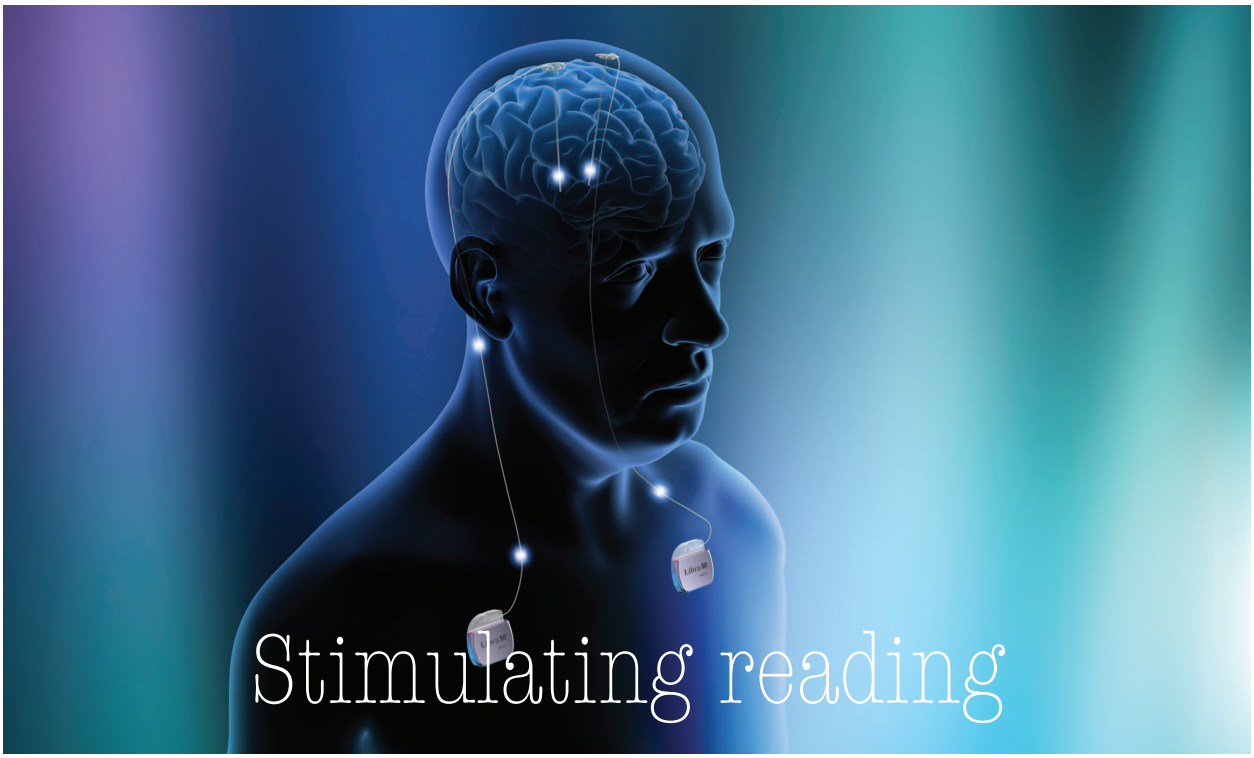


© St. Jude Medical Inc

Stimulating reading

Dr Simon Thomson, of the International Neuromodulation Society, details a much-overlooked set of treatment procedures that can revolutionise care for chronic illnesses…

For advanced economies, the management of chronic illness, and in particular of chronic neurological illness, is set to become the major health priority for the next two decades. A family of therapies that treat the nervous system itself, known collectively as neuromodulation, is expected to play a bigger role in healthcare delivery than previously thought.

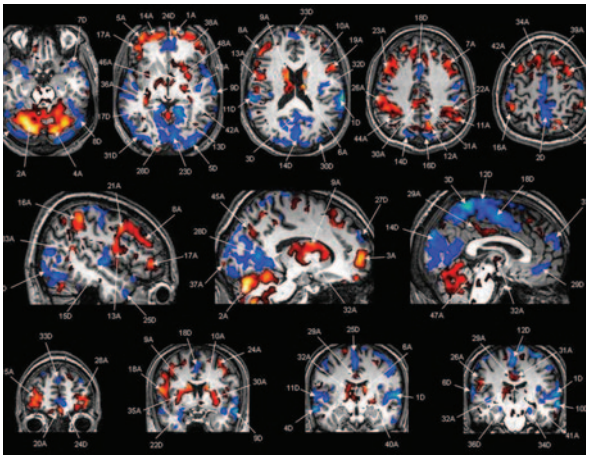
Healthcare priorities in the last two decades have emphasised cancer and cardio respiratory care, and major advances in health policy, health technology and implementation processes have led to patients living longer and better lives. As populations live longer with chronic disease, however, healthcare priorities will need to shift. This is driven by changing needs, such as the somewhat paradoxical increase in prevalence of some chronic pain conditions such as angina, and also in response to changing capabilities and standards of care.

Pain is among the most common reasons for healthcare utilisation, and is becoming viewed as yet another vital area for doctors to assess. This is no surprise, since studies indicate chronic pain affects 17% of all Europeans. 8% of those complaints are attributable to neuropathic pain, which is caused by disease or damage to the nervous system itself. Medication only adequately controls symptoms in about one-third of neuropathic pain cases, and so complaints are often on-going.

People living with ongoing intractable neuropathic pain have poor health-related quality of life, with an impact seen upon employment, healthcare usage, mental health and relationships – effects that create an expense for society to bear. Many neuropathic pain patients, however, can be helped with the integration of neuromodulation treatment into a well organised suite of usual care and – importantly – as a replacement for revision spinal surgery. Despite superlative surgical skill, this surgery not only puts the patient through a gruelling operation and recovery, but historically has low success rates, as well as requiring an intensive expenditure of healthcare resources.

Shown to be effective for neuropathic pain, neuromodulation using spinal cord stimulation (SCS) is a pain-relief approach that is reversible, and can be trialled in advance by the patient. SCS applies mild electrical stimulation to nervous system networks through miniaturised electrode arrays implanted above the spinal dura. In popular use since the 1990s, SCS is frequently a minimally invasive approach that draws upon and extends experience with medical devices that treat heart rhythm problems through the use of cardiac pacemakers and defibrillators.

The family of neuromodulation therapies is not limited to one type of stimulation approach. Neuromodulation generally is defined as interaction with the central, peripheral or autonomic nervous system for therapeutic effect, by means of targeted electrical stimulation or pharmacological delivery from implanted devices. Thus, cochlear implants – an established means of stimulating the auditory nerve for the hard-of-hearing, bypassing damaged sensory cells of the inner ear – is one such therapy. Neuromodulation therapies aid appropriately-selected patients who suffer from diverse conditions such



© Neuromodulation: Technology at the Neural Interface

Stimulation of the occipital nerves, located just under the skin at the back of the head, shows effects on other brain structures that may mediate pain, such as migraine. Functional magnetic resonance imaging in a healthy subject reveals areas of activation (red) and deactivation (blue) during stimulation. Following a randomised controlled double-blind clinical study, occipital nerve stimulation for managing the pain and disability of chronic intractable migraine was cleared for marketing in Europe in 2011

as Parkinson's disease, epilepsy, spasticity, chronic critical limb ischemia, and urinary or faecal incontinence.

However, until potential candidates are able to access coordinated clinical care that includes neuromodulation, current management will usually result in many patients either being inadequately treated, or will impose a burden of treatment that is too great. Consider the development of extra-pyramidal complications of Parkinson's disease drug treatment, or invasive surgical procedures used for incontinence, and the attraction of neuromodulation is clear.

High quality data arising from clinical research of spinal cord stimulation is enough to encourage multidisciplinary specialists that costly and relatively risky spinal surgery should become a treatment of the past. The benefits do not stop there; continuous intrathecal baclofen is available to prevent and treat severe spasticity in multiple sclerosis, cerebral palsy and spinal cord injury. Additionally, faecal incontinence following birth trauma or urinary incontinence for the overactive bladder can be greatly improved following sacral nerve stimulation implant. All of these treatments are available to some degree in advanced economies such as the UK.

The National Institute for Clinical Excellence (NICE) develops internationally-recognised evidence-based guidelines on the most effective ways to diagnose, treat and prevent disease. In 2008, NICE published guidance on the use of SCS in refractory neuropathic pain that recognises its clinical and cost-effectiveness (TAG 159, 2008). As a result, NHS commissioning bodies are being encouraged to commission appropriately, since failure to do so may waste scarce NHS resources.

Despite this policy guidance, a surprising full third of all NHS primary care trusts fail to commission a single SCS procedure. Best estimates show 10 to 30 times more SCS procedures are needed to meet requirements. Meanwhile, patients are continuing to be managed with unnecessary surgery, medication or no treatment at all, which leads to poor health-related quality of life at greater overall annual healthcare costs.

Though there is as yet a lack of adequate cost-effectiveness evidence, SCS may also yield benefits for refractory angina pectoris. The condition creates persistent chest pain which cannot be managed using conventional approaches such as angioplasty, heart bypass surgery, and medication. Chronic cases will have lasted more than three months, with pain caused by insufficient oxygen reaching the tissue. It is estimated that about 50,000 patients are diagnosed each year in Europe with this disabling and distressing condition, which leads to frequent hospital visits and restriction of normal daily routines.

An NIHR-funded project has commenced that examines the feasibility of adding SCS to usual refractory angina management. At present there are three centres involved in the study: Refractory Angina Spinal Cord stimulation and usuAL care (RASCAL) in Basildon, Dudley and Middlesborough. Pain specialists and cardiologists have teamed up to recruit volunteer cardiology clinic patients who present with chronic stable angina. Study criteria require the condition persists despite optimal medication, and that revascularisation is either unfeasible or its risks are unjustified. The feasibility study opened in December 2011 and will last for 18 months. It is hoped that data from this carefully designed undertaking will inform the development of a national research programme following successful application for funding to the NIHR.

SCS can also be used in the treatment of ischemic pain. It is particularly important that vascular centres and pain centres work together to treat chronic critical limb ischemia, and to pursue randomised controlled clinical trials to determine its feasibility and cost-effectiveness.

Through clinical investigation and reasoned leadership, healthcare policies eventually change. However, once achieved, the implementation of change throughout the health economy is slow in fields as tradition-bound as medicine and health systems management prove to be.

Compared to cancer and cardio respiratory disorders, the uptake of new technology and even the most benign treatment paradigms, as illustrated by SCS, is extremely gradual. In the management of long-term conditions in particular, there may be ingrained resistance against change in medical attitudes toward treatment approaches. However, it is time to move neuromodulation from a therapeutic curiosity to its rightful place as an important part of the strategy to improve quality of life for patients and caregivers affected by chronic long-term conditions, while simultaneously producing a longer-term cost saving to the health economy.

Dr Simon Thomson
President
International Neuromodulation Society
Tel: +1 415 683 3237
ins@neuromodulation.com
www.neuromodulation.com