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Pain Consult

DEPARTMENT OF PAIN MANAGEMENT | 2014



Chronic Pelvic Pain

New Center Taps Teamwork to Meet the Challenge

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Dear Colleagues,

“Collaborative Care Is More Effective.” That’s the title of the second chapter of *The Cleveland Clinic Way*, the new book from Cleveland Clinic CEO and President Toby Cosgrove, MD, outlining eight trends — including collaborative care — that will define the future of medicine.

It is likewise a sort of informal theme of this issue of *Pain Consult* from Cleveland Clinic’s Department of Pain Management.

Cleveland Clinic organizes its physicians, surgeons and other caregivers into patient-centered institutes to foster collaborative care that transcends traditional disciplinary boundaries. We believe this culture of team-based care leads to exchanges that produce richer ways of approaching complex cases. Almost nowhere is this cooperative culture more evident than in pain medicine, and this issue is full of examples:

- Collaboration and teamwork are the *raisons d’être* of our newly formalized Pelvic Pain Center, as detailed in our cover story. The Pelvic Pain Center brings together physicians from a multitude of specialties — under the direction of a pain management specialist — to provide highly coordinated management for patients with this notoriously challenging condition. “The doctors at Cleveland Clinic work as a team,” testifies the patient in the story’s case profile.
- The p. 8 story on cancer pain illustrates how our pain management specialists partner closely with palliative medicine physicians to provide nuanced, multimodality pain control that enhances cancer patients’ quality of life while allowing oncologists to focus on oncology.
- The pair of stories on pp. 10 and 12 touch on our department’s involvement with two separate Cleveland Clinic care paths — for chronic abdominal pain and low back pain — whose development and implementation have been highly interdisciplinary projects. Each story spotlights how our ethic of collaboration with specialist colleagues from across Cleveland Clinic helps bring an abundance of expertise to bear for challenging cases.

The chronic abdominal pain article also explores how we are aggressively taking on the inappropriate use of opioids for this condition. Indeed, chronic opioid use is another informal theme of the issue, with stories explaining why it’s such a bad bargain for almost all patients (p. 6) and how other modalities can supplement and reduce chronic opioid use for its primary legitimate indication — cancer pain (p. 8).

I hope you enjoy this issue, and I urge you to share our infographic of pain wellness tips in the center spread (also at clevelandclinic.org/painwellnesstips) with a patient today.

Richard W. Rosenquist, MD

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Teaming Up to Tackle Chronic Pelvic Pain

Cleveland Clinic's new Pelvic Pain Center offers a multidisciplinary approach — along with hope — to patients with chronic pelvic pain.



A sampling of the Pelvic Pain Center's multidisciplinary team. Left to right: psychiatrist Manu Mathews, MD; gynecologist Mary Jean Uy-Kroh, MD; pain specialist Joseph Abdelmalak, MD; vascular and interventional radiologist Gordon McLennan, MD; urogynecologist Megan Tarr, MD; and gynecologist Margaret McKenzie, MD.

People living with chronic pelvic pain (CPP) often feel frustrated, alienated and misunderstood by friends, family and even physicians. CPP is typically characterized by deep-seated, aching pain that can disrupt sleep and work, lead to urinary urgency and frequency, and cause discomfort during sex and urination. Because the conditions contributing to CPP are varied — ranging from endometriosis to colitis to interstitial cystitis and more — treatment can be difficult (see sidebar, next page).

Continued next page >

NO 'GOING IT ALONE' IN CPP MANAGEMENT

"Treating chronic pelvic pain requires collaborative practice," says Joseph Abdelmalak, MD, a member of Cleveland Clinic's Department of Pain Management whose specialties include CPP. "Surgeons perform the surgeries while pain specialists manage the pain; it becomes a team effort with each member implementing his or her expertise. Working together to help our patients has actually become the best approach to chronic pelvic pain."

In 2013, Dr. Abdelmalak facilitated the creation of Cleveland Clinic's Pelvic Pain Center to foster interdisciplinary collaboration and holistic treatment of patients with CPP. The center comprises approximately 20 physicians who consult closely and meet quarterly to exchange experiences, present case studies, share journal articles and discuss treatment options for patients. The group includes physicians from pain management, obstetrics/gynecology, urology, urogynecology, psychiatry and interventional radiology.

"The Pelvic Pain Center is very important because it takes a long time to treat these patients," says Marie Fidela Paraiso, MD, Head of the Center for Urogynecology and Reconstructive Pelvic Surgery in Cleveland Clinic's Ob/Gyn & Women's Health Institute. "Most of the time, they have been to several other centers, have not been helped and have charts two to three inches thick. In an interdisciplinary center such as ours, we can put our heads together to treat very difficult problems that may be attributed to several disease processes."

CARE COORDINATION LOOMS LARGE

At his initial consultation with a patient, Dr. Abdelmalak obtains a detailed history and conducts a thorough physical examination with particular attention to the

abdominal, pelvic, musculoskeletal and neurologic exams. "Then we sit down with a plan," he says. "I tell the patient that refractory pelvic pain is a chronic disease, not something I can treat with one injection or one pill. But I assure them that it's treatable and we will work together."

The patient plan usually includes other specialists from the Pelvic Pain Center, whom Dr. Abdelmalak contacts to schedule same-day or next-day appointments, if possible. Everyone in the Pelvic Pain Center is committed to this timely referral-based system, which especially benefits out-of-state patients, who account for about one-third of the center's patient base. "When all of us meet the patient in one day," says Dr. Abdelmalak, "it not only saves the patient time and cuts expenses, but it helps in achieving the success and fruition of our treatments."

MORE CONTINUITY FOR PATIENTS

Gordon McLennan, MD, in the Department of Diagnostic Radiology, is part of the Pelvic Pain Center team. For women whose pain is caused by pelvic congestion syndrome, he offers noninvasive techniques to embolize the implicated ovarian veins and pelvic varices. But 25 percent of his patients do not get full or partial relief from the embolization, so he refers those patients to Dr. Abdelmalak for a pudendal nerve block. The combination of embolization and nerve blocks typically works for these patients.

Dr. McLennan says he has long been "frustrated that patients [with CPP] get bounced from physician to physician." He adds that while other healthcare centers employ a multidisciplinary approach to treatment, Cleveland Clinic's Pelvic Pain Center is unique. "Having Pain Manage-

THE ESSENTIALS OF CHRONIC PELVIC PAIN

What is its diagnostic profile?

Chronic pelvic pain (CPP) is defined as nonmenstrual pelvic pain lasting more than three months that is severe enough to cause functional disability and require medical or surgical treatment.

Who is typically affected?

Approximately 70 to 80 percent of CPP cases are women, though men can be affected too, especially if they have chronic prostatitis.

What causes CPP?

There are many causes, including reproductive, urologic, gastrointestinal, psychosexual, vascular, neurologic and spinal issues. Often more than one cause is involved. In addition, 30 to 50 percent of CPP cases have no obvious pathology, making diagnosis and management challenging.

How is it treated?

There are numerous options. Conservative measures include lifestyle modifications, exercise, dietary changes and pelvic floor muscle relaxation therapy. Some cases require medication, such as NSAIDs, antidepressants, anticonvulsants, hormonal therapy or opioids. In addition, nerve blocks or surgery may be indicated.



Figure. Image of a pudendal nerve block of the kind used in Mrs. A.

ment involved is a bit novel and absolutely adds to the value we provide,” he says.

Dr. Paraiso agrees. She operates on many patients with pelvic organ prolapse. “If surgery hasn’t helped and we can’t establish any other organic cause for their pain, we bring in others to help treat the pain medically or interventionally,” she says. “We deal with pain in a collaborative way.”

When specialists work hand in hand to treat CPP, patients benefit both physically and emotionally (see sidebar). The Pelvic Pain Center’s comprehensive, collaborative approach offers hope to patients — many of whom have suffered for years. “Each patient here is known by name,” says Dr. Abdelmalak. “Our patients deserve and receive world-class healthcare, and their continued progress is a top concern of our team.”

To refer a patient to the Pelvic Pain Center, call 216.444.PAIN. Dr. Abdelmalak can be reached at abdelmj@ccf.org.

A PATIENT’S PERSPECTIVE ON CHRONIC PELVIC PAIN

Three years ago, Mrs. A (pseudonym to protect her privacy) would come home from work and take a brisk three-mile walk around her neighborhood in Pittsburgh. Then, after undergoing urogynecologic surgery in October 2011, she was lucky to be able to finish a leisurely stroll around the block.

Mrs. A, 59, suffers from chronic pelvic pain dating back to that operation, which involved a hysterectomy and laparoscopic surgery to implant transvaginal mesh to address uterovaginal prolapse. Her pelvic pain began the day after the surgery. The following week, she was prescribed opioids and subsequently diagnosed with postsurgical trauma to the pelvic region.

In early 2012, Mrs. A began pelvic physical therapy and saw a gastroenterologist, who diagnosed levator ani syndrome — pain and pressure in the rectum, sacrum and coccyx. She missed weeks of work and began seeing a pain management specialist, who prescribed anticonvulsants, opioids and antidepressants. None worked, and many caused allergic reactions.

“I felt like I was free-falling,” she says. “I was pushed from the surgeon to the gastroenterologist to the pain doctor. Nobody wanted to help me.” After researching pelvic pain online, she headed to Cleveland Clinic because of its reputation and relatively short drive time — about two hours — from Pittsburgh.

Cleveland Clinic urogynecologist Marie Fidela Paraiso, MD, began treating Mrs. A in August 2012. Realizing that the patient’s case was complex, she collaborated with colleagues, including Joseph Abdelmalak, MD, a pain management specialist, and colorectal surgeon Tracy Hull, MD.

When Mrs. A. met Dr. Abdelmalak, she felt hopeful for the first time since her pain began. “I was in the office for more than an hour,” she recalls. “He let me talk, and he understood my emotion and frustration.”

Her team of Cleveland Clinic specialists tried medical management, physical therapy, a pessary and pelvic floor exercise. Ultimately, in June 2013, Mrs. A underwent a laparotomy, a sigmoid resection and an augmentation of her prolapse repair. Since then she has also received numerous pudendal, ganglion impar and coccygeal nerve blocks (Figure). While her pain is not gone, the treatments help reduce its severity and provide some temporary relief, she says. She remains hopeful the relief will increase as she continues to explore additional treatments with Dr. Abdelmalak.

“The doctors at Cleveland Clinic work as a team,” she says. “They show so much compassion, and I don’t feel like I’m hanging out to dry by myself. That is huge to a patient dealing with a long-term condition that changes your quality of life.”

A Hard Lesson Learned Over Two Decades: Why Specialists Rarely Use Opioids for Chronic Pain



// FEATURING RICHARD W. ROSENQUIST, MD //

As ever more scrutiny is focused on the use of opioids in the United States, two principles about their use for chronic pain should loom largest in clinicians' minds, advises Richard W. Rosenquist, MD:

- The role of opioids in treating chronic pain is very small and limited to a narrow subset of patients.
- Any plan to start a patient on opioids must include a plan to monitor the medications' effect using specific outcome measures and to stop their use if defined treatment goals are not met.

"In general, pain specialists rarely prescribe opioids anymore for chronic pain unless it's cancer-related pain," says Dr. Rosenquist, Chairman of Cleveland Clinic's Department of Pain Management.

OVERCOMING A MISJUDGMENT FROM A QUARTER CENTURY AGO

But it wasn't always that way. In the late 1980s, an effort took hold among pain specialists to improve chronic pain treatment through expanded opioid use. "Opioids were known to be effective for acute pain, so the thinking was, Why not use them for patients with chronic pain who needed greater relief?" explains Dr. Rosenquist.

Many pain specialists at the time believed that if chronic opioids were limited to legitimate indications, patients would not become addicted. "But reality caught up with us," Dr. Rosenquist notes. "We learned that people who get started on opioids have a much

"After a while, patients are lucky to get 20 or 30 percent relief." – Richard W. Rosenquist, MD

higher conversion to active addiction than previously thought. Also, physical dependence on opioids develops quickly, and in some people it turns into physical addiction."

A STEEP SOCIETAL TOLL

These lessons did not become clear for years, however, and prescribing of opioids surged during the 1990s and early 2000s. Opioid abuse increased in tandem, and the consequences have been filling headlines for several years now:

- 15,000 to 18,000 U.S. deaths per year attributable to prescription opioid overdose
- The proliferation of — and later crack-down on — "pill mills" that spurred a subindustry of individuals reselling opioids for profit
- Burgeoning rates of addiction to heroin, a less-expensive opiate that addicts turn to for cost reasons or when they can no longer access prescription opioids because of the pill mill crackdown

OTHER REASONS TO NIX CHRONIC OPIOIDS

These huge addiction-related costs are a major reason why the pain medicine community has dramatically scaled back use of opioids for chronic pain in recent

years — but they are hardly the only one, says Dr. Rosenquist.

Another reason is disappointing efficacy. "People thought opioids had no ceiling effect, but it turns out they don't yield much pain relief in the chronic setting," he explains. "After a while, patients are lucky to get 20 or 30 percent relief." Improvement in functional outcomes and general well-being is often even less, he adds.

Many patients on chronic opioids feel worse overall because of these agents' now well-established side effects, including immunosuppression, endocrine abnormalities, constipation, sedation and depression. Cruellest of all, some patients experience worsened pain after starting chronic opioids, an effect known as opioid-induced hyperalgesia.

THE RARE CASES WHEN CHRONIC OPIOIDS ARE INDICATED

So when do Dr. Rosenquist and his colleagues consider opioids outside the acute pain setting? "We commonly use them to treat cancer pain, either alone or in combination with other therapies," he says (see next story). "We also will consider them when there are medical contraindications to other choices for chronic noncancer pain control. In those cases, we use opioids in low doses and aim to maintain the

dose at a steady state. In general, high doses are rarely successful.”

He adds that continued opioid use is contingent on demonstrated improvement in functional outcomes, not just pain scores. “If you give an antibiotic for a UTI and it doesn't treat the infection, you stop it. The same principle applies. Many patients are on opioids for a long time without ever achieving a good outcome, yet their providers fail to question it and try something different.”

SUGGESTED READING

For a compelling account of the changing view of opioids, Dr. Rosenquist recommends a Dec. 17, 2012, *Wall Street Journal* story profiling New York pain specialist Russell Portenoy, MD (“A Pain-Drug Champion Has Second Thoughts”; subscription required for online access).

TODAY'S CHALLENGE: CARING FOR DISPLACED PATIENTS

Many of the Department of Pain Management's current efforts surrounding opioids aim to address the needs of those patients who have endured longtime opioid use. That's particularly true now that many unscrupulous providers have stopped prescribing opioids in the wake of regulatory crackdowns, leaving their patients desperate for new prescribers.

The Department of Pain Management is implementing a new algorithm for managing these displaced patients.

The foundation of the approach is simply getting patients to the right provider after an evaluation of their pain and current opioid use status. Patients whose condition includes an addiction component

need to have that addressed first, so they are referred to Cleveland Clinic's Alcohol and Drug Recovery Center or its distinctive interdisciplinary Chronic Pain Rehabilitation Program. The latter is a comprehensive three- to four-week outpatient program designed to reduce both pain and chemical dependency and help patients foster coping skills and improved function.

Once addiction is addressed, Dr. Rosenquist's team restarts the patient's pain management with a proper evaluation to uncover the underlying cause of the pain process. That typically leads to a multimodality treatment strategy that may include psychological approaches, interventional approaches, physical therapy and more. “What we often offer

could be called a pain wellness program,” Dr. Rosenquist says.

Beyond these efforts, the Department of Pain Management has partnered with Cleveland Clinic's Digestive Disease Institute and Neurological Institute to develop a care path and a multidisciplinary clinic specifically for chronic abdominal pain (see p. 10). A major impetus is the prevalence of inappropriate opioid use for the condition. “I can't think of anything with less evidence than opioids for abdominal pain,” says Dr. Rosenquist. “So we're aiming to tackle that problem head-on.”

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Are We Limited to Opioids When It Comes to Cancer Pain?



// FEATURING SHRIF COSTANDI, MD, AND HAROLD GOFORTH, MD //

When one of Dr. Harold Goforth's rectal cancer patients failed to respond to chemotherapy and oral pain medication over six months, palliative surgery was offered. Unfortunately, the patient was inoperable. With no other options, Dr. Goforth, a member of Cleveland Clinic's Department of Hematology and Medical Oncology, referred the patient to pain management specialist Shrif Costandi, MD, who administered neurolytic hypogastric and ganglion impar blocks that yielded significant pain improvement.

"Most patients with cancer pain can be managed medically," says Dr. Goforth. "But for those with incomplete symptom relief, there's a large role for advanced pain techniques." That's when he calls on colleagues like Dr. Costandi, of Cleveland Clinic's Department of Pain Management.

OPIOIDS: A FRONT-LINE TOOL, BUT NOT THE ONLY TOOL

Cleveland Clinic adheres to the World Health Organization's three-step ladder for cancer pain management, which depends on the level of pain. As a tertiary care center, Cleveland Clinic treats many cancer patients with complex pain conditions. "Opioids are usually the initial line of therapy used and are indeed an effective modality for many patients," says Dr. Costandi.

Dr. Goforth says the majority of cancer patients can be managed medically with a combination of opioids and nonopioids. However, opioids are notorious for side effects such as excessive drowsiness, nausea, vomiting, constipation and hormonal disturbances. "We offer other interventions that aim for pain relief with

improved quality of life during the patient's life expectancy," explains Dr. Costandi.

THREE CLASSES OF INTERVENTIONAL MODALITIES

Because cancer is a complex, progressive disease, treating cancer pain is challenging. Interventional pain management modalities play an important role, notes Dr. Costandi. He classifies them in three main categories, all of which can be used in tandem with opioids:

- 1) **Nerve blocks.** These can be divided into three broad types according to their purpose:
 - **Diagnostic blocks** are intended to identify pain generators. These include the transversus abdominis plane (TAP) block, which pinpoints whether the pain originates from the abdominal wall (somatic) or the internal organs (visceral).



Figure 1. A neurolytic hypogastric plexus block for advanced colon cancer.

- **Prognostic blocks** predict the potential benefit of ablating the blocked nerves. One type, the sympathetic nerve block, is indicated to control visceral cancer pain. Common examples are celiac plexus blocks and superior hypogastric plexus blocks.
- **Therapeutic blocks** aim to alleviate pain and improve patients' functionality.

Patients who obtain short-term but substantial relief with prognostic blocks can benefit from therapeutic blocks such as a neurolytic block. Neurolytic celiac and superior hypogastric blocks (Figure 1) are an established treatment option for upper abdominal and pelvic malignancies, respectively.

2) Vertebral interventions. These include vertebral augmentation procedures (VAPs) and the OsteoCool® RF Ablation System.

VAPs are complex procedures to treat and relieve pain from compression fractures due to spinal metastasis, which is common in multiple myeloma and other cancers. Two kinds of VAPs are performed by highly trained interventional pain specialists or neurosurgeons:

- Vertebroplasty, which involves percutaneous injection of bone cement, under image guidance, into the collapsed vertebral body
- Kyphoplasty, which introduces an inflatable balloon into the collapsed vertebral body to restore height and create a cavity to be filled with bone cement to stabilize the bone and relieve the disabling pain (Figure 2)

“VAP patients show significant improvement in pain almost immediately,” says Dr. Costandi. “Multiple studies have demonstrated noticeable pain reduction as well as improvement in function.”

OsteoCool is a technique that uses bipolar water-cooled radiofrequency ablation to treat spinal pain secondary to metastatic vertebral tumors. Clinical experience at Cleveland Clinic, which was among the first centers to investigate this technique, shows local disease control, marked pain reduction and quality-of-life improvements from a single treatment.

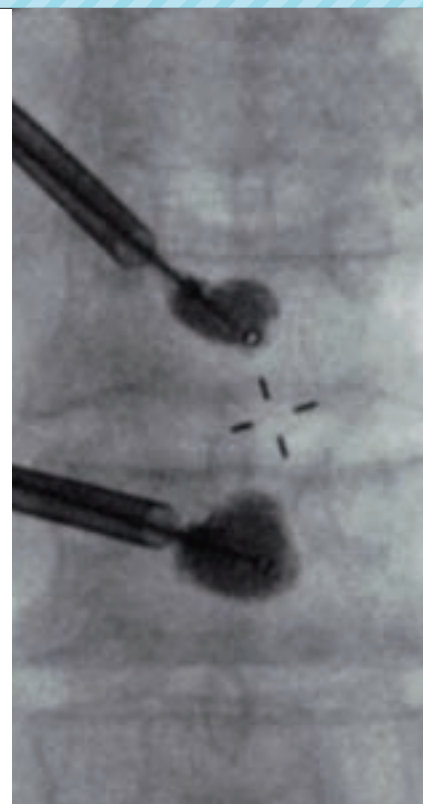
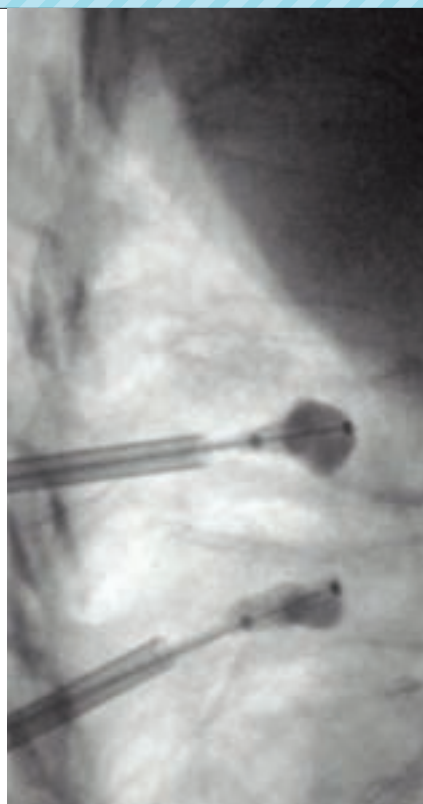


Figure 2. Images showing T7 and T8 kyphoplasty in a patient with multiple myeloma.

3) Implantable therapies. These modalities include implanted neurostimulators, used for selected cancer patients presenting with intractable focal neuropathic pain, and intrathecal drug delivery devices. The latter are considered for patients who fail to respond to oral opioids and may benefit from an alternate medication or who experience pain relief from opioids but are limited by severe side effects. Intrathecal pump implants optimize pain relief for patients with a life expectancy of more than three months. For patients with shorter life expectancy, a subcutaneous port with a tunneled catheter is usually placed instead.

WHY COLLABORATION IS CRITICAL IN CANCER PAIN MANAGEMENT

Physicians from oncology, pain management and palliative medicine work together at Cleveland Clinic to determine the best interventions for each patient. “It’s extremely important to collaborate,”

says Dr. Costandi, “because each specialist brings a unique skill set and knowledge base to the patient’s care.”

“Pain control and cancer-related symptom management by palliative medicine and pain specialists is paramount in achieving clinical success,” adds Dr. Goforth. “Oncologists can actually spend more time on oncology.”

“If cancer pain is refractory to conventional pharmacotherapy or if patients cannot tolerate escalating doses, physicians should definitely consider other interventions,” Dr. Costandi notes. “The goal is to improve patients’ functionality and help them enjoy the remainder of their lives. That’s the least we can offer, and they deserve it.”

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Dr. Goforth can be reached at goforth@ccf.org or 216.445.9122.

Chronic Abdominal Pain: Collaboration and a Care Path Chart a Course for Progress



// FEATURING BRUCE VROOMAN, MD //

When a patient with chronic abdominal pain (CAP) is referred to a Cleveland Clinic pain physician such as Bruce Vrooman, MD, management is infused with interdisciplinary collaboration from the start.

“The first step is a thorough workup in conjunction with a gastroenterologist — and sometimes a colorectal or general surgeon — to determine whether an acute process is taking place,” says Dr. Vrooman, a board-certified pain management specialist and anesthesiologist in the Department of Pain Management.

Depending on the workup findings, Dr. Vrooman and colleagues identify potential diagnostic and therapeutic interventions, which typically start conservatively — and again with collaboration across specialties. “We often focus on lifestyle modifications, biofeedback, cognitive behavioral therapy, stress reduction and similar approaches, which are done in association with psychologists in Cleveland Clinic’s Neurological Center for Pain,” he says.

GIVING CHRONIC ABDOMINAL PAIN ITS DUE

This multidisciplinary approach to CAP has become so well established at Cleveland Clinic that the relevant players — the Department of Pain Management, the Digestive Disease Institute and the Neurological Center for Pain (within the Neurological Institute) — are in the process of formalizing it with the creation of a Chronic Abdominal Pain

Clinic this year. The collaboration has also translated to development of a novel Cleveland Clinic care path that tackles the important issue of chronic opioid therapy in patients with CAP.

The launch of the Chronic Abdominal Pain Clinic not only will give patients and referring physicians a point around which to coordinate related care, it also recognizes the complexity of a condition whose causes may be known or unknown and which often vexes patients and clinicians alike.

TARGETED NERVE BLOCKS AND STIMULATION MODALITIES

In those more vexing cases, Dr. Vrooman says, initial conservative measures may require supplementation with medication management and/or minimally invasive procedures such as nerve blocks. The latter often include differential epidural nerve blocks, an injection along the abdominal wall, or blocks for visceral pain such as celiac plexus or splanchnic nerve blocks.

“There also may be a role for neurostimulation — either peripheral nerve stimulation or spinal cord stimulation — for various abdominal pain conditions,” notes Dr. Vrooman, who is involved in several

clinical trials evaluating these treatments.

“Studies have demonstrated that neurostimulation is an effective therapy for conditions such as chronic pancreatitis and visceral hyperalgesia,” he says. “This is an area of medicine that combines technology and minimally invasive procedures under the overarching goal of reducing pain and improving functionality.”

SPECIAL CHALLENGES FROM OPIOIDS ...

Special challenges are posed by burgeoning numbers of patients who are prescribed opioids for CAP, with varying degrees of efficacy. “Often outside physicians will place patients on escalating opioid doses without a corresponding reduction in pain,” Dr. Vrooman says. “There is little to no evidence-based literature behind chronic opioid therapy for CAP, yet it frequently is prescribed with little to no positive effect.”

Patients with CAP on opioid therapy can experience opioid-induced hyperalgesia and sensitization, and they have increased emergency room and hospital admissions and longer hospital stays compared with those not on opioids. “The result is a major healthcare problem,” Dr. Vrooman notes.

... AND A CARE PATH TO ADDRESS THEM

Cleveland Clinic is countering that problem with its new Chronic Abdominal Pain Care Path, a joint effort among the Department of Pain Management, the Digestive Disease Institute and the Neurological Center for Pain modeled on other recent Cleveland Clinic care paths (see sidebar).

The care path, which focuses largely on decreasing chronic opioid use, “standardizes our approach to reducing the deleterious effects of opioid therapy in CAP,” Dr. Vrooman explains. “It has the goal of

simultaneously improving pain, functionality and overall health while also coordinating patients’ multidisciplinary care.”

Development of the care path and new clinic coincides with enhanced efforts to make specialized care for CAP accessible at Cleveland Clinic as widely and quickly as possible, particularly in situations where opioids might otherwise be prescribed or when patients are already on inappropriate opioid therapy.

“While it might sometimes seem easier to prescribe opioids for a patient with CAP, we make a concerted effort to evaluate

alternatives with fewer risks and side effects,” Dr. Vrooman says. “It takes time to listen and evaluate a patient thoroughly to determine the best treatment plan, but it’s worth the effort.”

Dr. Vrooman can be reached at vroomab@ccf.org or 216.445.9641.

THE LOWDOWN ON CLEVELAND CLINIC CARE PATHS

The Chronic Abdominal Pain Care Path and the Spine Care Path (see next article) are two among dozens of condition-specific care paths developed throughout Cleveland Clinic in the past three years.

The care paths are more than just practice guidelines. They leverage the electronic medical record (EMR) and process-based tools to encourage adherence to practice guidelines and guide clinical work flow to promote consistent, evidence-based, value-oriented care.

Care paths start as evidence- or consensus-based guides developed by multidisciplinary teams of Cleveland Clinic experts for the management of specific conditions. The aim is to standardize care around the best evidence, clearly identify meaningful outcomes and identify relevant process metrics.

The guides are translated to tools tied to the EMR, including standardized documentation templates and clinical decision-support and predictive analytical tools. Data are captured in the EMR for ongoing analysis, to generate metrics for individual physicians and facilities, and to drive continuous quality improvement.

“The objective is to provide clinicians a tool to capture the process of care in structured notes and order sets, support clinical decision-making based on the care path, and

regularly assess health status and process measures during treatment,” explains Daniel Mazanec, MD, Associate Director of Cleveland Clinic’s Center for Spine Health, who led development of the Spine Care Path for management of back pain.

“Care paths ensure that all patients presenting with similar issues undergo the same evaluation methodology,” adds Philippe Berenger, MD, of the Department of Pain Management, who provided input on the Spine Care Path.

Another goal of select care paths is to improve and accelerate access to care. “This can be very important for patients experiencing abdominal pain, especially if inappropriate opioid therapy is involved,” says Department of Pain Management physician Bruce Vrooman, MD, who helped lead development of the Chronic Abdominal Pain Care Path.

The care paths are at various stages of implementation, with the acute care portion of the Spine Care Path having undergone pilot testing at three Cleveland Clinic family health centers. Impressive reductions were demonstrated in opioid prescribing, imaging at the initial visit and early referrals for intraspinal injections. Pilot testing has been extended to the subacute care portion (management at six to 12 weeks), and current efforts around the Spine Care Path are focused on full integration into the EMR for use by clinicians across the Cleveland Clinic health system.

Low Back Pain: New Strategies to Avoid Straying from Best Practice



// FEATURING PHILIPPE BERENGER, MD //

Nearly a dozen clinical practice guidelines on managing low back pain have been published in the past decade, yet there's little evidence they've altered physician practice, improved patient outcomes or enhanced the value of care. That needs to change, says Philippe Berenger, MD, a staff physician in Cleveland Clinic's Department of Pain Management.

"Promising new treatments for low back pain are constantly emerging, but many ultimately prove no more effective than past treatments," he explains. "It's critical to confirm that new therapies are supported by evidence and that clinical guidelines are followed to ensure optimal outcomes and cost-effective care."

Cleveland Clinic is taking on these challenges in two broad ways: with its new Spine Care Path to systematically reduce variation from evidence-based care, and via highly integrated, enterprisewide collaboration for the most challenging cases.

FROM VOLUME TO VALUE

The Cleveland Clinic Spine Care Path is a process-based tool designed for integration in the electronic medical record (EMR) to guide clinical work flow and help providers make evidence-based guidelines operational (see sidebar, p. 11).

The care path was developed by Cleveland Clinic's Center for Spine Health with input from Department of Pain Management staff like Dr. Berenger. One goal was to match appropriate treatments and providers to patients at various points along the care continuum for low back pain.

"We know acute back pain is common and often resolves with simple therapy or even no therapy," Dr. Berenger says. "For patients without red flags, imaging is rarely required." These patients may be best served through prompt access to care from physical therapists or nurse practitioners as entry-level providers. When pain persists beyond four to six weeks, the care path defines when referral to spine or pain specialists, spine surgeons or behavioral health providers is indicated.

Another objective was reducing variation from evidence-based practice, which can be costly — and potentially harmful — without benefiting patients. "Providing care along a specific pathway helps avoid overtesting and excessive imaging," Dr. Berenger notes.

HOW THE CARE PATH WORKS

Under the care path, when patients first present with acute back pain, they are evaluated for red flags suggestive of malignancy or other underlying disease. If red flags are ruled out, management is guided through a consistent, evidence-based protocol that follows these principles:

- Imaging is not necessary
- Activity is encouraged as tolerated

- Simple nonopioid analgesics are used as needed
- For persistent pain, follow up as needed in approximately four weeks (with possible referral to a spine or pain specialist at that point, if indicated)

Central to the process is the Spine Care Path's integration into the EMR, which assists the clinician by flexibly encouraging adherence to guidelines-based care at every turn. Likewise, patient-reported data are fed into the EMR at each visit as patients complete validated pain and function questionnaires on tablet devices using a Cleveland Clinic-developed intake tool called the Knowledge Program. This allows patient progress to be monitored and correlated with process measures like imaging use and appropriate referrals, which will enable the care path to be continually improved over time.

IF CONSERVATIVE CARE COMES UP SHORT

Identifying the pain generator is important in guiding low back pain management, especially in cases that don't respond to conservative measures like first-line drugs or physical therapy. Isolating the pain generator is often an initial focus when patients require referral to a spine or pain specialist.

For such patients, Dr. Berenger may use diagnostic blocks (e.g., facet blocks, joint anesthetic injections, discograms or medial nerve branch blocks) to isolate the pain generator and guide interventional management. Once a pain generator is identified, some of these same blocks can be used therapeutically at the implicated disk or nerve, typically along with physical therapy. Patients often respond to such management and can be maintained on it or gradually weaned from it.

Those who do not gain adequate relief may be referred for further evaluation, including for spine surgery or enrollment in a clinical trial for interventions such as disk biacuplasty or minimally invasive neurostimulation (see sidebar).

TAKING TREATMENT BEYOND THE BACK

Dr. Berenger and colleagues also comprehensively evaluate for confounding conditions, such as fibromyalgia or rheumatologic disease, through blood tests, X-rays and consults. “Even when back pain can be attributed to structural problems, confounding conditions or psychosocial issues still need to be addressed for the patient to recover and regain function,” he says.

That’s when Cleveland Clinic’s collaborative approach — formalized under the Spine Care Path — can yield the greatest benefits. “We offer enterprisewide evaluation for challenging cases, drawing on the Center for Spine Health, the Department of Pain Management, our comprehensive Chronic Pain Rehabilitation Program, neurologists, behavioral health providers and others,” Dr. Berenger notes. “Patients can expect a better experience — and much less jumping between unconnected providers — with all these specialists with different skill sets cooperating to deliver an outcome that’s meaningful to them.”

Dr. Berenger can be reached at berengp@ccf.org or 440.695.4000.

NEUROSTIMULATION FOR LOW BACK PAIN: MINIMALLY INVASIVE APPROACHES EMERGING

In the most refractory cases of low back pain, Dr. Berenger and colleagues may refer patients for spinal cord stimulation, including two new minimally invasive modalities being offered at Cleveland Clinic:

- **A percutaneous delivery system for neurostimulation** as an alternative to lead placement by laminotomy/laminectomy
- **An epidural approach to dorsal root ganglion (DRG) stimulation** allowing precise stimulation of anatomic targets implicated in chronic pain

“Neurostimulation is a great modality for treating intractable leg pain, but it’s traditionally been difficult to use for axial low back pain,” says Department of Pain Management specialist Nagy Mekhail, MD, PhD.

For stimulation to reach the target nerves, it must penetrate the cerebrospinal fluid, which is thickest in the thoracic region. The energy delivered by neurostimulation often is insufficient to broach this barrier. Until recently, overcoming this obstacle meant placing multiple leads or implanting paddle leads through laminotomy/laminectomy surgery.

The percutaneous approach to neurostimulation (Epiducer™ Lead Introduction System, St. Jude Medical) allows introduction of multiple leads without interfering with the integrity of the spine by laminotomy or laminectomy and without the major incisions typically required to place more than one lead, says Dr. Mekhail. The single entry port accommodates up to three leads, which can be configured to tailor neurostimulation to a patient’s unique pain patterns.

The percutaneous lead delivery system is FDA-approved and has successfully relieved chronic low back pain in a handful of patients treated so far by the Department of Pain Management, says Dr. Mekhail. “Candidates are patients with intractable back pain (unresponsive to conventional spinal cord stimulation) not caused by correctable pathology or with epidural scarring,” he notes.

The other minimally invasive approach, DRG stimulation, preferentially targets the primary sensory neurons responsible for chronic pain in the lower extremities, including low back pain. It is currently available in the U.S. only via clinical trials. Cleveland Clinic is participating in a multicenter trial of DRG stimulation in patients with chronic intractable leg pain secondary to complex regional pain syndrome or peripheral causalgia.

In DRG stimulation, which was profiled in last year’s *Pain Consult* (see p. 14 at clevelandclinic.org/painconsult2013), electrodes with contacts are threaded via the epidural space through the intervertebral foramen to the dorsal root ganglia. The electrical fields generated selectively stimulate different areas of the ganglia.

Dr. Mekhail can be reached at mekhain@ccf.org or 216.445.8329.

Microglial Inflammation: A Promising Target in Neuropathic Pain Figures in Memory Deficiency Too

Cleveland Clinic researchers pursue a potentially treatable common pathway.

Promising research by Cleveland Clinic investigators demonstrates that microglial inflammation is a common pathway — and a potentially treatable one — for neuropathic pain and other treatment-resistant neuroinflammatory conditions, including Alzheimer disease (AD).

“Microglial inflammation is a mechanism of many CNS disorders — neuropathic pain, AD, multiple sclerosis, parkinsonism, you name it,” says lead researcher Mohamed Naguib, MD, of Cleveland Clinic’s Anesthesiology Institute, which includes the Department of Pain Management.

His team has synthesized a molecule called MDA7, a cannabinoid type 2 (CB2) receptor-selective agonist, to inhibit microglial inflammation in hopes of effectively treating neuropathic pain and other conditions. “MDA7 prevents microglial activation and recruitment, which represent the elemental pathway of microglial inflammation,” explains Dr. Naguib.

EFFICACY IN A RODENT MODEL OF CHEMO-INDUCED NEUROPATHIC PAIN

The researchers demonstrated as much in a 2012 paper in *Anesthesia and Analgesia* (2012;114[5]:1104-1120) reporting findings from a rodent model of paclitaxel-induced neuropathy, which is associated with activation of microglia followed by the activation and proliferation of astrocytes and the expression and release of pro-inflammatory cytokines. They found that MDA7 prevented paclitaxel-induced allodynia in rats and mice in a dose- and time-sensitive fashion without compromising paclitaxel’s anticancer

effects. MDA7’s anti-allodynia effect was absent in CB2^{-/-} mice and was countered by CB2 antagonists, which suggests it directly involves CB2 receptor activation.

Because all neuropathic pain shares the mechanism of microglial inflammation, Dr. Naguib expects the same effect in neuropathic pain types outside the chemotherapy setting. “We started with chemotherapy-induced neuropathy because it’s an area of unmet therapeutic need,” he says.

SIMILAR EFFICACY IN CRPS

His team recently finished a study using a vascular occlusion model in the rat to replicate another form of chronic pain with a microglial inflammation mechanism, complex regional pain syndrome (CRPS). MDA7 was again highly effective, both at the molecular level and in terms of phenotypic response. They expect to submit the CRPS study for publication this year.

PROMISE FOR ALZHEIMER DISEASE

The wider biomedical community learned of the team’s work via an exciting study in February’s *Nature Neuroscience* (2014; 17[2]:223-231) linking microglia-mediated inflammatory changes in a postsynaptic protein, neuroligin 1, to amyloid-associated memory deficiency in rodents.

Current models of AD hold that amyloid plaques accumulate in the brain, overwhelming the microglia that serve as the nervous system’s main form of active immune defense. When the microglia cannot clear out amyloid rapidly enough, they become inflamed, which leads to gene modifications in the brain.

“As our research into microglial inflammation advanced, it became clear how important this inflammation is to a variety of disease processes, which led down the Alzheimer path,” says Dr. Naguib.

His team’s *Nature Neuroscience* study showed that the microglial inflammation-induced gene changes in the brain include suppressed expression of the neuroligin 1 protein — and that this suppression leads to hippocampal glutamatergic dysfunction and memory deficiency in rodents. The effects were ameliorated by inhibiting microglial activation. “These findings link neuroinflammation, synaptic efficacy and memory, thus providing insight into the pathogenesis of amyloid-associated diseases,” the researchers concluded.

Dr. Naguib notes that much research remains, but the findings suggest that MDA7 represents a promising new therapeutic approach to AD and other conditions involving microglia-mediated neuroinflammation, such as multiple sclerosis and Parkinson disease.

NEXT STEPS

In the near term, the researchers are focused on gaining funding to move MDA7 into phase 1 human studies for chemotherapy-induced neuropathy, which they hope to begin by 2015. Studies of MDA7 in animal models of AD will take longer, due to the longitudinal nature of AD, but Dr. Naguib says the team is committed to pursuing that research as well.

Dr. Naguib can be contacted at naguibm@ccf.org or 216.444.6328.

Pain Management Trials Now Enrolling Patients

Cleveland Clinic's Department of Pain Management is enrolling patients in a range of clinical studies, including those below. To explore referring a patient, see the contact listing for each study. For more trial listings, visit clevelandclinic.org/paintrials.

SELECTED CLINICAL TRIALS IN THE DEPARTMENT OF PAIN MANAGEMENT				
Study name	Site PI and contact	Description/objective	Patient population/key inclusion criteria	Sponsor
A Prospective, Randomized, Multicenter, Open-Label Clinical Trial Comparing Disc Biacuplasty with Medical Management for Discogenic Lumbar Back Pain	<ul style="list-style-type: none"> PI: Nagy Mekhail, MD, PhD Contact: Hani Yousef, MD, 216.444.8013 	Randomized phase 4 trial evaluating safety and efficacy of the TransDiscal System (TDS) in treating discogenic pain of the lumbar spine using a modified disc biacuplasty procedure. Control group will receive medical management (standard of care). Primary efficacy measure is VAS score at 6 months post-treatment.	Patients 21 or older with history of chronic low back pain unresponsive to nonoperative care, VAS score \geq 5 relating specifically to average daily low back pain, and back pain that is more prominent than leg pain and exacerbated by flexion, bending or prolonged sitting	Kimberly-Clark Corp.
A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency Ablation Techniques of Thoracic Facets' Medial Branches to Manage Thoracic Pain	<ul style="list-style-type: none"> PI: Nagy Mekhail, MD, PhD (national PI) Contact: Madonna Michael, MD, 216.445.8270 	Randomized, double-blind trial comparing standard thermal radiofrequency ablation (RFA) with cooled RFA for chronic thoracic back pain. Primary outcome measure is VAS pain score at 6 months.	Patients 18 or older with chronic thoracic spine-mediated back pain \geq 3 months in duration not responsive to oral medication and physical therapy	Cleveland Clinic (with Kimberly-Clark Corp. as collaborator)
Treatment of Knee Pain with Topical Diclofenac Cream 8% or Diclofenac Gel 1%	<ul style="list-style-type: none"> PI: Daniel Leizman, MD (national PI) Contact: Madonna Michael, MD, 216.445.8270 	Randomized, double-blind trial to evaluate whether diclofenac 8% cream is more efficacious than diclofenac 1% gel without an increase in systemic toxicity	Patients 18 or older with acute or chronic knee pain or with postoperative knee pain lasting more than 2 months	FPR Specialty Pharmacy
Effect of the Temperature Used in Thermal Radiofrequency Ablation on Outcomes of Lumbar Facet Medial Branch Denervation Procedures: A Randomized Double-Blind Trial	<ul style="list-style-type: none"> PI: Nagy Mekhail, MD, PhD Contact: Hani Yousef, MD, 216.444.8013 	Randomized, double-blind study in patients undergoing thermal radiofrequency ablation of three or four lumbar facet medial branches on one side only. Will assess effect of the temperature used (80°C vs. 90°C) in terms of pain relief and potential complications over 1 year.	Patients 18 or older with predominantly axial low back pain \geq 3 months in duration with no radicular pain below the knee. Enrollees will have chronic back pain attributed to lumbar facet joint arthropathy based on clinical evaluation, with no previous back surgery at the planned treatment levels.	Cleveland Clinic Department of Pain Management
Bioness® StimRouter™ Neuromodulation System for Chronic Pain Therapy	<ul style="list-style-type: none"> PI: Nagy Mekhail, MD, PhD Contact: Hani Yousef, MD, 216.444.8013 	Randomized, double-blind, partial-crossover study investigating whether the StimRouter neuromodulation system leads to clinically important pain relief after 3 months of treatment, and what side effects may be associated with the therapy	Patients 22 or older with severe intractable chronic pain of peripheral nerve origin associated with post-traumatic/postsurgical neuralgia for 3 months or more	Bioness Inc.
Functional Capacity Evaluation of Patients Undergoing Lumbar Spinal Cord Stimulation Therapy	<ul style="list-style-type: none"> PI: Daniel Leizman, MD Contact: Hani Yousef, MD, 216.444.8013 	Nonblinded, nonrandomized study comparing the newly developed functional capacity score at baseline to subjective measures of improvement obtained by typical patient questionnaires and analysis of morphine-equivalent daily opiate medication use following lumbar spinal cord stimulation	Patients 18 or older with a diagnosis of chronic back pain with radicular lower limb pain extension and successful completion of a spinal cord stimulator trial	Medtronic

VAS = visual analog scale

The Department of Pain Management

WHO WE ARE

25 Physicians with board certification in pain medicine

98 Employees

06 Research staff (physicians + PhD researchers)

WHO WE TREAT – AND HOW

(2013 NUMBERS)

 **75,869** Patient visits
55,086 Outpatient visits | 20,783 Inpatient visits

 **22** International patients

 **41,454** Procedures

 **11,342** Imaging studies sent to Cleveland Clinic Imaging Institute


OUR OTHER MISSIONS

 **9** Active research projects with grant or private funding

 **\$1.74M** External funding for active research projects (2013)
\$1.4M Grant/private research funding
\$340,000 Department of Defense research funding

 **30-40** Residents per year

 **10** Fellows per year

 **320** Attendees at our 16th Annual Pain Management Symposium, February 2014

WHAT ELSE WE'VE BEEN UP TO (2013-2014)

- Developed/contributed to six condition-specific Cleveland Clinic care paths to operationalize evidence-based chronic pain care
- Established a Pelvic Pain Center
- Launched a Chronic Abdominal Pain Clinic
- Completed site remodeling/expansion of our offices at Cleveland Clinic's Fairview and South Pointe medical office buildings

Department of Pain Management Staff

Our specialists are available at multiple locations across Northeast Ohio.



Richard W. Rosenquist, MD

Department Chair

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Specialties: Abdominal pain, back pain, complex regional pain syndrome, spinal cord stimulation, peripheral nerve stimulation, head and neck pain

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South Pointe Hospital, Euclid Hospital

Specialties: Osteopathic manipulation therapy, acupuncture, anti-inflammatory diet, cranial sacral therapy, headache, back pain

New Staff

The Department of Pain Management welcomes a new specialist:



Robert Bolash, MD

Specialty interests:

Back pain, neck pain, degenerative joint disease, cancer pain, pain management

Location:

Cleveland Clinic main campus
216.444.3134
bolashr@ccf.org

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Coming Soon: *Fundamentals of Pain Management*

September 2014 is the publication date for *Fundamentals of Pain Management* (Springer), a pain medicine textbook edited by Cleveland Clinic pain medicine specialists Richard W. Rosenquist, MD, and Jianguo Cheng, MD, PhD.

They've directed their international team of expert authors to explore the essentials of pain medicine in 36 chapters developed for physicians of diverse backgrounds. "Our objectives have been accuracy, simplicity and reader-friendliness to allow quick grasping of the key principles and skills of pain management for specialists and nonspecialists alike," says Dr. Cheng.

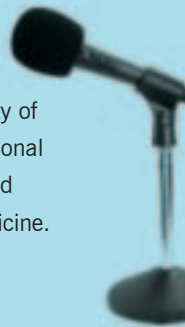
Look for the title soon (in print and electronic versions) at springer.com.

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In 2014, Cleveland Clinic was ranked one of America's top 4 hospitals in *U.S. News & World Report's* "Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 13 specialty areas, and the top in heart care (for the 20th straight year) and urologic care.



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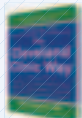
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The Cleveland Clinic Way

By Toby Cosgrove, MD
CEO and President, Cleveland Clinic

Great things happen when a medical center puts patients first. Visit clevelandclinic.org/ClevelandClinicWay for details or to order a copy.