New Technique for Hip and Knee Pain Relief p 3
Dear Colleagues,

Welcome to the 2017 edition of Pain Consult. In this issue, we highlight the excellent results we have seen with radiofrequency ablation as a minimally invasive method for treating hip and knee pain (p. 3), and we share details about interventions that are having a profound impact on reducing cancer pain for patients (p. 6). We also take a closer look at the adverse impact of long-term opioid use on hormones (p. 9).

This brings me to the topic on all of our minds today — the ongoing opioid crisis. We are faced with alarming statistics:

• Nearly 2 million Americans are addicted to prescription opioids.
• 3 out of 4 new heroin users start with prescription drugs.
• In 2016, there were 64,000 deaths in the U.S. from opioid overdose and nearly as many are expected in 2017 (according to the Trump Administration).

Without significant changes, there could be 90,000 deaths a year in the future (according to a STAT forecast article, June 27, 2017). To face this issue head-on, Cleveland Clinic has changed its prescribing practices in accordance with Ohio regulators and the Centers for Disease Control and Prevention, and we are doing a more thorough risk assessment of patients’ addiction histories. Our patients sign an opioid agreement if they will be taking opioids on a chronic basis, and we monitor them using urine drug screening.

We have also expanded our emphasis on health and wellness as part of the recovery process. This must be a key part of chronic pain treatment if we are to move away from opioid usage. In this issue, see our wellness feature on p. 12 for more details. For more on the opioid crisis, see my Q&A on p. 14.

As healthcare delivery evolves, our Pain Management team is pleased to have seven of our physicians web-enabled to provide virtual visits to patients via Cleveland Clinic Express Care® Online. We offer this service for post-procedure patients and for patients experiencing mild back or neck pain who need an appointment, with plans to expand access.

I encourage you to visit our Consult QD physician website, where we post pain management stories on the latest news and innovations. There are two topics I’d like to highlight — the first is an article about our reintroduction of the mild® procedure for lumbar spinal stenosis, and the second is on new shared medical appointments for fibromyalgia patients. To read these articles and more, go to consultqd.org/painmanagement.

Finally, I invite you to attend our 20th Annual Pain Management Symposium in Florida in February. (For details, go to ccfcmne.org/2018Pain.) I hope you find this issue informative and urge you to contact me and my colleagues with your feedback and thoughts.

Richard W. Rosenquist, MD
Chairman, Department of Pain Management
rosenqr@ccf.org | 216.445.8388
When it comes to managing hip and knee pain, surgery is not always the answer. Conditions such as morbid obesity, diabetes and severe heart disease may make patients less than ideal candidates for joint replacement surgery. Patients in their 40s or 50s may be considered too young for a joint replacement, since joint replacements only last a limited amount of time. In addition, some patients may continue to suffer from joint pain even after having a hip or knee replacement.

Experts from Cleveland Clinic’s Department of Pain Management offer radiofrequency ablation (RFA) as a minimally invasive method of hip and knee pain management.

“For many patients considering a joint replacement, pain is their main motivation for treatment rather than joint instability,” explains pain management specialist Jianguo Cheng, MD, PhD. “With RFA, we can still reduce pain and improve functionality, but without the increased risk of complications associated with surgery.”

**SPECIFIC NERVE ABLATION**

RFA is a neurolytic technique that uses heat to produce controlled tissue destruction through a process called thermocoagulation. With a radiofrequency of 350,000 to 500,000 Hz, the hot needle tip coagulates the nerve proteins, stopping them from functioning. This targeted nerve destruction interferes with the conduction and transmission of pain signals from the joint to the brain. In patients with hip pain, RFA targets the articular branches of the femoral and obturator nerves. For patients with knee problems, RFA targets the genicular nerves. Although complications from RFA are very rare, they may include nerve and vessel puncture, bleeding and infection.

**IMPROVED RFA TOOLS AND TECHNIQUES**

While RFA has been used to treat back pain since 1975, the past 10 years have brought the most significant improvements in radiofrequency instrumentation and nerve targeting techniques. According to Dr. Cheng, “The goal of the physician is to place
the needle as close to the targeted nerve as possible, which helps maximize the therapeutic effects while minimizing the ablation of nearby body structures.”

Dr. Cheng’s team recently completed a research project designed to optimize the RFA technique to reduce procedural pain in the knee. “Because the knee is very sensitive to pain and patients are not anesthetized during RFA, it has been reported in literature and observed in our clinic that some patients experience extreme pain during the procedure,” explains Dr. Cheng. “We reduced procedural pain by minimizing the needle penetration distance from the skin to the target nerves and reducing irritation to the periosteum.” This was achieved by collecting magnetic resonance imaging (MRI) data of the knee from various patients and determining the best angle of needle placement.

The past 10 years have brought the most significant improvement in radiofrequency instrumentation and nerve targeting techniques.

The hips present some unique challenges related to nerve targeting. Especially in obese patients, excess abdominal fat may make it harder to place the needle in the groin area without puncturing a femoral nerve/artery or penetrating the abdo-

RFA works best in patients with isolated joint pain without multiple pain complaints.

Why might pain relief last longer for some patients? According to Dr. Cheng, “there may be different rates of regrowth and regeneration in the nerves. Even with advanced imaging technology, the small size of these nerves makes it very difficult to study and measure the growth rates of nerves.”

IDENTIFYING THE BEST CANDIDATES

RFA works best in patients with isolated joint pain without multiple pain complaints. This pain could be caused by a variety of environmental and genetic factors that have strained their joints. “Patients with severe fibromyalgia or other causes of all-over body pain are not good candidates for RFA,” explains Dr. Cheng. “Unfortunately, treating the hip or knee isn’t going to impact their problems with other connective tissues, which may continue to cause chronic pain.”

RESULTS OF RFA TREATMENT

As with most medical treatments, individual responses to RFA treatment will vary. Patients with isolated knee or hip pain have reported satisfactory pain relief for three months to two years. Over time, the joint pain is likely to return once the lesioned nerves regrow. However, RFA has been shown to be safe to administer repeatedly in patients, with consistent pain reduction results.

Dr. Cheng is a staff physician with the Department of Pain Management. He can be reached at chengj@ccf.org.
Dr. Cheng’s probe placement targets the medial superior genicular nerve, the lateral superior genicular nerve and the medial interior genicular nerve in the knee joint.
Improving Quality of Life for Cancer Patients Through Targeted Drug Delivery

Over time, chemotherapy and radiation therapy can lead to severe neuropathic pain for cancer patients. Other sources of cancer pain come from bone metastases and nerve and spinal cord compression, as well as pressure on the organs. Cleveland Clinic Pain Management specialists work in collaboration with oncology physicians and palliative care specialists to help cancer patients control pain when other remedies fail.

“Sometimes the pain becomes unbearable for patients, and medications cannot provide very good pain control,” says Shrif Costandi, MD, of Cleveland Clinic’s Department of Pain Management. “This is when we can help, by pinpointing the patient’s source of pain and providing targeted drug delivery to improve pain control.”

Dr. Costandi relays a recent patient success story. In August 2016, a 60-year-old lung cancer patient’s excruciating pain was abated with the implant of a special pump to deliver medication in his spine. The patient’s cancer had metastasized to his bones and brain, and he had been on several opioid medications for a few years. Dr. Costandi noted that between the poor pain control and the disabling side effects of his escalating

The pump is about the size of a small fist.

Here, an intrathecal pump is being removed and a new one is being placed in a patient’s abdomen, the catheter is located in the lower part of the spine.
opioids, the patient reported that he no longer wanted to live. The intrathecal pump was implanted to deliver local anesthetics and opioids with variable concentrations, at a much smaller dose than when they are taken by other routes.

“The patient was happy to find out that there were other viable and more effective therapeutic options,” says Dr. Costandi. “It was a remarkable improvement for this patient, showing how effective the intrathecal pump can be for long-term cancer patients.”

The pump relieves pain and improves function without the often debilitating side effects of opioids.

“In the setting of malignancy, these therapies give us hope.”
- Shrif Costandi, MD

may benefit from an alternate therapy as well as those 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.

“This and other interventional therapies can greatly improve a cancer patient’s quality of life and help them to wean off of opioids, especially if they are experiencing severe side effects,” he says.

OSTEOCOOL™ SURGICAL TECHNIQUE

In recent years, another therapy that is becoming more established as an alternative or additional technique to help relieve cancer pain uses the OsteoCool system, notes Dr. Costandi. This technique uses bipolar water-cooled radiofrequency ablation to treat spinal pain that is secondary to metastatic vertebral tumors. This outpatient procedure involves a probe being inserted at the vertebral level. It is best for patients who have one to three lesions that have been localized to the spine, are not candidates for radiation therapy and do not have a neurological deficit — or spinal cord compression.

“We have seen great outcomes with OsteoCool,” says Dr. Costandi. “It helps patients improve quality of life with minimal recovery time and lessens overall opioid use and its associated fatigue.”

The pump relieves pain and improves function without the often debilitating side effects of opioids, which over the long term can include severe constipation and feelings of drowsiness and dizziness. At this patient’s six-month follow-up appointment in early 2017 to check on his pump and medication dosage, the patient reported that his cancer pain was minimal and that his quality of life had greatly improved.

During a recent flare-up of this patient’s pain, Dr. Costandi says the patient still opted not to take additional oral opioid medication for the breakthrough pain. Instead, the patient requested that he receive the patient therapy manager option, which enables patients to self-administer pain medication through the intrathecal pump. This allowed the patient to increase, within limits, the amount of the drug he needed at specific moments of pain. It turned out to be a successful option for this patient.

Dr. Costandi says the intrathecal drug pump implant works well for patients who fail to respond to oral opioids and
DRG STIMULATION

Dorsal root ganglion (DRG) stimulation is a neuromodulation therapy, similar to traditional spinal cord stimulation (SCS), that is being applied more and more to relieve cancer pain. Rather than placing electrodes over the posterior aspect of the spinal cord as in SCS, leads are implanted on the dorsal root ganglion, a cluster of neurons in the posterior root of spinal nerves that modulate all bodily sensations. DRG stimulation offers a highly directed stimulation field, which can focus stimulation on the painful area. The Food and Drug Administration has approved DRG stimulation for lower-extremity complex regional pain syndrome, which could include neuropathic pain conditions and chronic pain following surgeries (like thoracotomy) commonly performed in cancer patients.

“Dr. Costandi is a staff physician with the Department of Pain Management. He can be reached at costans2@ccf.org.

Select Pain Management Trials Now Enrolling

Cleveland Clinic’s Department of Pain Management is enrolling patients in a range of ongoing clinical studies, including those listed here. For more trial listings, visit clevelandclinic.org/paintrials.

<table>
<thead>
<tr>
<th>Study Overview</th>
<th>Investigator and Contact</th>
<th>Key Inclusion Criteria</th>
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<tbody>
<tr>
<td>NEVRO</td>
<td>PI: Jijun Xu, MD, PhD</td>
<td>Patients with painful diabetic neuropathy of the lower limbs who remain symptomatic despite therapy with pregabalin and ≥1 other class of analgesic</td>
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<td></td>
<td>Contact: Meera Kumari, MD</td>
<td>Call: 216.445.0466</td>
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<td>EVOKE</td>
<td>PI: Shrif Costandi, MD</td>
<td>Patients with chronic pain of the trunk and limbs who have failed to respond to medical management</td>
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<td></td>
<td>Contact: Sarah Guirguis, MD</td>
<td>Call: 216.445.8270</td>
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<td>MESOBLAST</td>
<td>PI: Nagy Mekhail, MD, PhD</td>
<td>Adults experiencing chronic low back pain with degenerative disk disease of the lumbar spine who have failed three months of conservative therapy</td>
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<td>Contact: Kanhaiya Poddar, MD</td>
<td>Call: 216.445.5132</td>
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<td>THORACIC RFA</td>
<td>PI: Shrif Costandi, MD</td>
<td>Patients with chronic thoracic spine pain who have failed medical and physical therapy, but have had a favorable response to thoracic facet blocks</td>
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<tr>
<td></td>
<td>Contact: Diana Mehanny, MD</td>
<td>Call: 216.445.5132</td>
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Do you have patients with suspected hormone deficiencies? Are you concerned about the potential side effects of their pain medication regimen?

Modern medical practice doesn’t just use medicine to treat symptoms. Doctors are now more focused on analyzing the side effects that patients are experiencing and adjusting treatment plans accordingly. If needed, physicians can prescribe additional medications that are designed to treat unpleasant side effects, including hormone imbalances.

To maximize patient outcomes, doctors and patients should discuss the side effects of pain medication, especially opioids. “Experts from Cleveland Clinic’s Department of Pain Management are trained to help physicians from other areas, including general practice and endocrinology, select pain treatment strategies that minimize potential or actual hormonal imbalances,” explains pain management specialist Robert Bolash, MD. “Using comprehensive testing and unique treatments, our multidisciplinary approach to pain management helps bring patients back into balance, improving their overall quality of life.”

**Hormonal Effects of Chronic Pain**

In general, people with chronic pain tend to suffer hormone-related complications. For example, long-term pain creates elevated levels of cortisol, the primary stress hormone. Excess cortisol can lead to many complications, including osteoporosis, obesity, depression, headache, immune deficiencies and sleep issues. Osteoporosis, for example, may develop in patients with chronic pain whose elevated cortisol levels prevent calcium from being absorbed by their bony tissues. Osteoporosis often damages the bones in the spine, increasing pain and the risk of bone fracture. Since many vertebral compression fractures can’t be immobilized, patients may severely restrict their movement to reduce the pain. “Unfortunately, immobility promotes a continuous cycle of back pain that leads to additional bone loss and more susceptibility to fracture,” says Dr. Bolash.

**In general, people with chronic pain tend to suffer hormone-related complications.**

- Dr. Robert Bolash, MD

**Hormonal Effects of Long-Term Opioid Use**

Patients with chronic pain may be prescribed opioids to manage pain. The long-term use of these pain medicines may accelerate the hormone imbalances that chronic pain sufferers are already susceptible to. According to the *BMJ*, opioids affect the hormone levels of 21 to 86 percent of male and female patients. Consider the following hormonal impacts of opioid use:

**Growth hormone**: Opioids may decrease the level of growth hormone. Low growth hormone is associated with anhedonia and social isolation.

**Thyroid hormone**: Patients who take opioids may experience thyroid problems after several years of treatment. In one study, thyroid hormone suppression wasn’t diagnosed until after five years of intrathecal opioid treatment.

**Sex hormones**: In women, opioids may decrease levels of luteinizing hormone, estradiol and progesterone. As these levels decrease, libido also diminishes. In men, opioids may decrease their testosterone, which lowers their libido and inhibits their ability to develop an erection and ejaculate. Severe testosterone loss has caused some men to develop breast tissue or other changes in body shape.
IMPORTANCE OF DISCUSSING SIDE EFFECTS

Patients may be reluctant to share information regarding their sex life or mood. And physicians may be hesitant to bring up these topics with patients. “Understanding sexual side effects and mood-related symptoms is key to uncovering hormone issues related to chronic opioid use,” notes Dr. Bolash. “That’s why it’s so important for physicians to take the lead in asking about these potentially taboo topics to get patients the help they really need.”

HORMONE TESTING AND COMPREHENSIVE PAIN RELIEF

Cleveland Clinic utilizes sophisticated blood tests to analyze hormone levels in patients based on their established sleep and wake cycles. Using the test results, specialists can tailor therapy to balance hormone levels. For example, men with decreased testosterone levels have found that testosterone supplementation may help restore and maintain their mood and libido. Replenishing this sex hormone is also known to decrease pain sensitivity in men, but can be costly and may increase the risk of cancer.

In addition to balancing hormones, pain management experts may modify medication dosage or delivery for improved results. For instance, patients may be given an implantable device designed to release an opioid medication in a targeted area, delivering only a fraction of the dose prescribed orally. This reduction can minimize the hormonal side effects in some patients. Alternatively, using interventional pain procedures, nonopioid analgesics or neuromodulation may permit patients to diminish or eliminate the need for opioid medications.

“Our goal is to treat the exact pain diagnosis and tailor the treatment plan to the specific needs of the patient,” explains Dr. Bolash. “If hormonal side effects result, we work quickly to identify the problem and modify treatment to normalize the patient’s health.”

LONG-TERM EFFECTS OF ELEVATED CORTISOL LEVELS
- Osteoporosis
- Obesity
- Depression
- Headache
- Immune deficiencies
- Sleep issues

Dr. Bolash is a staff physician with the Department of Pain Management. He can be reached at bolashr@ccf.org.
The Department of **Pain Management**

**WHO WE ARE**

23
Physicians with board certification in pain medicine

5.1
Research staff
(physician and PhD researchers)

For a full list of Pain Management staff, go to clevelandclinic.org/painmanagementdoctors.

**OUR OTHER MISSIONS**

25 Active research projects

$578,000 External funding for research

24 Residents for the year
(2 rotations per month)

14 Fellows for the year
(pain and research fellows)

**WHO WE TREAT – AND HOW**

(2016 NUMBERS)

83,797 Patient visits

182 International patients

39,437 Procedures

8,666 Imaging studies
sent to Cleveland Clinic Imaging Institute

**OTHER KEY ACCOMPLISHMENTS OF 2016-2017**

- New shared medical appointments for fibromyalgia patients in collaboration with Rheumatology and Neurology
- Acute pain service for inpatients at Cleveland Clinic Fairview Hospital
- Virtual visits now offered by 7 providers

[For a full list of Pain Management staff, go to clevelandclinic.org/painmanagementdoctors.]
When patients present with a chronic pain condition, we often attribute it to their age, wear and tear, or genetics. We indicate that they couldn't avoid it. It was out of their control.

But that's not always true. Many pain conditions aren't completely out of a patient's control. Sometimes pain is related to lifestyle choices or diseases that result from lifestyle choices.

Research shows that lifestyle is a contributing factor in 78 to 90 percent of chronic disease. And for those with a chronic disease — which is half of all U.S. adults, according to the Centers for Disease Control and Prevention — managing pain is more difficult.

**PATIENTS CAN DO MORE**

Disease can initiate, perpetuate or exacerbate pain. Degenerative disease, autoimmune disease, cancer, infectious disease and trauma are common triggers of chronic pain syndromes. The body's response to illness or injury — which includes inflammation, immune response or epigenetic changes — can contribute to pain as well.

While we can prescribe nonsteroidal anti-inflammatory drugs or give steroid injections to put out the fire of pain, too often patients reignite the flame with their lifestyle.

Patients can do more to minimize pain on their own by maximizing their wellness. But they need to be taught how.

**FOUR FACTORS THAT LESSEN PAIN**

When a patient is looking for long-term pain relief, I educate them on four lifestyle factors:

**Sleep.** Most recuperation, rejuvenation and detoxification in the body is done during sleep. Poor sleep is a major contributor to chronic disease. Approximately 50 to 70 million Americans suffer from a chronic disorder of sleep and wakefulness. Disordered sleep hinders daily functioning, is associated with increased risk of injury and adversely affects health (increased risk of hypertension, diabetes, obesity, depression, heart attack and stroke). Americans spend hundreds of
billions of dollars a year on doctor visits, hospital services and medications for sleep problems.

It is estimated that 4 percent of U.S. adults use sleep aids. Unfortunately, many still do not achieve good quality sleep. Instead of sleep aids, I recommend techniques for better sleep hygiene, evaluate patients for sleep disorders and refer them for a sleep medicine consult when necessary.

Movement. A typical day for many patients suffering from chronic pain includes hours of couch time. Physical activity hurts, but inactivity can make pain worse. Rather than telling pain patients they need to "exercise," I encourage them to “move throughout the day.” Setting a timer for every 20 minutes as a reminder to get up and walk around the living room can seem less daunting than starting an exercise regimen. Building consistent movement into their day can aid recovery enough to help them tolerate an exercise program later.

Stress management. Stress exacerbates pain, yet it's controllable. I encourage patients to optimize their environments, removing toxins, such as interpersonal conflict, noise and clutter. I advise them to develop good social connections, which are important for emotional support. And I help them identify stress relievers that work for them — possibly exercise, meditation, prayer or mindfulness — and refer them to a psychologist or health coach if needed.

Diet. Pain patients are often malnourished. Nutritional deficiency, usually resulting from unhealthy food choices, contributes to pain. Teaching patients how sugar, processed carbohydrates and damaging fats can increase inflammation and otherwise aggravate pain can help inspire healthier diets.

**EDUCATING PATIENTS IS THE FIRST STEP**

Educating patients on how to live healthy — and improve or prevent chronic disease — is the first step to combating chronic pain. Wellness can be a more effective treatment than pain medication, which sometimes causes additional discomfort and unwanted side effects.

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**Dr. Dews is Vice President of Medical Operations and Medical Director of the Pain Management Clinic at Cleveland Clinic Hillcrest Hospital.**

References


"Poor sleep is a major contributor to chronic disease."

Dr. Dews builds relationships with her patients and tries to guide them in making healthier lifestyle choices, which leads to better pain management.
new rules go in effect soon to limit health professionals to prescribing only up to seven days of painkillers for adults and five days for kids and teens, with no more than 30 morphine equivalents per day. These limits will apply to acute pain patients, with exceptions for cancer and hospice patients. We will also have to provide the diagnosis that requires opioid analgesics on the prescription and clearly document the reason for any variation from the acute prescribing rules.

HOW SHOULD PHYSICIANS AND OTHER AUTHORITIES APPROACH THE ISSUE?

We have to address the current crisis, and we need to stem the tide going forward. Broadly, there are three populations to consider. The first is the opioid naive patient who presents with an early chronic pain condition and who should be managed with nonopioid alternatives, with rare exceptions. The second group is patients with chronic pain who were started on opioid therapy and need to be weaned off and treated with nonopioid approaches. And finally, we have patients with clear-cut addiction who need access to appropriate short- and long-term treatment.

The first patient requires education, and we need to adhere to stricter prescribing practices and set realistic expectations with regard to pain and its treatment. In most cases, it is not as simple as a pill, and it will require significant effort on the part of the patient. We need to help them to understand the different types of pain, including pain that serves as a protective mechanism, pain that is related to disordered neurological signals, and pain that is part of the healing process, such as muscle soreness after exercise.

The second patient also requires education, which means helping them understand the lack of evidence for improved outcomes with opioids and the significant evidence around increased pain and adverse effects in the short and long term.

Finally, the addicted patient will require significantly more funding and a marked increase in providers with the expertise to care for them.

SO HOW DO YOU APPROACH YOUR PAIN PATIENTS?

At Cleveland Clinic, we often see patients after a pain clinic has closed who are looking to us to fill their previous prescription. We communicate with them before their appointment that we aren't just going to refill their prescription. Our goal will be to develop a nonopioid-based treatment plan for their pain.

At the first appointment with a patient, I ask, “How can I help you get back to
“We have to listen, we have to educate and we have to change expectations about pain.”

Dr. Rosenquist explains to patients that it’s going to take time and self-care to manage pain following a procedure.

Best Wishes …

After 30 years on staff, Michael Stanton-Hicks, MD, of Cleveland Clinic’s Department of Pain Management, is retiring. For the past five years he served in a consultative role and saw patients on a part-time basis. After 55 years of practicing pain medicine, he distinguished himself in the care of complex regional pain syndrome (CRPS), serving as principal investigator in CRPS studies and traveling widely to lecture on the topic.

In June, Dr. Stanton-Hicks was recognized as Teacher of the Year by the graduating fellows. In November, he will receive the 2017 American Society of Regional Anesthesia and Pain Management John J. Bonica Award, which recognizes outstanding contributions to the development, teaching and practice of pain management.

Colleagues say Dr. Stanton-Hicks had a profound impact on their practice. The department wishes him well and will continue to benefit from his great influence.
**Pain Management Staff**
For a full list of staff, go to clevelandclinic.org/painmanagementdoctors.

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Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,400 physicians and researchers represent 140 medical specialties and subspecialties. We are a main campus, more than 150 northern Ohio outpatient locations (including 18 full-service family health centers and three health and wellness centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2017, Cleveland Clinic ranked No. 2 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 No. 1 in heart care since 1995.

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