OHSIPP SUMMER NEWSLETTER

The Official Newsletter for the Ohio Society of Interventional Pain Physicians

QUICK NOTES

OHSIPP ANNUAL MEETING:
September 25th 8am -1pm
Columbus Hilton Polaris

JOHN KASICH FUNDRAISER:
July 15th 5pm - 8pm
RSVP Required
Location: Dr. Amol Soin's Home
Special Guest: Newt Gingrich

ISSUE CONTENTS:

Our Evolving Health Care System

I am pleased to present the summer edition of the OHSIPP Newsletter. We have had a busy several months with some historic changes. With the passage of President Obama's Health Care reform package, medicine as we now practice will undergo some changes.

Additionally, OHSIPP has been working hard locally here in the Columbus statehouse to get pain management specific legislation passed, while attempting to prevent passage of legislation that may inappropriately hinder our ability to properly care for our patients.

This newsletter also features two Interventional Pain Management procedural updates in describing MILD from Vertos Medical (minimally invasive lumbar decompression) and peripheral neuromodulation advancements from Neuros

OHSIPP President Bob Masone, MD at the Cleveland Clinic Pain Meeting in California

Medical, which is an Ohio Based Neurostimulation startup. Because of this, we also have featured peripheral neurostimulation in a scientific article. I hope you enjoy the newletter, and feel free to contact me with comments.

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PRESCRIPTION DRUG TASK FORCE:

Governor Ted Strickland has created a prescription drug task force. The purpose of the task force is to identify appropriate prescribing guidelines for narcotic medications in an effort to prevent abuse and diversion of the medications.

Additionally, a secondary aim of the task force is to identify rouge physicians and practices that are operating "pill mills". The Governor is rolling up his sleeves to combat the excessive amount of preventable deaths stemming from recreational prescription drug abuse.

UPDATE FROM THE OHIO CONGRESS:

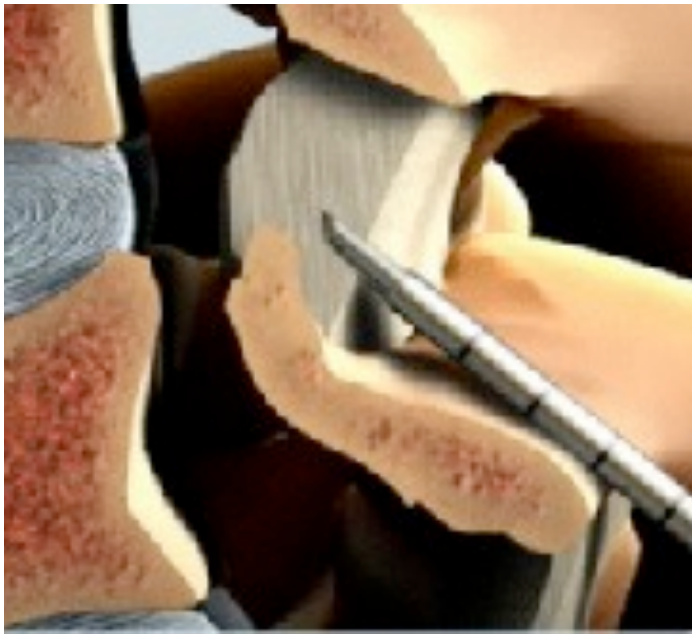
Over the past few months, I have traveled to the Statehouse in Columbus to engage various senators and representatives in an effort to create awareness on the issues we face. I am pleased to report that we have achieved some notable successes in getting pain management-specific legislation passed.

House Bill 477 was passed designating September as "Pain Awareness Month." I testified in support of this bill, and answered various questions from the House Health Committee about the field of pain management. This is an opportunity to connect with patients regarding the therapies available, and to highlight some of our patients' treatment options.

I have heard that several hospitals in Ohio will be having some events designed to promote the Pain Awareness Campaign during the month. I encourage you all to try to participate in these types of activities. If your hospital is not aware of the Pain Awareness Campaign in September, consider contacting your public relations administrator to set up some activities.

House Bill 206 was also passed. This bill granted the ability for nurse practitioners to write for scheduled II medication. We at OSHIPP strongly opposed this bill. Unfortunately, it passed through the house with ease. It seemed strange that the house would pass this bill while at the same time work on House Bill 547, which is designed to limit prescription drug abuse by attempting to limit the access and prescribing ability for scheduled II medications. Additionally the governor created a task force to find ways to decrease the number of scheduled II medications in Ohio- so it would not make sense to add to the prescribing base by allowing nurses to write them. The good news is that the bill still has to pass the senate, and after talking with many senators, it appears highly unlikely that this bill will pass the senate and become law. We may have lost a battle with the house vote, but I am quite confident we will win the war when the bill dies in the senate. I will keep you updated.

House Bill 547 is currently being debated. This is the bill which was created out of Governor Strickland's Prescription Drug Abuse Task Force. This bill affects our practices directly. To my knowledge, there has never been a bill that will impact the way we do things more than this one. In the most recent draft I read, pain management clinics will have to undergo a special licensure process, over and above what we already have. There may possibly be a provision that legislates how often and when physicians are required to check the OARS (Ohio Automated Rx Service) database to see if patients are doctor shopping. This bill expands the role of the state medical board to police pain management clinics, and will allow for the creation of what "defines" a pain management clinic. I will be following this bill very closely, and will be meeting with several house and senate members to discuss specifics. You will be receiving updates via email on this very important bill.



New Technique:

MINIMALLY INVASIVE LUMBAR DECOMPRESSION

Vertos Medical has introduced a new technique to treat Lumbar Spinal Stenosis called MILD (minimally invasive lumbar decompression) Through a small incision, physicians guide a trocar, bone sculptor, and tissue sculptor to debulk the ligamentum flavum. Portions of the lamina are also removed. Ideal candidates include patients who suffer from spinal stenosis due to ligamantum flavum hypertrophy and have failed conservative care, epidural injections and are not a surgical candidate.

UPDATE FROM THE US CONGRESS

As you know, Congress passed the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, which was defined as "health care reform". Over the next four years, several of the provisions will be enacted and enforced. Today, I will discuss the major points that go into effect within the first year.

Insurance companies are barred from dropping people when they are sick, lifetime coverage limits are eliminated, and annual limits are restricted. Young adults can stay on their parent's insurance until the age 26. Uninsured adults with pre-exisiting conditions can get coverage through a new program that will expire in 2014 once the insurance exchanges take effect. A tax credit is available for some small businesses to help provide coverage and a temporary reinsurance program is available for early retirees between the ages of 55 and 64.

From a physician standpoint, ownership in physician owned hospitals will no longer be allowed starting January 1st 2011. Additionally, there will be additional medicare taxes levied on capital gains for high income earners. Also of note are the planned expansion of Government Sponsored insurance plans such as Medicaid while at the same time there are planned budget cuts to these same programs. Basically creating a larger medicaid population while providing the program with less funding to operate.

Sadly, the spirited reform bill also does not have appropriate provisions to cut costs. While it does a great job of increasing access to care, the cost savings described by the Congressional Budget Office are quite unrealistic and historically have been proven to be not possible.

The other issue at hand is the Sustainable Growth Rate formula for medicare. The house voted 417 - 1 in favor of reversing the planned 21% decrease in reimbursement for the next 6 months. The Senate confirmed it unanimously. President Obama mentioned that "kicking these cuts down the road just isn't the solution to the problem." OHSIPP and several other physician and non physician groups have been actively urging congress to permanently address and fix the issue with the SGR formula to prevent this from becoming a recurring issue.

September is Pain Awareness Month:

This September will be officially designated as pain awareness month. Please make your best efforts to help us highlight all the treatment options we have for patients who suffer from chronic pain.

Dr. Amol Soin Pictured with Lee Fisher (Dem Nominee for Senate) on the left and with Rob Portman (Rep Nominee for Senate) on the right.

OHSIPP MEETS WITH US SENATE CANDIDATES:

This years race for the US Senate pairs formidable candidates from both parties.

Representing the democrats is the current Lieutenant Governor Lee Fisher. Fisher first entered into politics in the early 1980s when he served as a member of the Ohio General Assembly, then the State Senate. He won statewide office serving as the Attorney General from 1991 - 1995.

The republicans are represented by Rob Portman. Mr. Portman served in the US Congress 2nd district for 12 years. He was well liked winning seven straight elections with over 70% of the vote. He has served in two presidential cabinet level positions including the US Trade Representative and was Director of the Office of Management and Budget (OMB) under President George Bush. Serving in the OMB is quite valuable for a senator as Portman has a working knowledge of several budget issues. Most importantly regarding medicare and flawed SGR system, I found Mr.. Portman's working knowledge to be superior.

Given the balance of power resting too firmly with one party, Portman's working knowledge of the federal budget, and strong opinions against the SGR formula, it seems he will be a better choice for the US Senate for OHSIPP members.

In fact, in the history of the United States there has never been a sitting US Senator who also served in the cabinet of a President as director of the OMB.

John Kaisch Fundraiser:

There will be a fundraiser for John Kaisch on July 15th from 5pm - 8pm. Between 5 - 6pm will be an intimate VIP session followed by the general reception. RSVP is required and the costs are $2,500 per couple for the VIP Session and $1,000 per person for the general reception. Special guest Newt Gingrich will be there as well. The event will take place in my (Amol Soin) home. Please check the following link for details:

http://www.KasichForOhio.com/GingrichEvent

FUTURE TECHNOLOGY HIGHLIGHT

NEUROS MEDICAL

Cleveland-based neurostimulation start-up company Neuros Medical is developing a peripheral nerve stimulation device designed to block pain transmission through the use of high frequency alternating current.

The Future of Peripheral Neuromodulation:

Unwanted or uncoordinated generation of nerve impulses is a major disabling factor in many medical conditions, such residual limb pain, dystonia, neuroma, chronic post surgical pain and chronic neuropathic pain states. If these impulses could be intercepted along the peripheral nerves over which they travel, then the disabling condition could be reduced or eliminated. This is where the technology from the new Cleveland Based Neuros Medical comes in via its patented peripheral neurostimulation device called “nerve block”.

The technique which involves the usage of High Frequency Alternating Current (HFAC), can produce a reliable, gradable and reversible nerve block in mammals. Using frequency around 5,000 to 30,000 Hz, a complete deploarizing nerve block occurs. Essentially HFAC functions as “electric lidocaine”, blocking sensory nerve transmission completely. The HFAC block may provide an important tool for use in the treatment of unwanted neural activity and be effective for potential clinical applications such as residual limb pain, chronic post surgical pain, migraines, chronic neuropathic pain states, and peripheral neuropathies.

Electrical currents produce activation or block of nerve conduction through their influence on the voltage-gated ion channels in the nerve membrane. HFAC appears to block nerve conduction through depolarization of the nerve membrane, despite the fact that there is a zero net charge delivered to the tissue.

High frequency alternating current represents an avenue to treat several chronic pain conditions. HFAC has the potential to create a reliable and gradable nerve block and can thus be an effective method to achieve analgesia.

Later on in this issue, you will see and read a complete scientific discussion regarding peripheral neuromodulation techniques. Some techniques have come under fire as simply being an expensive TENS unit. This device is unique in that the cuff lead is placed directly on the peripheral nerve and have been shown to achieve a complete “nerve block”.

In any case, it is exciting to see that an Ohio based company is emerging as a frontrunner in development of peripheral neuromodulation techniques.

Peripheral Nerve Field Stimulation for Chronic non malignant pain.

Salim Hayek, MD, PHD
Elias Veizi, MD, PHD

Chronic peripheral non-malignant pain affects a large percentage of population and is often inadequately treated which results in low quality of life, medication abuse, and establishment of mood disorders. A variety of conservative treatments do not provide complete or lasting pain relief and furthermore there are significant side effects associated with long term consumption of agents used to manage chronic neuropathic pain such as membrane stabilizers, tricyclic antidepressants, anticonvulsants or opioids. Neuromodulation by means of electrical stimulation has been a useful alternative as a method for treating chronic pain. It has been evolving tremendously since the "gate theory" developed by Melzac and Wall in 1965 opened the door for this application. Manipulation of pain pathways by neuromodulation can occur at many levels from peripheral nerve endings, large peripheral nerves, spinal cord tracts, deep brain centers and up to the motor cortex.

Shealey, working out of University Hospitals Case Medical Center, pioneered the use of dorsal column stimulation (DCS), now known as spinal cord stimulation (SCS), for the control of chronic pain in 1967. Almost in parallel, and looking at ways to improve the technique with new modalities of neuromodulation to treat patients failing SCS, peripheral nerve stimulation was developed. While SCS targets dorsal columns of the spinal cord, peripheral nerve stimulation (PNS) targets fibers of the peripheral nerve along its path. Correct placement of leads close to the nerve trunks requires an incision, nerve exposure and alignment along or wrapping of the nerve trunk depending on the leads used. Additionally, there have been no specific leads developed for that application and the procedure is not without complication and not always effective. In some cases, percutaneous spinal cord stimulation leads are introduced through a needle in close proximity to target nerves. The latest application developed in this direction, peripheral nerve field stimulation (PNfS), involves placement of electrodes subcutaneously and not necessarily in close proximity to known nerves, with goal of achieving paresthesia coverage at the specific topographic area of pain. The nomenclature is somewhat confusing since only surgical placement of leads close to the nerve can be considered bona fide PNS while percutaneous peripheral nerve stimulation could be considered similar to PNfS. In PNfS spinal cord stimulator leads are placed subcutaneously in the area of pain to stimulate the region of the affected nerves or the dermatomal distribution of these nerves, which then converge back on the spinal cord. To date the exact mechanism of action of PNfS is not known; however it is believed that the principle behind PNfS is the same as with SCS but the target is different (small peripheral sensory nerve endings at the painful area). Generally, the most important effect (but not the only one) of stimulation is central, by stimulating ascending pathways and effecting neuronal inhibition. Demonstration that stimulation of higher pain centers (that result in inhibition of pain pathways) can be achieved as effectively by PNfS like SCS is lacking. A recent study demonstrated increase in brain activity by fMRI in the somatosensory cortex upon median nerve stimulation which means that likely there may be a central effect from PNfS. Other authors have considered theoretically that a local effect of electromagnetic field generated by PNfS on small peripheral sensory nerve fibers could lead to neuromodulation of pain pathways and pain relief. Retrograde effects of PNfS as well as effect on local vasculature have not been explored at all. In conclusion, even though it has gained a fairly wide use lately, the basic mechanisms by which PNfS results in effective pain relief remain unknown and its true effects unproven as studies up to this point are largely anecdotal.

Recently, effective treatment of various neuropathic pain syndromes using percutaneous PNfS has been reported in a growing list of clinical settings, primarily in the head and neck regions, but also the low back, limb and inguinal areas as well. PNfS is being applied in individual cases where conventional treatments have failed to control pain or optimal paresthesia coverage by SCS cannot be achieved. However, there is no consensus yet as to what are indications for this novel form of neuromodulation. This has lead sometimes to an unreasonable overuse of this technique. PNfS is applied in a combination with SCS or as a stand alone application. Few case reports and limited published experience indicate that this form of neuromudulation may be used in refractory cases for the following indications: 1) Chronic low back axial pain post lumbar spine surgery. While SCS is a widely accepted and increasingly used treatment modality for "failed back surgery syndrome' (FBSS), many practitioners reserve SCS to treat primarily radicular leg pain rather than axial low back pain because SCS is often inadequate in achieving low back paresthesia or relieving truncal pain. Even when low back paresthesias are achieved, the perception threshold (PT) is fairly close to discomfort threshold (DT) since usually unpleasant chest and abdominal wall stimulation may occur. Combination of SCS and PNfS has been shown to be successful in a limited observational study by Bernstein in 2008. Using both spinal cord stimulation and PNFS in conjunction for lower back and leg pain they concluded that a combination of the 2 techniques provided greater benefit than either alone.

2) Occipital neuralgia. This probably is the major application for PNfS and the procedure is referred as ONS (occipital nerve stimulation). Even though a wide range of syndromes are characterized as "occipital neuralgia" encouraging results have been published regarding the effectiveness of ONS in providing pain relief, decreasing number of acute episodes and decreasing analgesic medication consumption. Still, the technique needs to be perfected since complications such as neck tightness, infection or muscle spasms lead to significant number of explants or failed procedures. In general, ONS may be effective in carefully selected patients suffering from migraine, occipital neuralgia, cervicogenic headache, cluster headache and facial pain.

3) Postherpetic neuralgia. PHN sometimes is characterized by severe pain along the distribution of the affected nerve and dorsal root ganglia that is not amenable to conservative treatment. Because usually pain is confined to a distinct dermatome good results have been reported by use of PNfS.

4) Carpal tunnel syndrome. Chronic neuropathic pain due to the constriction and mechanical damage of the median nerve results in severe disability. There is some evidence that PNS of the median nerve and/or its branches is effective and results in pain relief and some improvement of function.

4) Inguinal nerve neuralgia following herniorrhaphy or chronic post-incisional pain (previous abdominal surgeries or thoracotomies). It is not unusual for chronic neuropathic pain phenomena to occur in patients post surgical procedures since during surgery some nerve fibers are cut or damaged. Occasionally, painful neuromas are formed at the tip of truncated nerve branches. PNfS along the incisional lines has been shown to be somewhat promising even though there is very limited evidence.

In general, the following nerves are most commonly targeted by percutaneous nerve stimulation: occipital nerve, supraorbital, infraorbital nerves, median, or axillary nerve, intercostals, ilioinguinal, iliohypogastric, cluneal, common peroneal, saphenous, lateral femoral cutaneous and superficial peroneal nerve.

Implanting the hardware for PNfS is usually straightforward with similar set of guidelines to SCS. In order to perform PNfS, the nerve and the area of pain is mapped out by exam, and the skin is prepped and draped. Local anesthesia is applied in a limited fashion and the needle is placed. The electrode delivery is achieved percutaneously through a needle inserted subcutaneously not very deep (usually not more than 10 mm). The area of desired coverage is mapped and the needle is placed sometimes in the middle of the painful field or along the previous surgery incision lines. Leads are introduced and the needle removed. If the leads are placed too deep it is likely the targeted nerve fibers are missed. If the leads are placed too superficial lead erosion through the skin can occur. Lead (s) is connected to a programmable external generator for the trial period which usually lasts from 2-7 days. Amplitude, frequency, and shape of electromagnetic field can all be manipulated to achieve optimal pain relief. The trial is considered successful if significant pain relief is achieved (usually for PNfS over 70%). After a successful trial the permanent leads are placed, anchored appropriately to fascia, and the generator internalized at an optimal anatomical space decided by the surgeon according to the patient's characteristics and the topography of the lead placement (different IPG placement for different lead locations). The risks of this procedure are limited to superficial infection, rarely peripheral nerve injury or dysfunction of the implanted system.

Appropriate use of implantable technologies for pain management should be based on extensive knowledge of pathophysiology of pain, clinical presentation of pain syndromes and evidence of effectiveness of the treatment modality. Technological advances on hardware are far exceeding our understanding of pain pathways and the effects of electrical modulation of the nervous system. Even the terminology used to describe various techniques does not accurately reflect the procedures. Percutaneous placement of leads for electrical stimulation may make the PNS and PNfS applications very similar.

There are significant advantages in using PNfS: a) the procedure is performed expeditiously under local anesthesia and the surgical site is quite superficial; b) the rate of complication appears to be very low; c) technically there are no issues with steering of leads (as is done for SCS) since they are delivered through the needle to the desired location and sought paresthesia are often readily obtained; d) there may be less problems with lead migration (as in SCS); e) similar to SCS, patients undergo a trial giving physicians valuable information on whether PNfS will be effective or not; f) if used in combination with SCS all leads may be connected to the same IPG, depending on the number of electrode contacts used.

The occipital nerve, ilioinguinal/ iliohypogastric nerve, cluneal nerve and the intercostal nerves may be receptive to stimulation of their peripheral fibers instead of stimulation the larger trunks. Preliminary published studies suggest that a significant proportion of patients with certain intractable pain syndromes may benefit from peripheral nerve stimulation. The evidence is limited at this time, that the benefits form PNfS are long-lasting. However, studies addressing efficacy are necessary to determine not only pain relief but also improvement in functional status.Sometimes more than one electrode is placed to achieve coverage on discontinuous small areas of pain; however careful consideration should be given on the benefits of placing multiple leads versus the option of SCS placement. Nonetheless, outcome data are necessary to compare the benefits of the procedure as a stand alone, in combination with SCS or in comparison with TENS unit.

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