had Modic changes at baseline.

The researchers had expected that these measures of degeneration would translate into worse long-term outcomes. So the results were a shock. “Contrary to our hypothesis, none of the degenerative MRI changes at baseline was associated with worse outcomes at 13-year followup,” said Udby.

Could Modic Changes Be Protective?

Modic changes have been a key focus for spine researchers in recent decades. And there has been a major treatment movement associated with them. Treatments directed at Modic changes (in the presence of back pain) have included fusion surgery, disc replacement, steroid injections, long-term antibiotic therapy, probiotics, and other nonsurgical treatments.

Several research teams have reported that Modic changes are strongly associated with the development of chronic low back pain. However, Udby and colleagues found



Continued on page 6

Surgical Opioid Dilemma

Major changes are occurring in multiple forms of surgery in the hope of preventing potentially destructive long-term opioid use. Spine surgery is a case in point.

“Opioid therapy is effective in controlling acute postoperative pain. However, the potential for abuse has been a national concern,” according to a recent study by Joshua M. Eisenberg, MD, presented at the annual meeting of the North American Spine Society (NASS) in Chicago. “Recent clinical trials have questioned the benefit/risk of chronic opioid therapy in musculoskeletal disorders.”

Coauthor Andrew Pugely, MD, of the University of Iowa presented the study at NASS. He opened by outlining a major dilemma. (See Eisenberg et al., 2019.)

“The US is in the midst of an opioid epidemic, with rates of catastrophic opioid overdoses at record highs. Spine specialists and orthopedists are some of the heaviest

Continued on page 10

IN THIS ISSUE

Tracking the Opioid Overtreatment Epidemic in a Novel Way 2

UnitedHealthcare Promoting PT and Chiropractic to Reduce Utilization of Spine Surgery and Opioids 3

Biologic Medications for Chronic Pain: Soaring Prices Denying Patients Sorely Needed Relief 3

Mind-Body Therapies Promising for Pain Patients Taking Opioids..... 4

Research Revolution: Patients Playing an Expanding Role in the Planning and Execution of Spine Research..... 5

A Q&A on Modic Changes 6

The BackPage Online: Free Online-Only Briefs at www.BackLetter.com..... 12

The BackPage 12

Preventing Back Pain: What Works?; What About Marijuana to Enhance Mental Health?; Acute vs. Chronic Pain: Is This Distinction Useful?

Tracking the Opioid Overtreatment Epidemic in a Novel Way

The deadly opioid overtreatment epidemic can be tracked in a number of ways: by the number of patients taking opioids for chronic pain, by the prevalence of opioid misuse disorders, by the diversion and abuse of opioids, by opioid overdoses, and by opioid overdose death rates.

Jasvinder Singh, MD, and colleagues recently looked at an ominous reflection of the opioid crisis: the prevalence of hospitalizations for opioid use disorders (OUDs) over the course of the opioid crisis. (See Singh et al., 2019.)

“Chronic musculoskeletal diseases are one of the most common reasons for chronic pain. Thus, this group is at risk of receiving opioids and potentially developing an opioid use disorder,” said Singh in a statement from the University of Alabama at Birmingham. “We were interested in understanding the magnitude of the OUD problem, especially with regards to its impact on hospitalization rates and time-trends. We wanted to assess if the problem had been stable or increasing over time. A knowledge of OUD-related hospitalization provides a good assessment of impact on patient morbidity, and also utilization of health services that are expensive.”

They employed the U.S. National Inpatient Sample from 1998 to 2014 to perform a retrospective study of the rates of OUD hospitalizations for five conditions or diseases: low back pain, osteoarthritis, rheumatoid arthritis, fibromyalgia, and gout.

Singh et al. found a low incidence of OUD-related hospitalizations for all these conditions from 1998 to 2000. This was a period in which the opioid crisis was just beginning to develop. There was heavy prescription of opioids in the United States. However, the risks of the population-wide

prescription of these medications were just becoming apparent.

Singh et al. found the prevalence of OUDs rose steadily for most of the 19 years of the study. Over the course of the study, they found a five-fold higher hospitalization rate for back pain patients with an OUD and a 35-fold higher rate for gout—compared with people without these musculoskeletal pain conditions.

The rates of OUD for patients with low back pain and gout appeared to plateau toward the end of the study period, but not for people with osteoarthritis, rheumatoid arthritis, or fibromyalgia.

“This study’s findings should alert patients and providers regarding chronic opioid use in people with rheumatic diseases and should encourage them to have an open dialog regarding the risk/benefit ratio at the time of starting or deciding to continue opioids,” according to Singh, in a statement published by the American College of Rheumatology.

He believes these findings should highlight all these conditions for policy initiatives to reduce problematic opioid use and influence funding agencies to underwrite further rigorous research in this area.

Disclosures: None declared.

Reference:

Singh J et al., Time-trends in Opioid Use Hospitalizations in Common Musculoskeletal Conditions: Gout, Osteoarthritis, Rheumatoid Arthritis, Fibromyalgia, and Low Back Pain, presented at the annual meeting, American College of Rheumatology, Atlanta, 2019; as yet unpublished.

THE BACKLETTER®

Executive Editor

Sam W. Wiesel, MD
Professor and Chairman, Department of Orthopaedic Surgery, Georgetown University Medical Center, Washington, D.C.

Publisher

Randi Davis

Editor

Mark L. Schoene
25 Storey Avenue, Suite 154, Newburyport, MA 01950

Associate Editor

Colin Nelson

Editorial Board

Michele C. Battié, PhD, *Chair, Department of Physical Therapy, University of Alberta, Canada*

Scott D. Boden, MD, *Director, Emory University Spine Center, Decatur, Georgia*

J. David Cassidy, PhD, *Professor of Epidemiology, University of Toronto, Toronto, Canada*

Terry P. Corbin, *Minnesota Shared Decision Making Collaborative, Minneapolis, Minnesota*

Richard A. Deyo, MD, *Kaiser Professor of Evidence-Based Family Medicine, Oregon Health and Science University, Portland, Oregon*

Steven R. Garfin, MD, *Chairman, Department of Orthopaedics, University of California at San Diego*

Nortin M. Hadler, MD, *Professor, Medicine and Microbiology/Immunology, University of North Carolina, Chapel Hill, North Carolina*

Scott Haldeman, MD, DC, PhD
Santa Ana, California

Hamilton Hall, MD, *Medical Director, Canadian Back Institute, Toronto, Ontario*

Timothy A. Harbst, MD, *Gundersen Clinic Ltd., LaCrosse, Wisconsin*

Rowland G. Hazard, MD, *Dartmouth Spine Center, Lebanon, New Hampshire*

Dana J. Lawrence, DC, *Associate Professor, Palmer College of Chiropractic, Davenport, IA*

Tom Mayer, MD, *Medical Director, PRIDE, Dallas, Texas*

William C. Meeker, DC, MPH, *Vice President for Research, Palmer College of Chiropractic, Davenport, IA*

Lyle J. Micheli, MD, *Director, Sports Medicine, Children's Hospital, Boston, Massachusetts*

Silvano Mior, DC, *Canadian Memorial Chiropractic College, Toronto, Ontario*

Thomas C. Namey, MD, *Professor of Medicine, Nutrition, and Exercise Science, Knoxville, Tennessee*

Kenneth L. Nudleman, MD, *Associate Chairman and Chief, Department of Neurology, University of California, Irvine, Orange, California*

H. Duane Saunders, MS, PT, *Founder, The Saunders Group, Minneapolis, Minnesota*

Haymo Wilhelm Thiel, DC, *Anglo-European College of Chiropractic, Bournemouth, UK*

C. David Tollison, PhD, *Carolinas Center for Advanced Management of Pain*



The Back Letter® (ISSN 0894-7376) is published monthly by Wolters Kluwer Health, Inc. at 14700 Citicorp Drive, Bldg 3, Hagerstown, MD 21742. Customer Service: Phone (800) 638-3030; Fax: (301) 223-2400; E-mail customerservice@ww.com. Visit our website at LWW.com. Publisher, Randi Davis.

Copyright © 2020 Wolters Kluwer Health, Inc. All rights reserved. Priority Postage paid at Hagerstown, MD, and at additional mailing offices. GST registration number: 895524239. POSTMASTER: Send address changes to The Back Letter®, Subscription Dept., Wolters Kluwer, P.O. Box 1610, Hagerstown, MD 21742.

SUBSCRIPTION RATES: *Individual*: US \$269.00, international \$392.00. *Institutional*: US \$639.00, international \$771.00. *In-training*: US \$138.00, international \$179.00. *Single copy*: \$62.00. GST Registration Number: 895524239. Send bulk pricing requests to Publisher. *Single copies*: \$52. COPYING: Contents of The Back Letter® are protected by copyright. Reproduction, photocopying, and storage or transmission by magnetic or electronic means are strictly prohibited. Violation of copyright will result in legal action, including civil and/or criminal penalties. Permission to reproduce must be secured in writing; go to the newsletter website (www.backletter.com), select the article, and click “Request Permissions” under “Article Tools,” or e-mail customer-care@copyright.com. Reprints: For commercial reprints and all quantities of 500 or more, e-mail reprintsolutions@wolterskluwer.com. For quantities of 500 or under, e-mail reprints@lww.com, call 866-903-6951, or fax 410-528-4434. PAID SUBSCRIBERS: Current issue and archives are available FREE online at www.backletter.com.

The Back Letter® is independent and not affiliated with any organization, vendor, or company. Opinions expressed do not necessarily reflect the views of the Publisher, Editor, or Editorial Board. A mention of products or services does not constitute endorsement. All comments are for general guidance only; professional counsel should be sought for specific situations. The Back Letter® is indexed in Academic OneFile, CINAHL, EBSCO A-Z, Ex Libris, HINARI, JournalGuide, ProQuest, and TDNet.

UnitedHealthcare Promoting PT and Chiropractic to Reduce Utilization of Spine Surgery and Opioids

In order to reduce the utilization of expensive and ineffective treatments for low back pain, UnitedHealthCare—the largest health insurance company in the United States—is starting to promote the use of both physical therapy (PT) and chiropractic for patients with low back pain.

“UnitedHealthcare has introduced a new benefit for people with acute low back pain that makes it more affordable to access physical therapy and chiropractic care, helping to improve health outcomes, reduce costs and avoid often unnecessary invasive treatments and opioid prescriptions,” according to a statement at the company’s website.

Under the new plan, patients in certain employer-sponsored plans would qualify for three appointments with a physical therapist or chiropractor without any out-of-pocket expenses such as copays or deductibles. They would also still qualify for additional PT or chiropractic coverage permitted under their insurance plans.

“Based on a UnitedHealthcare analysis, by 2021 this benefit design has the potential to reduce the number of spinal imaging tests by 22%, spinal surgeries by 21%, opioid use by 19%, and lower the total cost of care for eligible plan participants and employers.”

This policy is predicated on the notion that surgery, other invasive interventions, and spinal imaging are all *overused* in the management of routine low back pain. It supports the recommendation of the most influential U.S. back pain guideline—that of the American College of Physicians.

“This new benefit design may help encourage people with low back pain to get

the right care at the right time and in the right setting, helping expand access to evidence-based and more affordable treatments,” said Anne Docimo, MD, UnitedHealthcare chief medical officer. “With millions of Americans experiencing low back pain currently or at some point during their lifetimes, we believe this benefit design will help make a meaningful difference by improving health outcomes while reducing costs.”

For a more detailed description of this policy and its rationale, see <https://newsroom.uhc.com/health/back-pain-white-paper-2019.html>

This new policy comes on the heels of several studies suggesting that patients who consulted a chiropractor or physical therapist ended up avoiding some expensive and risky treatments.

For instance, Lewis E. Kazis, ScD and colleagues recently performed a retrospective study of 216,504 adults with new-onset back pain from 2008 to 2013. Patients who received initial care from chiropractors or physical therapists were less likely to opt for opioid therapy over the short- and long-term compared to those who sought care from an MD. (See Kazis et al., 2019).

In another recent retrospective study, BK Frogner et al., studied adults with a new primary diagnosis of low back pain in the period from 2009 through 2013. “When LBP patients saw a PT first, there was lower utilization of high-cost medical services as well as lower opioid use, and cost shifts reflecting the change in utilization,” according to the study. (See Frogner et al., 2018).

Unfortunately, there are some methodological limitations in these types of studies.



DCs, PTs, and MDs often see patients with different characteristics and varying baseline healthcare status. And those populations aren’t always easily comparable.

References:

- Frogner BK et al., Physical therapy as the first point of care to treat low back pain: An instrumental variables approach to estimate impact on opioid prescription, health care utilization, and costs.
- Kazis LE et al, Observational retrospective study of the association of initial healthcare provider for new-onset low back pain with early and long-term opioid use, *BMJ Open*, 2019 Sep 20; 9(9):e028633. doi: 10.1136/bmjopen-2018-028633.
- UnitedHealthCare, New UnitedHealthcare benefit for low back pain helps reduce invasive procedures and address the opioid epidemic, 2019, <https://newsroom.uhc.com/news-releases/back-pain-program.html>.

Biologic Medications for Chronic Pain: Soaring Prices Denying Patients Sorely Needed Relief

Drug companies in the United States have been charging insurers, third-party payers, and patients outrageous prices for biologic medications such as etanercept, infliximab, and adalimumab. Some biologics can cost more than \$60,000 per year.

Biologics are genetically engineered proteins that are designed to reduce

inflammation and slow disease progression. They approach being miracle cures for people with rheumatoid arthritis, psoriatic arthritis, Crohn’s disease, and other inflammatory diseases—including illnesses with a back- or neck-pain component.

These prices stress even the most affluent patients. The pricing of these drugs is keeping some people sick. They are simply

out of the price range of working people without insurance—and people with high deductibles and copays. Those who utilize them without adequate insurance coverage often face financial crises.

These drugs account for a huge proportion of the U.S. drug budget. According to a

Continued on page 4

Mind-Body Therapies: A Promising Approach for Pain Patients Taking Opioids

Over eight million Americans are on long-term opioid therapy for back and other forms of chronic pain. Over two million have opioid abuse disorders.

Many of these patients will need to taper their use of opioids—and will be looking for therapies that might help alleviate opioid-treated pain.

A recent systematic review suggests that several mind-body therapies may fit that bill. Eric L. Garland, PhD, of the University of Utah and colleagues performed a meta-analysis of 60 randomized clinical trials that examined the impact of mind-body therapies on pain and opioid use.

They focused on mind-body therapies that took a psychological approach. These included meditation, mindfulness, hypnosis, guided imagery, relaxation, therapeutic suggestion, and cognitive behavioral therapy (CBT). They excluded therapies with a strong physical or mechanical component—such as yoga, spinal manipulation, and acupuncture.

And the psychologically oriented therapies had a positive impact. “To our knowledge, this study represents the first systematic evaluation of the therapeutic benefits of MBTs for opioid-treated clinical pain in studies including more than 6000 patients. Overall meta-analytic results revealed that MBTs had a statistically significant, moderate association with reduced pain intensity and a statistically significant, small association with reduced opioid dosing compared with a range of control arms,” according to the study in *JAMA Internal Medicine*.

Several mind-body therapies appeared to stand out. Studies of meditation, hypnosis, and cognitive behavioral therapy in general had a significantly positive impact on opioid-related outcomes, including opioid dosing, craving, and opioid misuse. Studies of relaxation, suggestion, and imagery appeared to have lesser effects.

“A different pattern emerged with regard to pain outcomes. Separate meta-analyses by

specific MBT type demonstrated significant associations of meditation, hypnosis, CBT, and suggestion with pain outcomes, with the largest effect sizes observed for meditation studies,” according to the author.

Garland suggested in a recent statement from the University of Utah that it is vital to take advantage of these therapeutic effects. “These findings are critical for medical and behavioral health professionals as they work with patients to determine the best and most effective treatments for pain,” Garland asserted.

“A study published earlier this year projected that by 2025, some 82,000 Americans will die each year from opioid overdose,” said Garland. “Our research suggests that mind-body therapies might help alleviate this crisis by reducing the amount of opioids patients need to take to cope with pain. If all of us—doctors, nurses, social workers, policymakers, insurance companies and patients—use this evidence as we make decisions, we can help stem the tide of the opioid epidemic.”

So how does the therapeutic effect occur? These therapies focus both on changing behavior and altering the function of the brain.

Many of these therapies are not widely available in healthcare systems—or easily available for many patients in terms of convenience and opportunity costs (i.e. the amount of time and effort necessary to access them.). However, Garland et al. pointed out that many of these therapies can be accessed at fairly low cost. After a brief training period many patients may be able to access them via pre-recorded tapes or podcasts—and various Internet sites.

“Behavioral health care professionals working alongside physicians could feasibly integrate MBTs into standard medical practice through coordinated care management, colocated care on site with some system integration, or a fully integrated, onsite care model (e.g. behavioral health integration



into primary care). In so far as mind-body therapies are associated with pain relief and opioid use reduction among patients prescribed opioids for a range of pain conditions, MBTs may help alleviate the opioid crisis,” according to the researchers.

To some extent, these are preliminary findings that need to be confirmed in larger and better-designed studies.

However, greater awareness of the benefits of mind-body therapies may be a win/win situation for patients with back and other forms of acute and chronic pain. Several of the therapies examined in this systematic review also appear to be modestly effective as primary treatments for low back pain. They may help people with pain avoid opioids altogether.

Reference:

Black N et al., Cannabinoids for the treatment of mental disorders and symptoms of mental disorders: a systematic review and meta-analysis [Epub ahead of print]. *Lancet Psychiatry*, 2019, pii: S2215-0366(19)30401-8. doi: 10.1016/S2215-0366(19)30401-8.

Biologic Medications

Continued from page 3

recent article at the *Health Affairs Blog*, the market for biologic drugs in the United States is large and growing. Total U.S. biologic sales in 2018 approached \$125 billion,

an increase of 50% since 2014. (See Brill and Ippolito, 2019.)

Katherine M. Stiffa and colleagues recently estimated that biologic treatments represent only 2% of the prescriptions in the United States, yet comprise 37% of net drug spending. (See Stiffa et al., 2019.)

How Did Biologics Get So Expensive?

But how did these drugs get so expensive? Natalie McCormick, PhD, of Harvard Medical School and colleagues recently

Continued on page 9

Research Revolution: Patients Playing an Expanding Role in the Planning and Execution of Spine Research

The past 30 years has witnessed an explosion in back pain and spine research, with a particularly impressive proliferation in the number of randomized controlled trials (RCTs).

A quarter century ago a single randomized trial was “news” in the *BackLetter* and other spine review publications. Now there are more than 12,000 RCTs, with additional trials appearing weekly.

Most of these trials were designed and conducted by researchers and clinicians. They did not take into account the viewpoints of the main beneficiaries of medical research: patients and the general public.

So most of these studies missed a vital viewpoint. And one could argue that many existing RCTs are biased as a result. Medicine is trying to make up lost ground in this area by emphasizing the importance of including patients as study advisers, contributors, reviewers, and authors. Some funding agencies will no longer fund major clinical trials that do not have patient participation. And some medical journals are beginning to recruit patients and the general public as contributors, reviewers, authors, and editors. As an example of increasing patient participation, the FDA has recently embarked on a program to get patients involved in clinical studies of medical devices.

“Typically, medical device developers work with health care providers, clinical researchers and the FDA to design and test medical devices to understand how the product will benefit patients, but the process often does not incorporate direct input from patients. Without patient input in the design and conduct of the clinical investigation, outcomes important to patients may not be captured, clinical visits may become overly burdensome and study enrollment could be negatively impacted. This can lead to increased time to conduct trials and increased burden to study participants and the health care system, resulting in delays in patient access to potentially lifesaving medical devices,” said Norman Sharpless, MD, the acting Commissioner of the FDA. (See Sharpless et al., 2019.)

“When we work with patients early-on, we can advance the development and

evaluation of innovative medical devices. Patient-centric clinical investigations may improve efficiency and quality in the design and conduct of clinical investigations ensuring that sponsors can enroll and retain patients and collect information that is more meaningful to patients. This may lead to greater uptake of results by patients and providers when making treatment decisions and, ultimately, to earlier U.S. patient access to innovative, safe, and effective medical devices,” Sharpless added.

The FDA has also published a draft guidance on patient participation in medical studies—which is currently in comment phase at the FDA website. (See FDA, 2019.)

The draft guidance emphasizes the potential advantages of widespread patient participation in research.

The FDA believes medical device clinical investigations prospectively designed with input from patient advisers may help to address common challenges faced in these clinical investigations:

- Faster study/research participant recruitment, enrollment, and study completion;
- Greater study/research participant commitment, resulting in decreased loss to follow-up;
- Greater study/research participant compliance resulting in fewer protocol deviations/violations;
- Fewer protocol revisions;
- Streamlined data collection resulting in better quality data; and
- More relevant data on outcomes that matter to patients.

The FDA also addressed obstacles to further patient participation:

- Perception that FDA does not allow patient engagement in the design and conduct of clinical investigations;
- Patient perceptions that their input is not valued by the clinical investigation protocol development team;
- Sponsors’ limited awareness, resources, and time to participate in patient engagement activities;
- Challenges finding patient advisers knowledgeable about clinical investigation methodology;

- Site investigators’ reluctance to allow sponsors to engage with patients except as study/research participants;
- Logistical challenges of engaging with patient advisers in-person, which may preclude their involvement in the design of clinical investigations; and
- Challenges with determining which patient advisers or patient organizations should be engaged, and if multiple patient advisers are engaged, how to reconcile the disparate perspectives.

That last point is a major stumbling block. How would the authors of a back-pain study determine which patient points of view should be included in an RCT?

Should they include “typical patients,” a broad range of patients, patients who are evidence-oriented, patients with a broad range of risk factors for various outcomes, or patients who represent certain common attitudes and points of view?

And one of the key questions is to what extent should study architects take into account large patient organizations, many of which are funded by industry—and may have biased points of view based on that collaboration. Device companies will be working overtime to identify patient groups that support novel devices.

Disclosures: None declared.

References:

- FDA, Patient Engagement in the Design and 2 Conduct of Medical Device Clinical Investigations, draft guidance for comment purposes, September 24, 2019; www.fda.gov/media/130917/download. Sharpless NE et al., Statement on FDA efforts to encourage patient engagement in medical device clinical investigations, September 23, 2019; www.fda.gov/news-events/press-announcements/statement-fda-efforts-encourage-patient-engagement-medical-device-clinical-investigations.

A Brief Q&A About Modic Changes and Low Back Pain

Was the spine community premature in identifying Modic changes as important causes of low back pain?	Yes. There has been a long tradition in spine research and spine care of identifying painful conditions prematurely. Researchers have often jumped to conclusions based on inadequate evidence. That has occurred in the case of Modic changes. However, researchers have subsequently done a good job in identifying contradictions and inconsistencies in the existing evidence. This is a healthy research movement.
Do Modic changes on MRI have a strong and consistent association with low back pain?	No. The evidence from studies to date is conflicting. For instance, in the recent review by Christofer Herlin et al., only half of the studies reported statistically significant positive associations between Modic changes and low back pain.
Do patients with Modic changes constitute an important subgroup of individuals with low back pain?	The evidence is conflicting.
Is there strong and consistent evidence that Modic changes stem from bacterial infection?	No. The evidence is conflicting.
Is there strong and consistent evidence from randomized controlled trials that antibiotic therapy may be a curative treatment for back pain in the presence of Modic changes?	No. Three randomized trials have addressed this question, with conflicting results. This is still an open research question.
Have researchers used consistent methods in detecting and classifying Modic changes?	No. Studies to date have not used similar methods and definitions to classify Modic changes. “Comparison of MC data between studies can be problematic. Various methodological factors impact detection and classification of MC, and the lack of reporting guidelines hinders interpretation and comparison of findings. Thus, it is critical to adopt imaging and reporting standards that codify acceptable methodological criteria,” according to a recent report of a task force from the International Society for the Study of the Lumbar Spine (See Fields et al., 2019.)

Modic Changes

Continued from page 1

the opposite to be true. “Baseline Modic changes [were] associated with significantly less long-term disability [at 13-year followup],” Udby reported.

This is the second study of Modic changes that found no association with back pain at long-term follow-up.

In a study published in 2018, Luis M. Romero-Muñoz, MD, and colleagues from Toledo, Spain, took MRI scans of two groups of patients (one with Modic changes and one without) and followed them up for 10 years. There were no differences in the intensity of pain, degree of impairment, or in the need for treatment. (See Romero-Muñoz et al., 2018.)

“There is no relationship between Modic changes in MRI and greater intensity of lumbar pain or need for medical or surgical treatment at 10 years of follow-up. Modic changes cannot be considered a sign of bad prognosis by themselves, or an indication

for surgery,” according to the Spanish researchers.

What Is the Mechanism for Pain Relief?

So why might Modic changes be associated with improved long-term outcomes, compared to back pain patients with no Modic changes?

There are three types of Modic changes commonly visualized on MRI.

In Modic type 1 changes, there is vascular development in the vertebral body and evidence of inflammation and edema, but no trabecular damage or marrow changes. Many researchers believe that the inflammation associated with type 1 Modic changes predisposes people to low back pain.

In Modic type 2 changes, there are alterations in bone marrow, with fatty replacement of the red, cellular marrow normally seen there. Inflammation is less obvious.

In Modic type 3 changes, there are fractures of the trabecular bone, along with

trabecular shortening and widening. (See wikivisually.com/wiki/modic_changes.)

Modic type 1 changes have been most strongly associated with low back pain in several previous studies and systematic reviews. They often transition into more stable type 2 and type 3 changes, which do not have as strong an association with low back pain.

Udby et al. suspect that this could be the underlying explanation for their findings. “The results presented in this study might be explained by progression of active inflammatory changes with bone edema in MC-1 to fat deposits and osteosclerosis (MC-2/- 3) . . .” Understanding the development of MCs over time and its impact on LBP is key in understanding the natural progress of disability and pain in LBP patients. This change in the patients with MCs from MC-1 to MC-2/-3 might explain the better long-term clinical status compared with the patients with isolated DD,” noted Udby et al. in a related study recently published in *Spine*. (See Udby et al., 2019.)

Continued on page 7

Modic Changes

Continued from page 6

Can Degeneration Be Therapeutic?

The pattern of improvement among patients with Modic changes in the Danish study led to an intriguing question during the discussion session that followed the study presentation at the NASS meeting.

“Was there any follow-up imaging?” asked an attendee from Canada. He wondered whether the discs with Modic changes might have undergone a natural spinal fusion over the intervening 13 years.

“The reason for the question is that years ago [spine research pioneer] Henry Farfan would say that the final phase of disc degeneration is restabilization,” he explained.

“My professors said that people [with severe degeneration] could go on to an auto-fusion where the discs would finally be fused by osteophytes that finally joined around the edges.”

“I think you are absolutely correct regarding the end-stage of disc degeneration,” Udby responded. “That is also what we see in different joints as well. When you look at the knee joints, if you let [degeneration] run its course people will sometimes have an improvement in their pain over the long term when the joint is almost fused.”

However, Udby qualified his comments. “I am not sure that is the case here. There could be a lot of things going on.”

Udby explained the lack of imaging at long-term follow-up. “There was no long-term MRI followup. Part of the reason was that the original MRI scans had been taken with a low-field MRI.” Most modern spine clinics now use high-field MRI, which would have precluded consistent results.

“We have seen that low-field and high-field MRI will find a different prevalence and pattern of Modic changes,” according to Udby.

So the lack of MRI at long-term followup is a gap in this study. It would have been useful to see if the type I Modic changes progressed to type II and II. However, the study in general certainly raises doubts about the role of Modic changes in the genesis and prognosis of low back pain.

Modic Changes and Back Pain: No Conclusive Answers After 30 Years

In fact, one can argue that a single word characterizes the entire body of evidence on

Modic changes at the moment. And that word is “uncertainty.” Recent research has raised doubts about many of the early assumptions regarding Modic changes. And the significance of Modic changes among people with and without back pain isn’t at all clear.

Adam Pearson, MD, recently reviewed research by Udby et al. at the Spine Blog and offered an important take-home message. “Thirty years after their description, the spine community still does not know what to make of Modic changes.” And he suggested they not be used to predict outcomes or guide treatment, particularly in the setting of chronic back pain. (See Pearson, 2019.)

There has been a long tradition in spine research and spine care of identifying and treating putatively painful conditions *prematurely*. Researchers have often jumped to conclusions on specific forms of back pain based on inadequate evidence. That certainly occurred in the case of Modic changes. Thousands of patients have undergone various treatments based on the presence of Modic changes in the face of back pain. At the current time there isn’t adequate evidence that any of these interventions were warranted outside of research settings.

However, the research process is certainly catching up—and reining in expectations regarding these endplate and vertebral body abnormalities.

Recent Systematic Review Warns Against Premature Conclusions

For example, early studies appeared to document a strong association between type I Modic changes and low back pain. But many subsequent studies have told a different story.

Three systematic reviews published between 2008 and 2015 found an association between Modic changes and low back pain. (See Jensen et al., 2008; Zhang et al., 2008; Brinjikji et al., 2015.)

However, the largest and most recent systematic review in this area raised doubts about his entire body of research. Christofer Herlin and colleagues warned against drawing firm conclusions in this area, because of the heterogeneity of studies on Modic changes and a variety of biases in the research process.

The review by Herlin et al. certainly did not portray Modic changes as “smoking

guns” for low back pain. Of the 30 relevant studies in the systematic review, only about half found a statistically significant association between Modic changes and low back pain. The rest did not. (See Herlin et al., 2018.)

What About Antibiotics for Modic Changes?

The authors of the most widely publicized randomized controlled trial in this area hypothesized that Modic changes are the product of post-surgical infection. Hanne Albert, PhD, et al. reported successful results after the administration of long-term antibiotic therapy. However, in the wake of two other randomized controlled trials on the role of antibiotics, the evidence in this area is now conflicting. And the viability of this hypothesis remains questionable. So, again, uncertainty prevails. (The February 2020 *BackLetter* will address this body of research). (See Albert et al., 2013; Al-Falahi et al., 2014; Bråten et al., 2019.)

Could Clinical Findings Identify Modic Changes?

A number of researchers have attempted to see whether any combination of clinical findings could identify patients with painful Modic changes. However, these results have thus far come to naught. In the latest example, Peter van der Wurff, PhD, and colleagues couldn’t any clinical predictors of Modic changes in a study of members of the Netherlands armed forces. “It is therefore not likely that LBP patients with Modic changes are very different from other LBP patients and that they form a specific subgroup. However, the study only explored a limited number of clinical findings and it is possible that larger samples allowing for more variables would conclude differently.”

Lack of Consistent Definitions and Methods

Two other issues also create uncertainty in this area. Udby pointed out that researchers studying Modic changes have not used the same definitions and methods. “We see that a lot of studies lack a clear definition of Modic changes,” he commented at his NASS presentation.

A task force from the International Society for the Study of the Lumbar Spine

Continued on page 8

Modic Changes

Continued from page 7

recently made a similar point. “Comparison of Modic changes data between studies can be problematic. Various methodological factors impact detection and classification of MC, and the lack of reporting guidelines hinders interpretation and comparison of findings. Thus, it is critical to adopt imaging and reporting standards that codify acceptable methodological criteria,” according to the ISSLS Degenerative Spinal Phenotype Group. (See Fields et al., 2019).

New Research May Have an Impact

Lastly, evolving research on disc, endplate, and vertebral body abnormalities may have an impact on many questions associated with Modic changes. For example, a recent study of endplate abnormalities among residents of eastern China with and without back pain came to surprising findings. Neither Modic changes nor disc degeneration were associated with low back pain. However, three types of endplate defects—focal, corner, and erosive—were associated with various measures of back pain. (See Chen et al., 2019.)

So understanding of Modic changes, and their influence on low back pain, remains incomplete.

Here is a brief description of the study by Udby, based on three sources. The study was originally discussed in a poster at the 2018 NASS meeting. It was presented at the annual meeting, and published recently in a slightly different form in *Spine*.

The patients in this study were originally participants in a randomized controlled trial conducted in 2004 and 2005. That study randomly allocated patients with persistent back pain to either cognitive training or physical therapy. The study subjects ranged from 18 to 60 years of age. They had a mean low back pain score of at least four out of 10 for the previous 14 days, pain for a minimum of four out of the past 12 months, and back pain greater than leg pain.

“In that RCT, patients in the two cohorts had similar results at one year follow-up. Since the cohorts were similar at both baseline and follow-up, the entire cohort, regardless of treatment arm, were pooled for the current study and analysis,” according to Udby et al.

Udby and colleagues quantified degenerative changes in the discs, facet joints, and

vertebral endplate/vertebral bodies: through the use of the Pfirrmann grading system (Pfirrmann scores greater than 3 represented disc degeneration), the Fujiwara grading system (score greater than 2 represented facet degeneration), and through the presence of any of the three types of Modic changes.

Patients completed numeric rating scales for back and leg pain, the Roland-Morris Disability Questionnaire, and the Low Back Pain Rating Scale. The researchers followed this cohort for 13 years. They controlled for a variety of potentially confounding factors (study in *Spine* for details.)

Here are some of the study results on Modic changes. “In contrast to previous studies, the current study did not find any differences in patient-reported outcomes at initial consultation in chronic [low back pain] LBP patients with or without Modic changes [MCs]. In this aspect, we found no clinical parameters distinguishing LBP patients with MCs from those without MCs,” according to Udby et al. in *Spine*.

By 13-year follow-up, the pattern had changed. Patients with Modic changes had modestly better results in terms of pain, disability, and sick leave.

Here are the conclusions of the printed study: “Modic changes are a common finding in LBP patients referred to a tertiary spine center due to long-lasting low back pain at initial consultation. No clear clinical features can separate patients with Modic changes from those without. Modic changes were not found to be negatively associated with long-term pain, disability, or sick leave. Rather, the study found that LBP patients with MCs had significantly less disability and sick leave at long-term follow-up. We encourage further studies to elucidate these findings.”

Disclosures: None declared.

References:

Albert H, et al., Antibiotic treatment in patients with chronic low back pain and vertebral bone edema (Modic type 1 changes): A double-blind randomized clinical controlled trial of efficacy, *European Spine Journal*, 2013; 22:697–707.
Al-Falahi MA et al., Antibiotic Treatment in Patients with Chronic Low Back Pain and Vertebral Bone Edema (Modic Type I Changes): A Randomized Clinical Controlled Trial of

Efficacy, *The Iraqi Postgraduate Medical Journal*, 2014; 13(3): 390–8.

Bråten LCH et al., Efficacy of antibiotic treatment in patients with chronic low back pain and Modic changes (the AIM study): double blind, randomised, placebo controlled, multicentre trial, *BMJ*, 2019; 367:l5654. doi: 10.1136/bmj.l5654.

Brinjikji W et al., MRI Findings of disc degeneration are more prevalent in adults with low back pain than in asymptomatic controls: A systematic review and meta-analysis, *American Journal of Neuroradiology*, 2015, 36(12):2394–9.

Fields AJ et al., Measuring and reporting of vertebral endplate bone marrow lesions as seen on MRI (Modic changes): recommendations from the ISSLS Degenerative Spinal Phenotypes Group, *European Spine Journal*, 2019, 28(10):2266–74.

Herlin C et al., Modic changes-Their associations with low back pain and activity limitation: A systematic literature review and meta-analysis, *PLoS One*, 2018 Aug 1;13(8):e0200677.

Pearson A, Do Modic changes predict long-term outcomes? The Spine Blog, 2019; <https://journals.lww.com/spine-journal/blog/SpineBlog/pages/post.aspx?PostID=603>.

Romero-Muñoz L et al., Are Modic changes in patients with chronic low back pain indicative of a worse clinical course? 10 years of followup [published online ahead of print March 31, 2018], *Revista Española de Cirugía Ortopédica y Traumatología*, doi:10.1016/j.recot.2018.01.005.

Udby P, Which MRI findings are associated with long-term disability in low back pain patients? Presented at the annual meeting of the North American Spine Society, Chicago, 2019.

Udby P et al., Modic changes are not associated with long-term pain and disability, *Spine*, 2019; 44(17):1186–92.

van der Wurff P et al., Exploratory study for clinical signs of MODIC changes in patients with low-back pain in the Netherlands armed forces, *Chiropractic and Manual Therapies*, 2019, 27(5): doi: 10.1186/s12998-018-0229-4.

Zhang YH et al., Modic changes: a systematic review of the literature, *European Spine Journal*, 2008, 17(10): 1289–99.

Table I: Systematic Reviews on the Association of Modic Changes With Low Back Pain

Review	Types of Studies Included	Results
Herlin C et al., 2018	Prospective or retrospective cross-sectional cohort studies and case-control studies. Included people of all ages.	Review found inconsistent associations between Modic changes and low back pain—and between Modic changes and activity limitation Patients with Modic changes may not represent a specific clinically relevant subgroup of people with back pain Recommended caution when using the label “Modic changes” as a diagnosis, explanation for low back pain, or indication for specific treatment
Brinjikji W et al., 2015	“Case-control and cross-sectional studies were included in this analysis.” Subjects were 50 years or younger.	This meta-analysis of epidemiologic studies demonstrated that MR imaging evidence of disc bulge, disc degeneration, disc extrusions and protrusions, Modic 1 changes, and spondylolysis had significant associations with low back pain in adult patients 50 years of age or younger. The association between these degenerative findings and pain should not be interpreted as causation “Modic 1 changes had a significant association with low back pain in our analysis.” However, Modic changes as a whole (Modic changes type 1–3) did not have an association with low back pain.
Zhang YH et al., 2008	To be included in the review, studies had to provide information about the epidemiology, natural history, clinical significance of MC. Included subjects of all ages	Modic changes are a common phenomenon on MRI. They have been strongly associated with back pain in various studies. However, the evidence is not consistent across studies. “The conclusion that patients with Modic changes are a specific subgroup within LBP patients may be premature.”
Jensen TS et al., 2008	Included a mixture of study types involving people of all ages.	Vertebral endplate signal changes are a common MRI finding in patients with non-specific LBP—and are associated with pain. However, similar changes may be found in people without LBP.

Biologic Medications

Continued from page 4

examined this issue in the U.S. Medicare & Medicaid programs.

They accessed Medicare Parts B and D along with Medicaid drug spending data from 2012 to 2016. They looked at all biologics approved for one or more rheumatic diseases.

They documented the five-year pattern of spending on these biologics. They isolated the role of four sources of spending growth: rising drug costs, number of people taking the drugs, treatment intensity (based on mean number of doses per claim), and the annual number of claims per recipient for each of the medications.

They found that from 2012 to 2016 annual spending on these biologics in U.S. Medicare & Medicaid programs roughly

doubled, from \$5.3 billion to \$10.3 billion for the 11 included biologics. Over that time frame, the price tags of these drugs increased by a mean of 52% in Medicare Part D and 20% in Medicare Part A.

Price Increases the Key Driver?

McCormick et al. found that the *majority* of spending growth for older Part B drugs (such as rituximab, abatacept, and infliximab) stemmed from price increases—of 72% to 88%. Even after the researchers took into account drug company rebates for patients, drug price increases accounted for 53% of the increase in Part D spending. (See McCormick et al., 2019.)

For newer drugs (e.g. golimumab, ustekinumab, tocilizumab, certolizumab, and belimumab) the total number of recipients was

the main driver, representing 63% to 81% of growth in spending.

The researchers advise paying careful attention to the pattern of costs for these medications, as they have major policy implications. Should U.S. society somehow regulate the initial costs of these drugs—or the progression of costs?

“With prices increasing, our findings underlie the importance of rheumatologists and patients discussing the costs of DMARD (Disease-modifying antirheumatic drugs) treatment and options for mitigating cost concerns and barriers to effective treatment. These will differ depending on each patient’s financial circumstances and extent of their Medicare coverage,” said McCormick. “We did not have access to individual-level data

Continued on page 11

Surgical Opioid Dilemma

Continued from page 1

prescribers,” he explained. Orthopedic surgery is the specialty field with the third highest opioid prescribing rate.

“We have established in previous research that preoperative opioid use often leads to protracted post-operative use,” said Pugely. “But we still don’t understand the long-term implications of operating on patients who are long-term opioid users.”

Study of a Large Surgical Database

So they performed a retrospective observational cohort study to examine the association between preoperative opioid use and mid- to long-term clinical outcomes after primary lumbar fusion surgery.

The researchers employed the Humana claims database, which included 28,795 men and women who underwent spinal fusion. A majority (59%) of the study subjects were women. More than 90% were older than 50 years. And the average cost of their claims was \$28,631.66.

Study subjects qualified as preoperative opioid users if they had an active opioid prescription three months before surgery.

Eisenberg et al. mapped out both intermediate and long-term outcomes including the following:

- Reoperation rates;
- Resource utilization (such as emergency visits, injections, and other interventions);
- Complications;
- Venous thromboembolic events;
- Infections;
- Postoperative wound healing; and
- Neurologic, respiratory, and cardiac complications.

Worse Outcomes Among Patients Taking Opioids

A disturbing 57% of the fusion patients were on preoperative opioid therapy. And those patients appeared to have a greater vulnerability to adverse outcomes than those not taking opioids.

“Preoperative chronic opioid use was strongly associated with prolonged post-operative opioid use,” according to the research team. “Our investigation quantifies

that patients on preoperative chronic opioid therapy were 395%, 535%, and 603% more likely to be on postoperative opioid prescriptions at 90 days, one year, and two years after lumbar spine surgery, compared to opioid-naïve patients.”

In the study, preoperative opioid users had an increased risk of reoperations, emergency visits, epidural or facet injections, kidney failure, venous thromboembolism, and other events.

Here are some of these risks, in the authors’ words, with risk ratios:

“Multivariable regression models identified chronic opioid therapy (COT) to be associated with increased risk of 90-day ED visits (OR:1.18; $p < 0.001$), epidural steroid injections (OR:1.44; $p = 0.032$), venous thromboembolism (OR:1.15; $p = 0.026$), and infections (OR:1.16; $p = 0.020$). At 1-year, COT was strongly associated with increased risk of reoperations (OR:1.30; $p = 0.021$), ED visits (OR:1.27; $p < 0.001$), epidural and facet-joint injections (OR: 1.40; $p < 0.001$, OR:1.49; $p < 0.001$), ARF (OR:1.15; $p = 0.021$), venous thromboembolism (OR: 1.11; $p = 0.042$), wound complications (OR:1.15; $p = 0.01$), and infections (OR:1.19, $p = 0.004$). Similarly, at 2-years COT was associated with an increased risk of reoperations (OR:1.25; $p = 0.009$), ED visits (OR:1.27; $p < 0.001$), and other adverse events in addition to respiratory complications (OR:1.20 $p = 0.002$). COT was associated with prolonged postoperative narcotic use at all time points: 90-days, 1-year and 2 years (OR:4.95; $p < 0.001$, OR: 6.34; $p < 0.001$, OR:7.03, $p < 0.001$).”

Time for Tapering Programs

Pugely recommended that spine surgery practices implement tapering programs, to help patients reduce opioid therapy before spine surgery. “Implementing a multidisciplinary opioid-tapering protocol prior to spine surgery can aid in optimizing outcomes and . . . postoperative opioid requirements,” he explained.

During the discussion section that followed this study, the moderator asked Pugely how he and his colleagues would explain these results and recommendations.

“For patients on long-term opioid therapy, it is not only about taking the pills,” Pugely responded. He explained that patients on long-term opioid therapy often have complicated psychological and pain

management issues. And they have a range of challenging comorbidities.

“My sense is that a chronic opioid user is more or less afraid to move. They are less likely to engage in rehabilitation after surgery. They are more likely to persevere on small issues of pain after surgery at six months and one year. They are the ones seeking additional treatments, including surgery. They may come back to your office time and again, which may prompt some physicians to order more imaging. This perseveration about pain will prompt additional interventions, which are not necessarily warranted.”

Does Stopping Opioid Therapy Improve Outcomes?

Spine surgeon and researcher Zoher Ghogawala, MD, asked a key question. “

“Terrific presentation on the overwhelming utilization of opioids among patients who have spine surgery. I think you showed quite convincingly that patients who take opioids before spinal surgery are more likely to be using opioids after surgery— [and likely to have inferior outcomes]. What evidence do we have that identifying patients who are chronic opioid users before surgery and trying to get them off opioids changes that course?”

“There isn’t any great evidence,” Pugely responded. “We are currently doing research on this issue.” He said he and his colleagues were studying the impact of engaging surgery candidates in multidisciplinary rehabilitation programs.

He emphasized that these programs do more than just try to get patients off opioid therapy. “The program involves physical therapy, occupational therapy, and alternative ways of managing pain. The patients work with pain specialists who really help people redefine how they think about pain. We will see if anything makes a difference.”

Disclosures: None declared.

Reference:

Eisenberg JM et al., Impact of preoperative chronic opioid therapy on long-term outcomes, reoperations, complications and resource utilization after lumbar arthrodesis, presented at the 2019 annual meeting of the North American Spine Society, Chicago; as yet unpublished.

MEETING CALENDAR

■ American Academy of Orthopaedic Surgeons Annual Meeting

March 12-16, 2020
2019 Las Vegas, Nevada

Contact: AAOS
9400 W. Higgins Road
Rosemont, IL 60018
Tel: 847-823-7186
Fax: 847-823-8125
www.aaos.org

■ International Association for the Study of Pain 2020 World Pain Congress

August 4-8, 2020
Amsterdam, The Netherlands

Contact: IASP
1510 H Street NW, Suite 600
Washington, DC 20005
Tel: 202-856-7400
Fax: 202-856-7401

■ 47th Annual Meeting, International Society for the Study of the Lumbar Spine, Combined with SpineWeek, 2020

April 27-May 1, 2019
Melbourne, Australia

Contact: Katarina Olinder Eriksson, Administrator, ISSLS
c/o Institute of Clinical Sciences
Sahlgrenska Academy
University of Gothenburg
PO Box 426 SE-405 30
Gothenburg, Sweden
Tel: 46-31-786-44-36
E-mail: katarina.olinder@gu.se

■ Eurospine 2020

October 7-9, 2020
Vienna, Austria

Contact: Eurospine, Spine Society of Europe
Attn: Judith Reichert
Schild Seefeldstrasse 16
8610 Uster-Zurich,
Switzerland
Tel: 41-44-994-1404
www.eurospinemeeting.org

Coming Soon:

- Antibiotics for Chronic Back Pain
- Major New Campaign to Limit Industry Funding of Medical Research
- The False Narratives That Still Permeate Spine Care
- International Fusion Rates: Why is the Rate So High in the US?
- Chronic Spinal Pain a Continuing Source of Financial Worries?
- Opioids Plus Other Central Nervous System Medications a Recipe for Fall Injuries

Biologic Medications

Continued from page 9

in this study but would like to investigate how price increases may impact patients' out-of-pocket costs and adherence to therapy over the long term, and which diagnoses had the biggest increases in biologic uptake. It will also be interesting to assess the impact of biosimilars on public spending."

Biosimilars are brand-name drugs that are highly similar, but not identical, to the index drug. According to the FDA, biosimilars are (1) made with the same types of natural sources; (2) provide the same treatment benefits; (3) have the same strength and dosage; and (4) have the same treatment benefits.

They hold the potential for modest reductions in costs. Biosimilars are often marketed at a slightly lower price than the original brand-name drugs but not at prices as low as those of generic medications.

Disclosures: None declared.

References:

- Brill A and Ippolito B, The economics of biologic drugs: A further response to Bach et al. [published online ahead of print August 8, 2019], *Health Affairs Blog*; doi:10.1377/hblog20190807.554429.
- McCormick N et al., Post-market price changes alone account for most recent spending growth for biologics, presented at the annual meeting, American

College of Rheumatology, Atlanta, 2019; as yet unpublished.

Stiffa K et al., Tracking the price of existing biologics when drugs enter the market, *Expert Review of Pharmacoeconomics & Outcomes Research*, 2019; 19(4):375-7. doi:10.1080/14737167.2019.1630274.

THE **BACKPAGE**

Preventing Back Pain: What Works?

People receive all sorts of advice on ways to prevent low back pain. They are advised to avoid sitting, bending over, awkward postures, heavy lifting, and exposure to vibration. They are often advised to make ergonomic adjustments, wear back belts, and rely on shoe insoles.

Most of these prevention methods share one important quality. They find scant support in rigorous scientific studies.

A recent study from China illustrates this point. Rongzhong Huang, MD, and colleagues performed a Bayesian network meta-analysis to summarize the comparative effectiveness of potential prevention methods. They included data from 40 randomized controlled trials.

Only exercise, with or without an educational component, stood out as a prevention method—with modest magnitude of effects.

“Exercise alone, as well as the combination of exercise with education, prevented episodes of [low back pain] LBP as well as LBP-associated work absenteeism. Other prevention strategies—did not achieve statistical significance,” according to Huang et al.

They would like to see further high-quality studies explore the potential preventive effects of exercise and other potentially preventive interventions. “We recommend large higher-quality RCTs, including head-to-head comparisons of preventive interventions, to validate these results.” (See *British Journal of Sports Medicine*, 2019; 0:1–7. doi:10.1136/bjsports-2018-100035.)

What About Marijuana to Enhance Mental Health?

Americans, Canadians, and citizens of other countries are flocking to marijuana products by the millions

to treat back and other forms of chronic pain. Rigorous studies have not yet confirmed that medicinal cannabinoids have a consistently positive effect on pain. And the risk/benefit profile is uncertain.

But what about marijuana products to enhance mental health—which of course plays a key role in the experience and prognosis of chronic pain? Nick Black and colleagues recently performed a systematic review and meta-analysis of trials addressing the effectiveness and safety of marijuana products in the treatment of depression, anxiety, attention-deficit hyperactivity disorder, Tourette syndrome, posttraumatic stress disorder, or psychosis, either as the

cannabis and cannabinoids are being made available for medical use. There is a notable absence of high-quality evidence to properly assess the effectiveness and safety of medicinal cannabinoids compared with placebo, and until evidence from randomised controlled trials is available, clinical guidelines cannot be drawn up around their use in mental health disorders,” said senior author Louisa Degenhardt in an accompanying statement at Lancet.com.

Acute vs. Chronic Pain: Is This Distinction Useful?

One of the main distinctions in classifying pain in modern

months after onset of a painful condition. Utilizing duration as a critical factor may obscure the role of other factors such as affective state, coping strategies and past history in perpetuating chronic pain,” he suggested.

He believes that the acute/chronic dichotomy has been a major contributor to the failure of modern pain models to consistently explain and alleviate pain. (See *Pain Management*, 2018; doi:10.2217/pmt-2018-0061.)

Mark I. Johnson made similar points in a recent essay entitled “The Landscape of Pain”. “There are no temporal correlates of physiological processes associated with pain based on time points used to distinguish acute and chronic,” he agreed.

And much of low back pain—particularly intermittent back pain—does not fall neatly into these categories.

Johnson also noted that many of the major statistics on pain stem from this same uncertain acute-chronic dichotomy.

“Chronic pain affects between 15–30% of the general adult population, with severe, debilitating chronic pain affecting 10–15% of adults. Health-care and socioeconomic costs of chronic pain are high and estimated to be 3–10% of gross national domestic product in Europe. In the United States annual costs related to health care delivery and lower worker productivity due to chronic pain is estimated to be between \$560 and \$635 billion dollars and greater than heart disease (\$309 billion), cancer (\$243 billion), and diabetes (\$188 billion).”

But are all these statistics based on false thinking and false distinctions? It is certainly a possibility, which further research should explore. (See *Medicina*, 2019; 55(5):182.)

The BackPage Online

See free online-only BackPage briefs at www.BackLetter.com.

This month:

- **Reforming Drug Pricing in the United States Will Require a Costly Trade-Off**
- **Powerful Movement to Help Patients Assess, Track, and Act On Their Major Health Priorities**
- **A Burst of Humor About Low Back Pain**

primary condition or secondary to other medical conditions.

They found 83 eligible studies, including 40 randomized controlled trials. “There is scarce evidence to suggest that cannabinoids improve depressive disorders and symptoms, anxiety disorders, attention-deficit hyperactivity disorder, Tourette syndrome, post-traumatic stress disorder, or psychosis.” They found “very low quality” evidence to support the use of cannabinoids in treating anxiety. “There remains insufficient evidence to provide guidance on the use of cannabinoids for treating mental disorders within a regulatory framework.” (See *Lancet Psychiatry*, 2019 Oct 25. pii: S2215-0366(19)30401-8.)

“Our findings have important implications in countries where

medicine is whether it is “acute” or “chronic.” Yet a number of researchers have questioned whether there is any validity to this classification.

Neurosurgeon John Loeser, MD, of the University of Washington recently suggested this classification originated in the 1970s as a practical way of determining who needed sophisticated pain management services. “Only chronic pain patients were thought to need referral to multidisciplinary pain centers,” he explained.

“The idea that acute pain transitions into chronic is without an evidential underpinning and, I believe, is an error in conceptualization. There is no known physiologic or anatomic change that occurs at 3 or 6