Pain Management Review Part 5

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Objectives

- Compare the analgesic efficacy of Tramadol Contramid OAD versus placebo in patients with pain due to osteoarthritis.
- Describe the left lateral approach in management of celiac plexus block.
- Study the value of magnetic resonance imaging in patients with painful lumbar spinal stenosis (LSS) undergoing lumbar epidural steroid injections.
- Describe a case of melorheostosis of the foot.
- Describe an erosion of the inferior epigastric artery: a rare complication of intrathecal drug delivery systems.
- Evaluate the efficacy of continuous epidural local anesthetic plus corticosteroid compared with single injection for the treatment of cervical brachial radicular pain.
- Describe sciatic neuropathy after lower-extremity trauma in a pediatric patient.
- Study the use of topiramate use in a patient with idiopathic glossodynia.
- Describe a case of recurrent trigeminal neuralgia secondary to Teflon felt.
- Discuss an open-label 52-week clinical extension comparing duloxetine with routine care in patients with diabetic peripheral neuropathic pain.

A comparison of the analgesic efficacy of Tramadol Contramid OAD versus placebo in patients with pain due to osteoarthritis.

Burch F et al

Journal: J Pain Symptom Manage 34(3):328-38, 2007. 27 References
Reprint: Labopharm Inc., 480 boul Armand Frappier, Laval, Québec, H7V 4B4, Canada (S Robertson, BScN)
Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

The objective of this multicenter, randomized, double blind, parallel-design study was to assess the analgesic efficacy and to compare the safety and clinical benefit of Tramadol Contramid® OAD to that of placebo in patients with pain due to osteoarthritis (OA).

A total of 1028 patients who met the screening criteria were enrolled at 108 outpatient clinics in the United States, Canada, France, and Romania between October 2004 and January 2006. Patients were from 40 to 80 years old and had pain due to OA of the knee.

Patients were titrated with Tramadol Contramid OAD in an open-label phase that included titration, taper, and washout. The compound was increased gradually by increments of 100 mg to a maximum of 300 mg with the possibility of decreasing to 200 mg. The final daily dose could be either 200 mg or 300 mg. Titration was followed by a 7-day taper period during which the dose was progressively decreased.

At the beginning of the double-blind phase, eligible patients were randomized to Tramadol Contramid OAD or placebo in a 2:1 ratio, in blocks of 6 according to a previously established randomization computer-generated schedule. Patients were asked to evaluate the intensity of their pain on the 11-point Pain Intensity Numerical Rating Scale (PI-NRS). Pain intensity was assessed at the and of the double-blind titration and, along with the physician and patient global ratings, at each visit on days 21, 42, 63, and 84 of the maintenance period.

Four hundred and ninety-one patients completed the 12-week maintenance period. Among patients randomized to Tramadol Contramid OAD, 106/432 (25%) selected 200 mg as the final dose and 325/432 (75%) selected 300 mg.

At the end of the 12-week maintenance period, 80% of patients randomized to Tramadol Contramid OAD indicated that their condition had improved, compared to 69% of the patients randomized to placebo.

Tramadol Contramid OAD demonstrated a statistically significant greater average reduction in the PI-NRS score compared to placebo over the entire treatment period. An absolute mean reduction of 3.0±2.1 on the PI-NRS was noted in the Tramadol Contramid OAD treatment group. The Global Impressions of Change indicated a high level of satisfaction with the analgesic effect both among patients and their physicians. The relatively low incidence of the most common adverse events reported during the double blind phase and their generally low intensity support the safety of Tramadol Contramid OAD.

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Celiac plexus block: a new technique using the left lateral approach.

Garcia-Eroles X et al

Journal: Clin J Pain 23(7):635-637, 2007. 12 References
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Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

A 62-year-old man presented with epigastric pain 3 years after surgery for Klatskin type cholangio-carcinoma. Medication was ineffective and caused untoward side effects. In December 2004, a left lateral celiac pl block using fluoroscopic control helical CT was carried out resulting in the immediate disappearance of pain. There were no technical problems, no pain on puncture, orthostatism, urinary alterations, or intra-abdo lesions.

The selection of the lateral approach was made because of interposition of the colon anteriorally and the

posterior approach was discarded owing to the proximity of the kidneys to the vertebral bodies T12 and L1 patient discomfort to adopt the prone position.

The transgastric left lateral of approach was considered because, although occasionally used in the percutaneous drainage of abdominal abscesses, this approach appeared to be the most propitious in this patient. Det description and photos of the CT scan during this procedure are shown in this article.

The neurolytic blockade was made with a mixture of 15 mL of alcohol 100% and 15 mL of lidocaine 2%. Tolerance to the block was excellent; no pain was experienced on injection. There were no hemodyn problems and the epigastric pain yielded immediately. The patient was discharged after 24 hours of observation with pain at the level of the right hypochondrium, controlled with transdermal fentanyl 25 mcg. After 3-m follow-up, the patient continued with the same treatment.

The new approaches of the celiac blockade are based on the availability of imaging techniques. In the authors' hospital, all celiac blocks are carried out with CT and preferably using the anterior approach. The local CT is an excellent tool owing to the quality and rapidity of the images and allows for alternative approaches.

Value of the magnetic resonance imaging in patients with painful lumbar spinal stenosis (LSS) undergoing lumbar epidural steroid injections.

Kapural L et al

Journal: Clin J Pain 23(7):571-575, 2007. 18 References
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Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

To diagnose lumbar spinal stenosis (LSS), magnetic resonance imaging (MRI) is a preferred imaging tool. There seems to be little relationship between the severity of stenosis, as presented on MRI, and pain scores or functional impairment. Furthermore, there is a high prevalence of disk bulges or protuberances on the MRI contributing variably to LSS without back pain, and those findings may frequently be coincidental.

Lumbar epidural steroid (LES) injections are commonly used before considering surgery, and sometimes may be used as alternatives to surgical decompression. This retrospective study examined the relationship between MRI findings and Visual Analog Scale (VAS) pain scores in a large LSS population and the value of MRI findings in predicting success of LES injections for painful LSS.

Seven hundred and nineteen LSS patients qualified for inclusion in this analysis. The mean age was 68.4 years and there were 411 women. The mean of the VAS pain score on initial visit was 7.2 and the average daily opioid use was 15 mg of morphine sulfate equivalent. The most frequently affected vertebral level was L4-5.

A data collection sheet was generated for each individual which included patient's age, sex, number of lumbar levels affected by stenosis, particular levels of stenosis, type of stenosis (central, lateral, both),

severity of lumbosacral stenosis (mild, moderate, and severe), VAS pain scores immediately before steroid injection and at 8 to 12 weeks follow-up after completion of a series of 1 to 3 injections. To create the Stenosis Pain Index (SPI) score, the severity scores of the patients' LSS (1 for mild, 2 for moderate, and 3 for severe) were added to the number of lumbar levels affected.

The improvement in VAS pain scores after LES injections correlated with SPI score increments in patients with LSS except in those with severe stenosis described on MRI and 3 or more levels affected by any magnitude of stenosis. That group is unlikely to benefit from LES injections.

Melorheostosis in the foot.

Kurklu M et al

Journal: Am J Phys Med Rehabil 86(10):868, 2007. 2 References
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A 26-year-old man (military staff) was seen for left-foot pain for the past 17 months. He described the pain as ensuing after military exercises (3-5 km running, pentathlon, decathlon) but not during routine daily activities or during rest. Physical examination was normal except for pain on the dorsal side of the second metatarsal bone during resistive plantar flexion of the second toe, left foot.

Radiologic evaluation of the feet showed massive sclerotic changes in the second metatarsal and phalangeal bones of the left foot. Laboratory tests were completely normal. Computed tomography of the feet and triphasic bone scintigraphy were both suggestive of melorheostosis. Eventually, an open biopsy was carried out, and the pathological diagnosis was consistent with nonspecific, reactive, regenerative, small, bony tissue, without malignant changes.

Followed conservatively with plantar orthosis, he was instructed to avoid the aforementioned exercises. After 26 months of follow-up, despite the persistence of the radiologic findings, the patient is currently quite well, with no painful symptoms unless he performs military exercise.

Melorheostosis is a rare disorder characterized by dense sclerotic bone. A single limb (lower limbs more often than upper ones) is most often afflicted with dense, eccentric involvement of one or more bones. Soft tissue abnormalities are common, and skin lesions resemble scleroderma. Joint swelling, muscle contractures, and tendon and ligament shortening, causing pain and limited range of motion, can be encountered. The diagnosis is usually established before the age of 20. Conservative treatment with pain management and daily life modification seem to be all that is necessary in these cases.

Erosion of the inferior epigastric artery: a rare complication of intrathecal drug delivery systems.

Narouze SN et al

Journal: Pain Med 8(5):468-470, 2007. 18 References

Reprint: Cleveland Clinic Foundation, Pain Management Center, 9500 Euclid Ave, Cleveland, Ohio 44195 (SN Narouze, MD, MSc)
Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

Complications of intrathecal drug delivery systems include those related to the surgical technique, malfunction of the system, and those related to the intrathecal catheter. Abdominal bleeding as a result of arterial erosion is a previously undescribed complication.

A 53-year-old man presented with abdominal pain, distention, and inability to pass urine for 2 days. His history included hypertension, diabetes mellitus, chronic renal insufficiency secondary to autoimmune nephropathy, deep venous thrombosis S/P inferior vena cave (IVC) filter replacement, paraplegia, and neurogenic bladder secondary to severe cervical canal stenosis. An intrathecal baclofen pump had been implanted in the left lower quadrant of his abdomen for treatment of spasticity 8 years before.

At the emergency department, his blood pressure was 63/34 mmHg, pulse rate 110/min, and temperature 36.3º C. Abdominal examination showed increased abdominal girth with left anterior abdominal wall tenderness. On insertion of a urethral catheter frank pus was expressed. The patient became hemodynamically unstable requiring intravenous fluid resuscitation and vasopressor support; he also required multiple transfusions of blood and blood products.

Abdominal ultrasound and computed tomography scan showed a large complex left anterior abdominal wall (rectus sheath) hematoma measuring 18.3 x 7.7 x 26 cm deep to the intrathecal pump with an additional large retroperitoneal pelvic hematoma measuring 12.8 x 9.6 x 13 cm that deviated the bladder, and bilateral hydronephrosis. Angiogram confirmed active arterial bleeding from a small branch of the mid part of the left inferior epigastric artery located 2 cm cephalad to the intrathecal pump. A successful selective embolization was performed.

The patient developed fever with increased white blood cell count requiring intravenous antibiotics for *E. coli* growing from the hematoma site, and evacuation of the hematoma. Later, he underwent intrathecal pump repositioning more laterally to the rectus sheath.

Complications of intrathecal drug delivery systems include surgical bleeding, infection, meningitis, epidural abscess, epidural hematoma, epidural lipomatosis, stenosis, neurological injury, cerebrospinal fluid leak, and postdural puncture headache that are related to the surgical technique. Pump complications include pump failure with either overinfusion or underinfusion, and pump rotation or malposition. Intrathecal catheter complications include sheared catheter, migration, kink, obstruction, disconnection and catheter tip inflammatory masses.

The inferior epigastric artery arises from the external iliac artery immediately above the inguinal ligament. It then pierces the transversalis fascia and passes anterior to the arcuate line to ascend between the rectus abdominis muscle and the posterior layer of its sheath where it gives off multiple terminal branches.

Hemorrhage of the inferior epigastric artery branches can occur spontaneously or as a result of increased

intra-abdominal pressure; twisting or abrupt changes in position; and minor trauma, causing rectus sheath hematoma that is typically self-limited. Significant bleeding from the artery has been reported as a complication of the percutaneous femoral vein catheterization, laparoscopic surgery, paracentesis, placement of a surgical drain or inadvertent puncture during surgical intervention, and pelvis fracture.

Recurrent blunt trauma to the pump site in this patient as he gets in and out of his wheelchair probably led to a gradual erosion of the inferior epigastric artery. This was overcome by moving the pump. Color Doppler ultrasound and arteriographic embolization is of utmost importance in the diagnosis and treatment of this complication.

Epidural local anesthetic plus corticosteroid for the treatment of cervical brachial radicular pain: single injection versus continuous infusion.

Pasqualucci A et al

Journal: Clin J Pain 23(7):551-557, 2007. 46 References
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Cervicobrachial pain (radicular pain) is characterized by an acute or chronic pain in the area of the last 4 cervical nerves and the first thoracic nerve. It is a common condition with an annual prevalence of 53.6%, with 41% of those occurring in males.

Variable efficacy has been demonstrated with physical treatments, and although pharmacologic treatment would appear to be a rational choice, it is not considered first-line, especially for chronic pain, because of the possible long-term side effects of some of the drugs. On the basis of positive results in lower back pain, the use of epidural corticosteroids with or without local anesthesia has been reported. Most studies agree that epidural corticosteroids provide a certain level of efficacy in the treatment of cervicobrachial and back pain (suggested to relate to their anti-edema effect and anti-inflammatory and immunosuppressive action in addition to the probable inhibition of neurotransmission with in C-fibers). On the contrary, the efficacy of the epidural local anesthetics is still unclear.

The purpose of this study was to evaluate the efficacy in cervicobrachial pain, with or without sensory and motor symptoms, resistant to conventional therapy, of continuous epidural local anesthetic in combination with a steroid bolus, compared with a single injection of the same drugs based on the time between pain onset and treatment initiation.

A prospective randomized study was conducted at four university medical centers in 160 patients affected with cervical brachial pain resistant to conventional therapy. These patients were divided into 4 groups (40 patients per group) on the basis of the time pain onset: group A, 40 patients with pain 15 to 30 days; group B, 40 patients with pain from 31 to 60 days; group C, 40 patients with pain from 61 to 180 days; and group D, 40 patients with pain greater than 180 days. Patients in each group were randomized on received therapy: 20 with single injection and 20 with continuous epidural. Pain in all instances was evaluated using

a visual analog score (VAS).

Patients in the single injection group were administered a series of epidural blocks every 4 to 5 days. The first block consisted of 0.25% bupivacaine with epinephrine (1:200,000) and a volume of 6 mL with 80 mg methylprednisolone acetate. The second block, after 4-5 days, was done with 6 mL of bupivacaine 0.5% with epinephrine 1: 200,000 with 40 mg methylprednisolone acetate, and the third block, with the same drugs, followed after another 4-5 days. Treatment was suspended upon reaching a Pain Control (PC) figure [calculated according to the following formula: PC (%) = (100) ($VAS_{initial}$-VAS_{final})/$VAS_{initial}$] of ≥ 80%.

Patients in the continuous epidural group received placement of an epidural catheter introduced at the level of C6-C7, or C7-T1, or T1-T2 intervertebral space. Bupivacaine (0.25% with epinephrine 1:200,000) in a volume of 6 mL combined with 80 mg methylprednisolone acetate was administered through the catheter. After a period of 12-24 hours, bupivacaine (0.25%) in a volume of 6 mL was administered every 6, 12, or 24 hours with the timing dependent upon ensuing pain-free periods of 24 hours. Methylprednisolone (40 mg) was administered every 4-5 days via the catheter. After a 24 to 36 hours interval after the first 10 days of administration, a VAS evaluation was performed. Treatment was suspended upon reaching a PC ≥ 80% for more than 24-36 hours, but if pain persisted, the cycle of treatment was repeated, with a total allowed treatment period of 30 days during which time the catheter was left in place. One week after the end of treatments, the level of PC was re-evaluated in all patients.

At the baseline, the number of hours of pain-free sleep (PFS) was recorded in all patients, and as this may contribute to quality of life, the difference in the number of hours of PFS pretreatment vs. post treatment was compared as a secondary end point.

The results of this study showed a statistically significant efficacy of the treatment of cervicobrachial pain and PFS with epidural local anesthetic plus corticosteroids in continuous infusion rather than a single injection, in patients with pain > 180 days. There seemed to be no statistically significant differences between the 2 treatments in patients with pain < 180 days.

The most important implications of corticosteroids therapy are the side effects such as suppression of the hypothalamic-pituitary axis, immunosuppression, or gastroduodenal damage. At the end of this study, the average dosage was 320 mg over 30 days, and none of the patients showed side effects connected to corticosteroid use.

Sciatic neuropathy after lower-extremity trauma: successful treatment of an uncommon pain and disability syndrome in an adolescent.

Saroyan JM et al

Journal: Am J Phys Med Rehabil 86(7):597-600, 2007. 18 References
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Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

The authors report the case of an adolescent male with neuropathic pain and weakness in the right lower extremity after simultaneous sacral fracture and stretch injury to the sciatic nerve, sustained during a motor vehicle injury.

A 14-year-old healthy male was struck by an automobile while riding his bicycle. He was dragged underneath the car for 150 ft. and sustained multiple abrasions and lacerations, including a very deep soft-tissue injury to the right buttock, involving the muscle and, possibly, the sciatic nerve. There was no associated head injury or loss of consciousness. He had a stable vertebral fracture in the left hemisacrum.

Two days later, the patient reported the new onset of neuropathic pain involving the second and third toes on the right side. His pain intensity was 2 out of 10 on the pain rating scale (NRS). He also had "shooting" (NRS = 9/10) pain that occurred 3 to 4 times per day and that lasted from a few minutes to 30 minutes. Pain management included high-dose opioids and nonsteroidal anti-inflammatory drugs, which provided no relief.

Referred to a pediatric pain-management specialist one month after his injury, there was a right-buttock lesion measuring 11 x 8 cm. There was weakening on thigh flexion, leg extension, foot dorsiflexion, and toe extension. The patient was unable to invert or evert the right foot. There was calf atrophy and a hypoesthesia involving the right lateral lower leg, the foot, the fifth toe, and the space between the first and second toes. Allodynia was present in the second and third toes. Ankle jerk reflex was absent on the right side. Concurrent psychological evaluation did not reveal clinically significant levels of anxiety or depression.

The diagnosis of femoral and sciatic neuropathy was tentatively made, with strong consideration given to the development of complex regional pain syndrome type 2. The nerve injury was considered to be either at the level of the sacrum, buttock, and/or right knee. Gabapentin was initiated.

The patient began a vigorous physical therapy schedule. A needle electromyogram was performed 5 months after the injury and the results were consistent with sciatic nerve injury proximal to the midthigh. Daily physical therapy with passive and active range of motion in both lower extremities, desensitization of the right lower extremity, and gait training was maintained.

The site of the sciatic nerve injury was identified by the denervational changes within the short head of the biceps, indicating a sciatic nerve injury proximal to the distal thigh, because this muscle is innervated by the sciatic nerve in the distal thigh. Another diagnostic challenge was distinguishing complex regional pain syndrome type 2 from a painful sciatic neuropathy. Severe pain, allodynia, edema, and erythema were all present in this patient after his injury, but these findings did not spread beyond the confines of the sciatic nerve territory.

This patient did not merit surgery and recovered well. Rehabilitation of the adolescent or pediatric patient presenting with neuropathic pain and motor deficits after a traumatic injury include early institution of

neuropathic pharmacotherapy, electrodiagnostic testing at 3 weeks after the injury, rigorous physical therapy for the prevention of disuse, psychological assessment, and consultation with a peripheral nerve surgeon.

Use of topiramate for glossodynia.

Siniscalchi A et al

Journal: Pain Med 8(6):531-534, 2007. 29 References
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Glossodynia is a multifunctional disorder characterized by painful sensations in the mouth and throat, and especially on the tongue. It has a prevalence of 4-5% in the general population. Multiple etiological factors of local, systemic, and psychological origin have been suggested. It has been managed by long-term therapy with systemic regimens of anxiolytics and antidepressants. In addition, gabapentin has been found as effective in this disorder.

Topiramate is a new antiepileptic drug that has shown efficacy in intercostal and trigeminal neuralgia. This article reports a case of a patient with glossodynia successfully treated with topiramate.

A 65-year-old woman with a 4-month history of glossodynia presented for consultation. Work-up revealed oral pain that occurred several times a day. There was no significant incidence of drug abuse, medical, or surgical history. Physical examination revealed no underlying disorders at the time of observation. Her tongue appeared normal both before and after eating, and, although her mandible was edentulous, there was a complete lower denture prosthesis.

A visual analogue scale (VAS) was rated as 6.2. Dental evaluation excluded oral pain induced by a denture factors. Oral culture excluded bacterial or fungal contaminations. A diagnosis of idiopathic glossodynia was made, and carbamazepine 200 mg every 8 hr was started. Two days later, the woman was discharged home on a regimen of carbamazepine 300 mg every 8 hr.

About 18 days after discharge, she was readmitted because of persistence of glossodynia and for the development of visual disturbances. Neurological examination revealed diplopia and ataxia while pharmacological blood evaluation demonstrated high levels of carbamazepine (14 mcg/mL; normal values less than 12 mcg/mL). Carbamazepine was promptly discontinued, and gabapentin 300 mg every 8 hr was initiated. Five days later, she was discharged with a complete remission of neurological adverse events. Four days after this, persistence of oral pain induced in increase in gabapentin dosage to 900 mg every 12 hr.

Four weeks later she demonstrated dizziness and somnolence and gabapentin was discontinued. Topiramate 50 mg every 12 hr was begun. After 4 weeks with no adverse events, this dosage was increased to 100 mg

every 12 hr and then, 2 weeks later, to 150 mg every 12 hr. Ambulatory evaluation revealed a VAS score of 2.5 with full resolution of symptoms and she was complaint free at 1-and 3-month follow-ups without dose adjustments of topiramate. At the writing of this article she was glossodynia free with no adverse events associated with topiramate.

The pathogenesis of idiopathic glossodynia remains unclear, and it recently has been suggested as a possible neuropathic basis of burning mouth syndrome demonstrating an altered excitability in the trigeminal nociceptive pathway at peripheral and/or central nervous system level. The various mechanisms of topiramate, which act at different neural transmission levels, blocking sodium and calcium channels, enhancing GABA concentration, and decreasing glutamate function at postsynaptic sites how, may explain the effects of topiramate in this patient.

Other advantages of topiramate include the lack of relevant adverse effects and few interactions with other drugs.

Recurrent trigeminal neuralgia secondary to Teflon felt.

Vitali AM et al

Journal: Acta Neurochir (Wien) 149(7):719-722, 2007. 35 References
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Microvascular decompression (MVD) has become a widely accepted treatment for trigeminal neuralgia (TN) and hemifacial spasms (HFS). Unfortunately, there is no standard protocol for this procedure. Some surgeons insert prostheses between the trigeminal nerve and the offending vessel, while others transpose the compressing vessel without touching the nerves. There have been several reports of recurrent TN secondary to the prosthesis used for separating the vessel and the nerve. Two of these cases were attributed to the compression of the trigeminal nerve by a hardened Teflon pledget. This article reports on a recurrent TN 12 years after MVD that was caused by a Teflon pledget that had pierced the trigeminal nerve.

A 45-year-old man presented with a recurrent left TN within the mandibular division. His neuralgia began in 1990 and ultimately required MVD in 1994. Teflon felt separated the offending vessel from the trigeminal nerve. His TN resolved immediately after surgery, but recurred 5 years later in the same distribution. This pain was refractory to medical management and percutaneous glycerol rhizotomies were performed in 1999 and 2001. Recently the pain had returned with spread to the maxillary division.

His neurological examination revealed a subjective decrease in pinprick sensation within the left V3 nerve distribution by about 50%. During the following MVD, the fifth nerve could be seen without impingement from any blood vessel.

Superiorly to the nerve and directly against it was a very firm foreign tissue that was identified as a Teflon

pledget from his previous MVD. The pledget was very hard and was transmitting the cerebellar pulsations into the nerve. When the pledget was removed, it was observed that it had pierced the trigeminal nerve and extended several millimeters below it. At the bottom of the indentation was a hole splitting the trigeminal nerve into 2 unequal parts. Photos of the operative field are shown in the article.

Nine months postoperatively he remains pain free and off all medication. He has reduced pinprick sensation in his left lower lip as before and a new area of subtle subjective reduced pinprick appreciation more laterally in the mandibular division.

The immediate success rate of MVD for the treatment of TN is as high as 96%, but the incidence of recurrence has been reported to range from 3 to 20%, with annual rates of recurrence between 2% and 3.5%. Many possible causes of failure of MVD have been discussed and investigated. One recognized cause of recurrent TN or HFS is failure of the prosthesis used to separate nerves from offending vessels. Autologous muscle, fascia, periosteum, Lyodura, cotton gauze, silicone sheets, Gelfoam, Surgicel, Dacron, Ivalon sponges, and Teflon have all been used. There are reports of complications with all of these materials, some being absorbed, and others becoming too hard and act as a "secondary missile," or cause adhesions.

An open-label 52-week clinical extension comparing duloxetine with routine care in patients with diabetic peripheral neuropathic pain.

Wernicke JF et al

Journal: Pain Med 8(6):503-513, 2007. 41 References
Reprint: Eli Lilly and Company, Indianapolis, IN 46285 (JF Wernicke, PhD, MD)
Faculty Disclosure: Abstracted by T. Newitt, who has nothing to disclose.

Diabetic peripheral neuropathic pain (DPNP) is typically a manifestation of distal symmetrical sensorimotor polyneuropathy, characterized by hyperalgesia, paresthesias, and allodynia. Ten to twenty percent of patients with diabetes may experience neuropathic pain. DPNP has been widely treated with tricyclic antidepressants (TCAs); however, their utility is limited by side effects. Other agents used to treat this disorder include antiarrhythmics, opioids, anticonvulsants, and selective serotonin (5-HT) and norepinephrine (NE) reuptake inhibitors

Duloxetine hydrochloride is a selective 5-HT and NE reuptake inhibitor that is relatively balanced in its affinity for 5-HT and NE reuptake inhibition. These inhibitors are involved in modulating descending inhibitory pain pathways in the brain and spinal cord. Altered levels of these neurotransmitters in these inhibitory pathways may contribute to the central sensitization and hyperexcitability of the spinal and supraspinal pain transmitting pathways, manifesting as persistent pain similar to that experienced by patients with DPNP.

Three randomized, controlled, 12-week trials confirmed the safety and efficacy of duloxetine 60 mg once daily (QD) and 60 mg twice daily (BID) in the management of patients with DPNP. Because patients with DPNP often require long-term management, therapeutic agents for DPNP must have satisfactory long-term

safety profiles. Extensions of the above 3 12-week DPNP trials were conducted to assess the long-term safety of duloxetine (with up to 65 weeks' exposure to duloxetine 60 mg BID or up to 52 weeks of routine care), and the impact of therapy on patient-reported health outcomes.

The trial was a 52-week randomized, open-label extension comparing duloxetine and routine care in patients with DPNP. The 65-week investigation included the previous 12-week acute therapy phase followed by a 1-week drug-tapering phase. Patients were randomized (2:1) to therapy with duloxetine or routine care. The routine care group was treated with therapies that the investigator and the patient believed gave the optimal benefit to the patient.

Safety of duloxetine was assessed by serious adverse events (SAEs), discontinuation rates, treatment-emergent adverse events (TEAEs) laboratory assessments, vital signs, electrocardiograms (ECGs), and electrophysiological assessments of peripheral nerves.

During the trial, an 11.2% duloxetine- versus 16.7% routine care-treated patients experienced ≥1 SAE. The most frequently reported SAEs for both groups together were cerebrovascular accident and diabetes mellitus hospitalization due to aggravation of diabetes, and these events were not considered to be drug-related. Fourteen (4.8%) patients discontinued due to any adverse event (including death). This included 11 (5.6%) duloxetine-treated patients and 3 (3.1%) routine care-treated patients.

A total of 157 (53.6%) patients reported at least 1 TEAE. The TEAE with a significant therapy-group difference, with patients in the duloxetine therapy group experiencing a higher percentage of events, was asthenia (5.6%) duloxetine-treated patients versus no routine-care treated patients.

The present results provide evidence that duloxetine has significant advantages on some health outcome measures, and appears to be safe for long-term therapy of patients with DPNP without significant psychiatric or medical comorbidities.