

PROMISING ALTERNATIVE TO OPIOIDS

By Antonia F. Chen, MD, MBA, Rothman Institute and David A. Lindley, DO,
Interventional Pain Management of Texas

Nearly 50 million Americans live with severe or chronic pain, and more than half (25.3 million) suffer from chronic pain, according to data compiled from a 2012 National Health Interview Survey conducted by the National Institutes of Health.¹ Pain management places a tremendous economic burden on the U.S. healthcare system, costing an estimated \$261 to \$300 billion (2010 USD) annually² and **is the leading cause of long-term disability.**^{1,3}

Chronic pain greatly reduces patient quality of life and can engender or worsen a variety of new and preexisting conditions associated with poor outcomes, such as depression, hypertension, diabetes, and cancer.³ The subjective nature of pain makes it difficult to completely control, and narcotic treatment options have led to the opioid crisis, which has prompted healthcare professionals and researchers to find alternate treatment options.³ For many chronic pain patients refractory to standard non-operative treatments, surgery may seem like the only possible solution.

CONVENTIONAL PHARMACOLOGICAL THERAPIES MAY COME WITH RISKS

While physical therapy can help relieve bothersome symptoms, conventional pain management therapy often concentrates on pharmacological treatment.⁴ While pharmacological options can provide some relief and may be appropriate for some patients, their use does not come without risks.⁵ Hepatotoxic risks of acetaminophen have been well established, and other non-steroidal anti-inflammatory drugs (NSAIDs) can cause gastrointestinal bleeding and promote or worsen gastrointestinal complications, such as ulcers

Some patients with chronic hip and knee pain who see me in clinic have already undergone pain management by a primary care physician or nonoperative physicians, and they're basically told that, after medication and injections, surgery is their only option—even when they may not want surgery,"
— Antonia Chen, MD, MBA, an orthopedic surgeon at the Rothman Institute of Orthopaedics

and gastroesophageal reflux. Prolonged NSAID use can also negate the effects of commonly prescribed blood pressure medications, such as angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers.

The partial opioid agonist tramadol remains widely used in pain management⁵, but its numerous drug interactions can further complicate an already complex medication regimen in older patients and other patients who may be at risk for some of the potentially harmful consequences of high pill burdens and polypharmacy.⁶ Tramadol also inhibits norepinephrine reuptake, which may produce undesirable effects in patients whose sympathetic nervous systems exhibit upregulated activity. Also, its serotonergic activity warrants some caution in patients who are taking selective serotonin reuptake inhibitors (SSRIs) and selective serotonin and norepinephrine reuptake inhibitors (SNRIs).

Additional pharmacological options in pain management may also present challenges for some patients:

- SSRIs and SNRIs used in pain management (particularly in neuropathic pain management) can have multiple drug interactions and can cause weight gain and diarrhea along with side effects reminiscent of adrenergic regulation (i.e., dry mouth and hyperstimulation).^{7,8,9}
- Select neuroleptic agents used in seizures, such as gabapentin, often produce sedative effects and can cause nausea, vomiting, diarrhea, or visual disturbances.¹⁰
- Intra-articular injections of corticosteroids and local anesthetics increase the risk for infections and are not options for patients with prostheses. Use of these injections can also accelerate cartilage degeneration. Therapeutic effects can be highly variable and short lived.

While some pain management physicians have begun using pharmacogenetic testing to individualize therapy, these services often remain cost prohibitive, as insurance companies are only now slowly beginning to come aboard.¹¹ However, the opioid epidemic has likely contributed to some of the recent buy-ins, as addiction, overuse and abuse have gained worldwide attention as a major health crisis. In fact, opioids and their side effects present the greatest pharmacological challenges. Ninety-one people die each day from opioid overdose, and it has claimed more than 500,000 lives between 2000 and 2015, according to the Centers for Disease Control and Prevention.¹² Opioid-related deaths have more than quadrupled since 1999, account for more than half of all overdose deaths and have claimed more than 500,000 lives between 2000 and 2015.

ALTERNATIVE PROCEDURE OFFERS ANOTHER OPTION AND CAN LIMIT USE

Thankfully, alternatives to opioids exist, and clinicians have lesser-known options such as cooled radiofrequency (RF) to manage pain. For David Lindley, DO, a pain management specialist at the Interventional Pain Management of Texas, the best way to evaluate the cooled RF procedure was to incorporate it into his own practice.

"I had a practice where I was using COOLIEF* Cooled RF for half of the week, and a traditional radiofrequency

procedure the other half of the week, and I saw a tremendous benefit in the COOLIEF* patient population," he says.

Lindley treats patients with lumbosacral abnormalities—a condition that accounts for 40% of all cases involving lower back pain cases.¹³ Studies indicate 70% of patients experience relief and Lindley says that he has seen at least that level of success in his own practice.

There was a higher percentage of patients achieving 50% or more relief with COOLIEF* Cooled Radiofrequency than traditional radiofrequency, and that's ultimately why I went with the COOLIEF* procedure 100% about two or three years ago.

—David Lindsey, DO

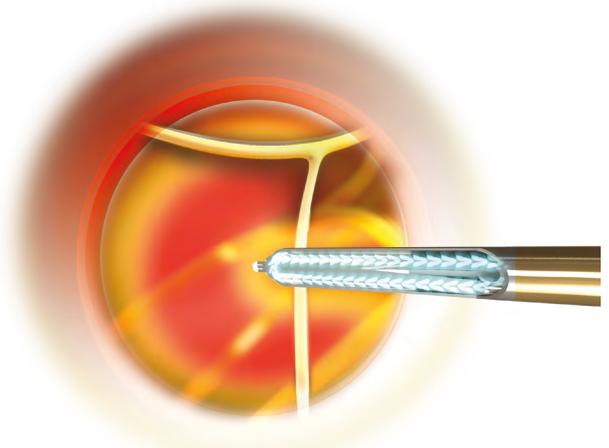
WHAT SETS COOLED RADIOFREQUENCY ABLATION APART FROM CONVENTIONAL RADIOFREQUENCY?

Radiofrequency procedures use an electrode-containing probe to deliver and concentrate energy into the affected area to promote analgesia.¹³ Because traditional RF technologies have no cooling mechanism, it produces small lesions of a rigid shape, and the surrounding tissue chars. These features require the probe's needle to be placed at a specific angle with a level of precision that leaves very little room for correction, variance or error. This stipulation makes analgesia much more difficult to achieve, because therapeutic success is limited to chance and clinical precision.

COOLIEF* Cooled RF employs the technology of cooled radiofrequency ablation—a procedure in which clinicians administer COOLIEF* Cooled RF, the only currently known thermal radiofrequency system using water-cooled technology to deactivate pain-causing sensory nerves.¹³ For example, when treating sacroiliac (SI) joint pain, the clinician will use the probe to create lesions lateral to the sacral foramina. An electrode housed within the hollow lumina of the probe creates a cooling effect, as circulating water removes heat from the probe. This forms a "heat sink" through which heat is removed from surrounding tissue lying near the probe.

This unique feature has the advantage of reducing charring to surrounding tissue and also allows more heat to dissipate to surrounding tissue than traditional probes by maintaining the integrity of the tissue. A larger lesion size from the probe increases the probability of disrupting nerve branches—the mechanism that ultimately produces analgesia.

For Lindley, these features improve the ease and outcomes of his practice.



When I was doing the traditional RF procedure, I would have to adjust the needle because it would have a radicular twitch,” Lindley explains. “With the COOLIEF* procedure, I still test the needle, but I’ve never had to adjust it because I personally never get a radicular twitch. The angle independence feature and spherical lesions save interoperative time.

—David Lindsey, DO

LITERATURE AND CLINICIANS REPORT 50- 90% PAIN RELIEF IN PATIENTS FOR UP TO 2 YEARS

Several recent studies provide evidence that the COOLIEF* procedure offers an effective alternative to analgesia.¹³ According to a study published in 2013, 75% (n = 15) of patients (n = 20) who had sacroiliac pain experienced a statistically significant decrease in lower back pain, noted by a decrease of 3 or more points on the Numeric Rating Scale (NRS). Investigators also noted an improvement in the mean Patient Global Impression of Change and a positive Global Perceived Effect in 80% of patients two years post-procedure—an indication that the COOLIEF* procedure provides a viable option for long-term management of chronic sacroiliac joint pain for up to 2 years.

“I tell my patients to expect between six to 18 months of 50% or more of relief, and my patients usually fall in the later range of that,” Lindsey says.

Cooled RF studies have also shown promise for patients with osteoarthritis (OA) of the knee.¹⁴ A large study that randomized 151 patients with OA of the knee to receive cooled RF (n = 76) and the intra-articular steroids (n = 75). 12 months following treatment, the cooled RF group experienced a mean decrease in NRS of 4.3 points from baseline and 65% of patients reported pain decrease of greater than or equal to 50%. Function improvement was also noted with a 17.3 point change in Oxford Knee Study scores, which was significantly better than their baseline (P <0.0001).

According to a study done in SI joints, cooled RF ablation produces a lesion ranging from 8 to 10 mm in diameter using a 4 mm active tip, whereas unipolar RF and bipolar RF procedures create lesions measuring up to 2 mm and 6 mm, respectively. COOLIEF* allows for dissipation of heat to a larger surface area than traditional electrodes without charring the surrounding tissues as occurs in the conventional uncooled procedure. Cooled radiofrequency ablation has a greater opportunity for benefit because it denervates a larger region of tissue lateral to the posterior sacral laminae, increasing the probability that disruption of the lateral sacral branch will occur.

MAJOR BENEFITS OF COOLIEF* PROCEDURE

- ✓ **Minimally invasive procedure**
- ✓ **Favorable side effect profile**
- ✓ **Quick and easy procedure training**
- ✓ **Easy-to-perform procedure**
- ✓ **Potential long-term pain relief**

THE POTENTIAL OUTCOME HAS SIGNIFICANT MEANING FOR PATIENTS

“Patients always want to go through the spectrum of treatment, where they try ancillary services, such as physical therapy, and medications such as NSAIDs, corticosteroid injections, and opioids. Once patients run out of these options, they have been turning to other options with limited data, such as stem cell and platelet rich plasma injections,” Chen points out. “On the other hand, COOLIEF* has the data to support its use for treating chronic pain conditions, such as knee osteoarthritis, and it’s often covered by insurance.”



RISKS, SIDE EFFECTS, AND CONTRAINDICATIONS

The COOLIEF* procedure has a relatively limited side effect profile. Patients may experience irritation at the site of probe insertion or experience postoperative tenderness that persists a few days to a week following the procedure.

As with any procedure, COOLIEF* has some precautions. For example, there is no guarantee of therapeutic success. “One risk of any procedure is that the patient may not experience pain relief,” Chen says.

Another potential side complication is hematoma formation, because the probe could potentially puncture a blood vessel and result in bleeding. She says this risk is mostly theoretical in nature, and that it rarely happens.

Although COOLIEF* is a suitable option for many chronic pain patients, there are some populations for whom the procedure is not appropriate. For example, patients who have soft tissue that prevents the deepest needles from reaching their target point are not candidates for COOLIEF*. According to Chen, this issue more strongly correlates to the depth of soft tissue rather than body mass index. Patients for whom COOLIEF* is contraindicated include obese patients and patients with implantable devices, as the electrode generates a current that may disrupt the current of the patient’s implant.

PROCEDURE IS EASY TO LEARN, EASY TO REPLICATE IN PRACTICE

Clinicians seeking training to provide the COOLIEF* procedure have a variety of options from which to choose. Many interventional pain management fellowships with experience in spine and joints often include cooled radiofrequency training. Shadowing clinicians trained in the COOLIEF* procedure and taking cadaver workshops offered by Avanos Medical provide additional options for practitioners who have not completed fellowships or whose fellowship program did not include cooled RF training. “The training for performing cooled RF is simpler and more straightforward than I expected it would be,” Chen said. “I recently underwent training to do a COOLIEF* of the knee. It was a 15-minute tutorial on anatomy with fluoroscopy on the C-arm, catheter placement, and turning on the electrodes.”

PROCEDURE SATISFIES PATIENTS, PHYSICIANS ALIKE, DECREASES NEEDS FOR OPIOIDS AND OVERALL PILL BURDEN

The analgesia experienced with nonpharmacological therapy can reduce the need for pain medications, including opioids. In addition to long-term benefits, Chen and Lindley say their patients who have had the COOLIEF* procedure can use fewer opioid and nonopioid pain medications. “Opioid use has definitely decreased,” Chen says. “I have anecdotally noticed that patients who were prescribed opioids from outside providers are using fewer opioids after these procedures.”

Lindley also does not prescribe opioids but echoes the sentiments, noting that he now prescribes fewer non-opioid regimens, and his patients report a need for fewer opioids from their primary care physicians. Both physicians say that in addition to enjoying the analgesic benefit that often rivals and surpasses the traditional procedure and corticosteroid injection, patients appreciate the fact that COOLIEF* provides another alternative to more invasive surgery.



“Another big benefit I see in the COOLIEF* procedure is that I can offer another option to my patients for pain relief for their arthritis symptoms that other modalities may not allow,” Chen says. “In this age of medicine, options are everything. The more options you give your patients, the happier they are.”

“The important thing with the COOLIEF* is that it’s got the lesion size, the shape, and the angle independence [that produce better analgesic responses than the traditional RFA procedures],” Lindley says.

Although more studies are needed, clinical data indicates cooled RF clearly offers physicians a viable alternative to more invasive procedures and can help fight the opioid addiction epidemic.

Antonia F. Chen, MD and David Lindley, DO have consulting/speaking/financial relationships with Avanos Medical, Inc.

To find a COOLIEF* representative in your area, please visit avanospainmanagement.com

There are inherent risks in all medical devices. For more detail on indications, cautions, warnings and contraindications, [click here](#).

1. NIH Study Shows Prevalence of Chronic or Severe Pain in U.S. Adults. American Pain Society Press Release. <http://americanpainsociety.org/about-us/press-room/ni-h-study-shows-prevalence-of-chronic-or-severe-pain-in-u-s-adults>.
2. Gaskin G, Richard P. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research: Appendix C: The Economic Costs of Pain in the United States. <https://www.ncbi.nlm.nih.gov/books/NBK92521/>
3. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research: Introduction. Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington (DC): National Academies Press (US); 2011. <https://www.ncbi.nlm.nih.gov/books/NBK92525/#ch1.s7>.
4. Treatment options for pain. The American Society of Regional Anesthesia and Pain Medicine. <https://www.asra.com/page/46/treatment-options-for-chronicpain>.
5. Park, HJ, Moon, DE. Pharmacologic Management of Chronic Pain. Korean J Pain. 2010 Jun; 23(2): 99-108. Published online 2010 May 31. doi: 0.3344/kjp.2010.23.2.99 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2886242/>.
6. Coggins, M. Today’s Geriatric Medicine. 8(4):6. Tramadol Safety Concerns. <http://www.todaygeriatricmedicine.com/archive/0715p6.shtml>
7. Serotonin and Norepinephrine Reuptake Inhibitors. The Mayo Clinic website. Available at: <https://www.mayoclinic.org/diseases-conditions/depression/indepth/antidepressants/art-20044970?pg=2>. June 21, 2016. Accessed on January 1, 2018.
8. Selective Serotonin Reuptake Inhibitors. The Mayo Clinic website. Available at: <https://www.mayoclinic.org/diseases-conditions/depression/in-depth/ssris/art-20044825?pg=1>. Last updated June 24, 2016. Accessed on January 1, 2018.
9. Fat Pharms: Antidepressants and Weight Gain. The WebMD website. Available at: <https://www.webmd.com/depression/features/antidepressants-weight-gain#1>. Last updated on June 28, 2011. Accessed on January 1, 2018.
10. Gabapentin (oral route). The Mayo Clinic website. Available at: <https://www.mayoclinic.org/drugs-supplements/gabapentin-oral-route/side-effects/drug-20064011>. Last updated March 1, 2017. January 1, 2018.
11. Ting S, Schug S. The pharmacogenomics of pain management” prospects for personalized medicine. J Pain Res. 2016; 9: 49-56. Published online 2016 Feb 10. doi: 10.2147/JPR.S55595PMCID: PMC4755469 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4755469/>
12. Drug overdose deaths in the United States continue to increase in 2015. <https://www.cdc.gov/drugoverdose/epidemic/index.html>
13. Ho KY, Hadi MA, Pasutharnchat K, Tan KH. Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases. Journal of Pain Research. 2013;6:505-511.
14. Buvanendran A, et.al. 12- Month follow-up of a prospective, multi-center, randomized, trial comparing safety and effectiveness of cooled radiofrequency ablation to corticosteroids injection for management of osteoarthritic knee pain. Free Paper Session 06: Chronic Pain Management. esra7-0369