Neuromodulation News: Autumn 2012

A Message from the President

This autumn, Berlin has been on my mind as the Neuromodulation Society of the United Kingdom and Ireland joins the German Neuromodulation Society for the 8th annual joint meeting there in November.

Even more neuromodulators will converge on Berlin in June, for the INS 11th World Congress from 8 – 13 June 2013. The INS 2013 planning team expects nearly 2,000 attendees will gather at the Estrel Hotel, which overlooks a scenic canal of the Spree River. All sessions and lodging will be conveniently under one roof. The location is easily accessible to airports and attractions at the centre of town. The scientific committee has been hard at work, and I can truly say this Congress is continuing in the strong tradition of offering the most comprehensive breadth of presentations in all areas of neuromodulation from world leaders in their field.

Abstract submissions are welcome through to 14 January 2013, and top abstracts will be selected for oral presentation. Please visit the INS Congress home page at www.neuromodulation.com/ins-congress to register, watch for the preliminary program, and submit abstracts.

Speaking of our website, this presence has been an integral part of our growing effort to reach practitioners and the public at large as INS continues to pursue its strategy to become a one-stop resource for all things regarding neuromodulation. Many of you have contributed to this effort in ways large and small, to great success. Since our public education strategy was put in action in December 2011, visits to the INS website have increased 75%, the number of pages viewed per visit has increased 66%, and length of visits has increased 60%. Site visitors from around the world speak some 70 different languages, and can conveniently use a site button that offers a Google translate function. Overall there was a 10% increase in repeat visitors over the past 11 months, and an 18% decrease in site visitors quickly exiting.

Staying current with the context in which this discipline is developing is supported by daily news briefs that appear on the INS home page and are a popular feature we provide.

You can see at the Web Team tab on the INS site that two dozen of our members and leaders have contributed by reviewing and creating content. Opportunities remain to help update and expand the extensive collection of explanatory material that presents all facets of this growing field. INS continues to commission fact sheets that members can customize with clinic contact information, and welcomes explanatory images to share that show neuromodulation patient care around the world. (A sample photo release form is available in our site's Members-Only Section.)

In a feature for members only, we have two means to interact virtually through the Internet. The first is a series of interactive panel discussions on our website's Members-Only Section, moderated by experts, formally known as our Expert Panel. Spearheaded largely by Director-at-Large Konstantin Slavin, MD, the panels have been hosted by a list of leading luminaries in neuromodulation, from past INS presidents Giancarlo Barolat, MD and Elliot Krames, MD, to President-Elect Tim Deer, MD, and directors-at-large Eric Buchser, MD, and Dr. Slavin. From 23 January through 6 February 2013, Dr. Krishna Kumar has agreed to moderate a question-and-answer session on "Spinal Cord Stimulation Candidacy".

For more immediate consultation, INS has created an ongoing discussion group for members that can be accessed either via email or web-only, utilizing the services of Google group. So far, 150 members have subscribed to our Google group, formally called INSforum. Since that time, the service has been made more robust, and we hope to see it used in earnest in the weeks and months to come. To join us there, please visit https://groups.google.com/forum/#!forum/insforum and follow registration instructions.

I will close with best regards, and hope to see you in Berlin in 2013!

Dr Simon Thomson, MBBS, FFPMRCA
President of INS

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The United Kingdom Neuromodulation Database Project – What is the Progress and Where Are We Headed?

An Update from Dr. Simon Thomson, MBBS FFPMRCA

Last month, a full steering group met with stakeholders regarding development of a national neuromodulation database that can help bring neuromodulation procedures into mainstream medical practice.

A vision of the benefits of planning ahead to coordinate gathering quality information drove creation of this initiative. Already, physicians from different medical backgrounds are using neuromodulation broadly to address a wide variety of chronic diseases. Meanwhile, there are increasing numbers of manufacturers, each with an increasing diversity of product ranges.

The annual number of newly implanted patients is steadily (albeit slowly from a low base) increasing. A rough estimate suggests that there are 3,000 to 3,500 new neuromodulation implants (spinal cord stimulation [SCS], sacral nerve stimulation [SNS], intrathecal drug delivery [ITDD] pumps, vagal nerve stimulation (VNS), motor cortex stimulation (MCS) and deep brain stimulation [DBS]) in England and Wales. Healthcare payers are starting to demand more information on device performance, safety and efficacy. Existing National Health Service databases have data numbers of procedures. On analysis of this data it is apparent that it is of insufficient quality to determine if patient procedure code refers to a trial, implant or revision procedure. Furthermore little is known about indications, implant centre performance, long-term efficacy, explantations, device performance, and complications. Finally in case of a product recall few implant centres are able to trace in which patient each device had been fitted.

There are many medical device databases that are in use. Each was introduced for different reasons, but usually after some mishap. This is clearly illustrated by the issues that arose from the awareness of hip joint replacement failures, metal on metal hip joints, mechanical cardiac valve failure and even silicone breast implants.

A national neuromodulation database will fulfill many functions, but it is NOT an electronic medical record. To be successful it has to have clear objectives and be friendly to the user so that it will be seen as helpful rather than a chore.

There are many stakeholders, not least those that represent implanters Faculty of Pain Medicine, (FPM), Society of British Neurological Surgeons (SBNS), neuro-urology, colorectal but also referrers (e.g. rehabilitation medicine, neurology, cardiology, general practice), National Institute of Clinical Excellence (NICE) (interventional procedures), Medical and Healthcare Products Regulatory Agency (MHRA), National Commissioning Board (NCB, NHS payer), Healthcare Quality Improvement Partnership (HQIP, quality improvement), Association of British Healthcare Industries (ABHI, manufacturers) and patients.

Neuromodulation Society of UK and Ireland (NSUKI) and I have led on this project. The last three years has been spent building a prototype for SCS, ITDD for pain and spasticity and piloting it in a number of test sites. Over the last year these sites have collected data. Outputs of this data have been presented and appear to have convinced many stakeholders that this is a necessary and worthwhile project. The problem being, many want the data but few wish to pay for the whole database project.

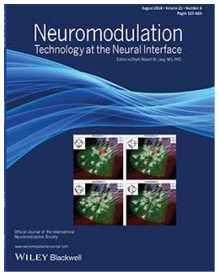
NSUKI have negotiated with all manufacturers of devices who have each provided NSUKI with an unrestricted grant over two years. NSUKI are commissioning National Institute of Cardiovascular Outcomes Research (NICOR) based at University College London to carry out the work. NICOR run many databases and have much expertise in managing data security, interactivity with other databases and working with medical societies. Indeed their chief designer, Dr. David Cunningham, in his own time created our functioning prototype, so in many ways a lot of work has already been done.

On the 15th October 2012 the full neuromodulation database steering group met for the first time in London. All invited stakeholders attended. A dataset group was created to fine-tune the existing data fields. The dataset was expanded to include occipital nerve stimulation for chronic headache and peripheral nerve field stimulation (PNS) for chronic low back pain specifically. The dataset group have included fields to collect all PNS activity.

Once the pledged grants have been collected NSUKI will enter into an agreement with NICOR to complete the work. A data management group will be created to clean and handle the data. A governance group will be created to help deal with potential conflicts of interest and to help enforce participation and if really necessary advise on how to deal with outliers. A research and publication group will be created to manage outputs and publications.

A really exciting opportunity is the linking of this database with other databases. For example, with the Clinical Practice Research Database (CPRD) link we will be able to track resources used by our patients before and after implantation.

Abstract Deadline:
Jan. 14, 2013



Now MEDLINE-Indexed!

Finding a solution to the funding of this database and project is one of the next steps. I am meeting the Chief Executive of HQIP. It is hoped that the Department of Health will resource and empower HQIP to provide the direct finance for existing and new databases. We hope that the neuromodulation database will be one of them.

During 2013 we will have a web-based secure database for all patients implanted with SCS, PNS and ITDD. I hope that the database will bring added value to all implanters. To date all those that I have discussed this with have expressed an interest in taking part. It is likely that commissioners will expect participation and that designation criterion of implanting centres will include national database participation.

The next phase will be to negotiate with the other various medical societies to use our portal for their data collection. So in addition to SCS, PNS and ITDD for pain and spasticity we will also have DBS, vagus nerve stimulation (VNS), motor cortex stimulation (MCS), and SNS data collection.

Implanters will be able to search for patients, serial number, product, diagnosis, year of procedure. They will collect baseline and routine follow-up data as well as add to the data at each future operative event. The dataset will be a system of easy-to-use drop-down menus with a minimal requirement of data fields but options for extra data collection fields if that implanter wishes. It will provide automatic outputs of patient demographics, activity, outcomes and complications. This will be confidential to the implanter and can be compared to an anonymous peer group. The research and publication group will create reports under the guidance of the governance board. Manufacturer-sensitive information (such as market share) will only be published for that manufacturer. Device complications will be notified to the manufacturer.

The output data will give real information on the long-term effectiveness of the modalities and will also track device performance. If this can be coupled with CPRD the potential for useful insights into cost-effectiveness of neuromodulation across the spectrum of indications will be profound. We will know which commissioning groups are commissioning sufficiently and if not, we can find out why. A similar database was created for implantable defibrillators after its NICE technology appraisal. Now it is thought that 95% of those that require ICD receive it. Contrast that figure with failed back surgery syndrome (FBSS) patients whose health-related quality of life can be transformed by more cost-effective treatment with SCS where less than 10% actually receive it.

This database will provide the data to help drive neuromodulation into mainstream healthcare.

Dr. Simon Thomson MBBS FFPMRCA
President of INS
NSUKI member

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Spinal Cord Stimulation in Patients Suffering from Critical Lower Limb Ischemia

G. Colini Baldeschi, MD, FIPP
Secretary, International Neuromodulation Society Italian chapter, 2010-2013
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Rome, Italy

Introduction

Chronic critical limb ischemia (CLI) is a serious, painful peripheral arterial disease defined by the presence of ischemic rest pain, non-healing wounds, or gangrene. Pain can be acute or chronic, and is divided into: 1) vascular pain, which originates from the vessel wall; 2) somatic pain, related to tissue ischemia; and 3) nerve pain, caused by ischemia of the nerve trunks. Chronic pain is generally mixed nociceptive pain (the peripheral nociceptors generate an action potential that propagates along the fibers to the central nervous system, and release into the surrounding environment vasoactive neuropeptides such as substance P, somatostatin and CGRP, which contribute to the state of neurogenic inflammation), and neuropathic pain due to ischemic degeneration of the nerves.

The severity of this condition is confirmed by a peer-reviewed summary of 19 studies, published in 2000, that found that within six months of initial treatment, 20% of CLI patients had died from various causes, 35% were alive with amputation, and 45% were alive without amputation.[1]

Interventional Pain Treatments

A number of interventions are used to treat the pain of CLI:
• Sympathetic blockade (Reid, 1970)
• Sympathectomy (Adson & Brown, 1925)
• Epidural analgesia (Gutierrez, 1935; Harger, 1941)
• Spinal cord stimulation (SCS) (Cook, 1973)

Target of the Therapy

Therapy for CLI has several goals:
• Improve the quality of life
• Reduce swelling from a dependent position
• Increase the pharmacological action
• Reduce the intake of drugs
• Improve local perfusion

Indications for Spinal Cord Stimulation

Patients may be referred to SCS when they have arterial occlusive disease stage III-IV (according to Fontaine[2]), are unsuitable for surgical revascularization and not responding to medical therapy. Their diagnoses may be such conditions as diabetic neuropathy associated with arterial occlusive disease, Raynaud's Syndrome, or vasculitis.

What do we mean by "SUCCESS"

• Reduction of at least 50% of ischemic pain
• Limb salvage or the reduction of the extension of the amputation

Patient Selection

Criteria for referring a patient with peripheral vascular disease to SCS include:
• More conservative therapies have failed or are not feasible
• Further surgery is not indicated
• The patient is not suffering from drug addiction
• The patient is suitable for treatment with SCS
• The patient does not suffer from psychological disorders
• There are no major contraindications (coagulopathies, sepsis, etc.)

Possible Spinal Cord Stimulation Mechanisms

Several explanations have been proposed regarding the mode of action of SCS:
• Gating mechanism
• Modulation of neural transmission of electrochemical information
• Orthodromic impulses via the brain stem may activate descending inhibitory tracts
• Modulation of sympathetic nervous system
• Release of neuromodulators and neurotransmitters
• Reduced dorsal horn excitability
• Increased GABA levels
• Induced adenosine release
• Decreased release of excitatory amino acids: glutamate and aspartate

Conclusion

Spinal neuromodulation is an effective therapy option in the management of patients affected by non-reconstructable chronic critical limb ischemia.

Annotated References

1. Amann W, Berg P, Gersbach P, Gamain J, Raphael JH, Ubbink DT, et al. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS) Eur J Vasc Endovasc Surg. 2003;26:280-286.

> SCS treatment of non-reconstructable critical leg ischemia provides a significantly better limb survival rate compared with conservative treatment. Patient selection based on TcpO2 and the results of trial screening further increase the probability of limb survival after SCS therapy.

2. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischemia. Cochrane Database of Systematic Reviews 2005.

> There is evidence that SCS is better than conservative treatment alone to achieve amputation risk reduction, pain relief and improvement of the clinical situation in patients with non-reconstructable chronic stable critical limb ischemia.

3. Ubbink DT, Vermeulen H. Spinal Cord Stimulation for Critical Leg Ischemia: A Review of Effectiveness and Optimal Patient Selection. Journal of Pain and Symptom Management 2006;31(4):S30-S35.

There was an 11% lower amputation rate after 12 months compared to those treated with optimum medical treatment. In addition, SCS patients required significantly fewer analgesics and showed a significant clinical improvement.

4. Gersbach PA, Argitis V, Gardaz JP, von Segesser LK, Haesler E. Late outcome of spinal cord stimulation for unreconstructable and limb-threatening lower limb ischemia. Eur J Vasc Endovasc Surg 2007 Feb 9.

In chronic critical limb ischemia patients the beneficial effects of SCS persist far beyond the first year of treatment and major amputation becomes infrequent after the second year.

5. Colini Baldeschi G., Carlizza A. 2011. Spinal Cord Stimulation: Predictive Parameters of Outcome in Patients Suffering from Critical Lower Limbs Ischemia. A Preliminary Study. Neuromodulation 2011; 14: 530–533.

Patients affected by non-reconstructable chronic limb ischemia can benefit from SCS not only in terms of relief from their ischemic pain, but also of wound healing and limb salvage. Pain relief is important in itself, as well as being correlated to limb salvage. As a matter of fact, tissue perfusion can be improved by the consequent reduction of edema by pain-relieving posture, and of reflected sympathetic vaso-constriction, and by greater patient mobility. The positive effect of SCS may be boosted by the selection of patients on the basis of local microcirculatory conditions, bearing in mind that microcirculatory perfusion deficit is the last cause of tissue loss. This study highlights the importance of transcutaneous oximetry with postural testing, a good outcome being indicated by a Δ TcPO2 of greater than 15 mmHg, but also by an absolute dependent limb value of ≥20 mmHg. These indicators suggest that even patients with baseline TcPO2 values of less than 10 mmHg can be “recovered” if they still have sufficient microcirculatory reserve capacity.

Footnotes:

1) Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg. 2000;31(1 pt 2):S1–S296.

2) In stage III peripheral arterial disease, patients experience pain at rest, especially at night when the patient is lying down, diminishing the effect of gravity on circulation; in stage IV disease, patients have ischemic ulcers or gangrene (which may be dry or humid).

Fontaine R, Kim M, Kieny R. Die chirurgische Behandlung der peripheren Durch-bluntungsstorungen. Helvetia Chirurgica Acta 1954; 5/6: 199-233.

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Medical Device Regulation Proposals in U.S., China and India

INS leadership was among stakeholders commenting on the FDA's proposals for medical device postmarket surveillance. The comment period ends Nov. 16. Under 2012 law, the FDA must expand its Sentinel System to include medical devices. During the same period, China and India were reported to have made moves regarding medical device regulation, too.

The FDA in September issued a four-part proposal in the Center for Devices and Radiological Health’s (CDRH) report, Strengthening Our National System for Medical Device Postmarket Surveillance: 1. Establish a unique device identification system and promote its incorporation into electronic health information. 2. Promote the development of national and international device registries for selected products. 3. Modernize adverse event reporting and analysis. 4. Develop and use new methods for evidence generation, synthesis and appraisal.

The FDA wants to conduct active surveillance in near real-time using routinely collected electronic health information containing unique device identifiers, quickly identify poorly performing devices, accurately characterize real-world clinical benefits and risks, and facilitate development of new devices and new uses through evidence generation, synthesis and appraisal.

Medical device postmarket surveillance presents unique challenges compared to drugs and biologics, according to the CDRH, due to the great diversity and complexity of medical devices, the iterative nature of medical device product development, the learning curve associated with technology adoption, and the relatively short product life cycle.

The FDA sought domestic and foreign stakeholders including the medical device industry, health care providers, patients, academia, third-party payers, hospitals and other health care facilities, health care data

holders, and other government agencies.

Elsewhere, China's State Food & Drug Administration released instructions that will require Chinese labels or packaging marks on foreign medical devices as of April 1, 2013, according to an Oct. 9, 2012 report by HealthpointCapital.

The report added that, India's Drug Controller General of India has begun a special effort scrutinizing manufacturing processes for discrepancies, and is considering introducing a bill this winter on drugs, cosmetics and medical devices, due to a growing consensus that a separate governing law is needed for medical devices.

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Members-Only Section Adds the Beginnings of an Image Bank

A number of images available for members' use have been gathered in an online image bank, and the INS welcomes your submissions (see the photo release form on that page after logging in with your Username and Password). Not only may the repository be a helpful resource for members' potential use in slides or in poster sessions, but also additional explanatory visuals may be published on the INS website to show the diversity of patient access around the world.

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Year Against Visceral Pain is the Latest Global Initiative Endorsed by INS

The INS endorses efforts of related organizations to raise awareness of conditions that may be addressed through neuromodulation. One such effort is the Global Year Against Visceral Pain that was initiated by the International Association for the Study of Pain (IASP) in October. Previously the INS announced endorsement of the ongoing Age of the Brain, which has been spurred by the European Brain Council.

The IASP believes that many forms of visceral pain are diseases in their own right and require focused and specific therapies, which is a view that is similar to the perspective on chronic pain held by many neuromodulation practitioners.

The IASP notes that visceral pain associated with ailments such as gallstones, acute pancreatitis, acute appendicitis, and diverticulitis are the most common reasons for visits to outpatient and inpatient gastrointestinal clinics, but visceral pain may also include chronic chest pain, bladder pain, gynecological pain, and pelvic pain. Up to 25% of the population report visceral pain at any one time, leading to substantial health care costs.

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Closed-Loop Stimulation System for Epilepsy Fact Sheet Posted

The latest web content about neuromodulation by members of the International Neuromodulation Society concerns the emergence of closed-loop stimulation to treat medically refractory epilepsy. The material includes explanations, illustrations and extensive references to research articles.

The material was prepared by Chengyuan Wu, MD, MSBmE, of the Thomas Jefferson University Hospital Department of Neurosurgery in Philadelphia, PA. Along with Ashwini Sharan, MD, who directs the Functional Neurosurgery Division there, Dr. Wu also authored a review in October in *Neuromodulation: Technology at the Neural Interface*, "Neurostimulation for the Treatment of Epilepsy: A Review of Current Surgical Interventions" (doi: 10.1111/j.1525-1403.2012.00501.x).

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INS Members Raise Awareness in the News

In May, Parig Patil, MD, and his patient appeared in a three-part series on The Doctors to discuss her deep brain stimulation surgery for Parkinson's disease.

In more recent months, there have been several other relatively high-profile news pieces related to neuromodulation.

In September, Sean Mackey, MD, PhD, chief of the Pain Management Division at Stanford University, was interviewed in the *Los Angeles Times* in an article about links between brain-mapping neuroscience research and eventual therapy refinements.

That same month, Ganesan Baranidharan, MD, a consultant in pain medicine at Leeds Teaching Hospitals NHS Trust in the UK, discusses using high-frequency spinal cord stimulation in an article in the *Daily Mail* that profiles a patient with failed back surgery syndrome.

In Argentina, meanwhile, more than one news article covered the establishment of a regional neuromodulation program in the province of Buenos Aires, called unique in all of Latin America, which involves Argentinean Neuromodulation Society chapter president and INS treasurer Fabián Piedimonte, MD, and Juan Carlos Andreani, MD, vice president of the Argentinian chapter (Sociedad Argentina de Sane Neuromodulación, SANE).

These examples are just a few of the members whose work was covered in the news recently. Many of the examples are collected in the INS newsroom page, at http://www.neuromodulation.com/newsroom#in-news.

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Mark Your Calendars

The next online, moderated question-and-answer session for practitioners will be Jan. 23 – Feb. 6, 2013, with Krishna Kumar, MD, founding president of the Canadian Neuromodulation Society, leading research author, and recipient of the INS's first Giant in Neuromodulation award.

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