



INTERVENTIONAL PAIN MEDICINE AND NEUROMODULATION SERVICE

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1. Prevalence and Burden of Chronic Pain

Chronic pain is defined by the International Association for the Study of Pain (IASP) as pain persisting in excess of 3 months.

In 2003, a large survey called “Pain in Europe” was conducted in Europe by a company specialized in health care market research (Breivik et al, 2006). The objective of this study was to assess the prevalence of chronic, non-malignant pain, and its impact on people’s lives. 46,000 people from 16 countries were interviewed using Computer Assisted Telephone Interview. Around 3,000 subjects by country were interviewed. Country-level data were weighted (based on gender, age and bias due to telephone interview) to be representative of the population surveyed (adults only). **19% of adults in Europe experience chronic pain (pain for at least 6 months):**

Most of the published studies are consistent with these findings and are described below: (www.efic.org/about_pain.htm):

- Neuropathic pain (classically conceived) affects 25-50% of patients attending most pain clinics.¹⁴
- A study carried out in Catalonia (Spain) reported pain prevalence of 78.6% in response to a phone interview asking about any pain complaint experienced in the last 6 months, regardless of its intensity and duration.
- A postal survey in Sweden found that pain or discomfort, including problems of short duration, were reported by 66% of those questioned, with 40% reporting ‘obvious’ pain lasting more than 6 months.
- A broadly based epidemiological study of chronic pain in the Grampian region of the UK found that 50% of those surveyed reported chronic pain or discomfort, including 16% with back pain and 16% with arthritis. In 16% of those surveyed chronic pain was severe.
- Data from a study in Sweden indicate that spinal pain is very common among 35-45 year old men and woman and that it is related to marked limitations in lifestyle for approximately one fourth of those who experience pain.
- The findings of a study in the Netherlands indicate that chronic pain is also a common complaint in childhood and adolescence.

The Alberta Heritage Foundation for Medical Research published a Health Technology Assessment report in 2002 on the prevalence of

chronic pain (www.ahfmr.ab.ca/programs.html). They reviewed 13 analyses and concluded that overall, **chronic pain prevalence ranges vary from 10.1% to 55.2%**. When it comes to **severe chronic pain, prevalence rates are increasing with age: 8% in children, 11% in adults and 15% in the elderly**.

The identified prevalence in Ireland was 13% of the adult population as compared to 26% amongst the Polish population¹. It is estimated that there are approximately 585,000 chronic pain sufferers in Ireland with 36% of all households affected. These figures are replicated throughout the world with a prevalence rate of 17.5 % of males and 20% of females in Australia². The prevalence rose with advancing age reaching a peak of 31 % in the 80-84 year old group. Chronic pain is reported as moderate in 65% of sufferers and severe / intolerable in 35%. In 46 % of sufferers, pain is reported as being unremitting¹.

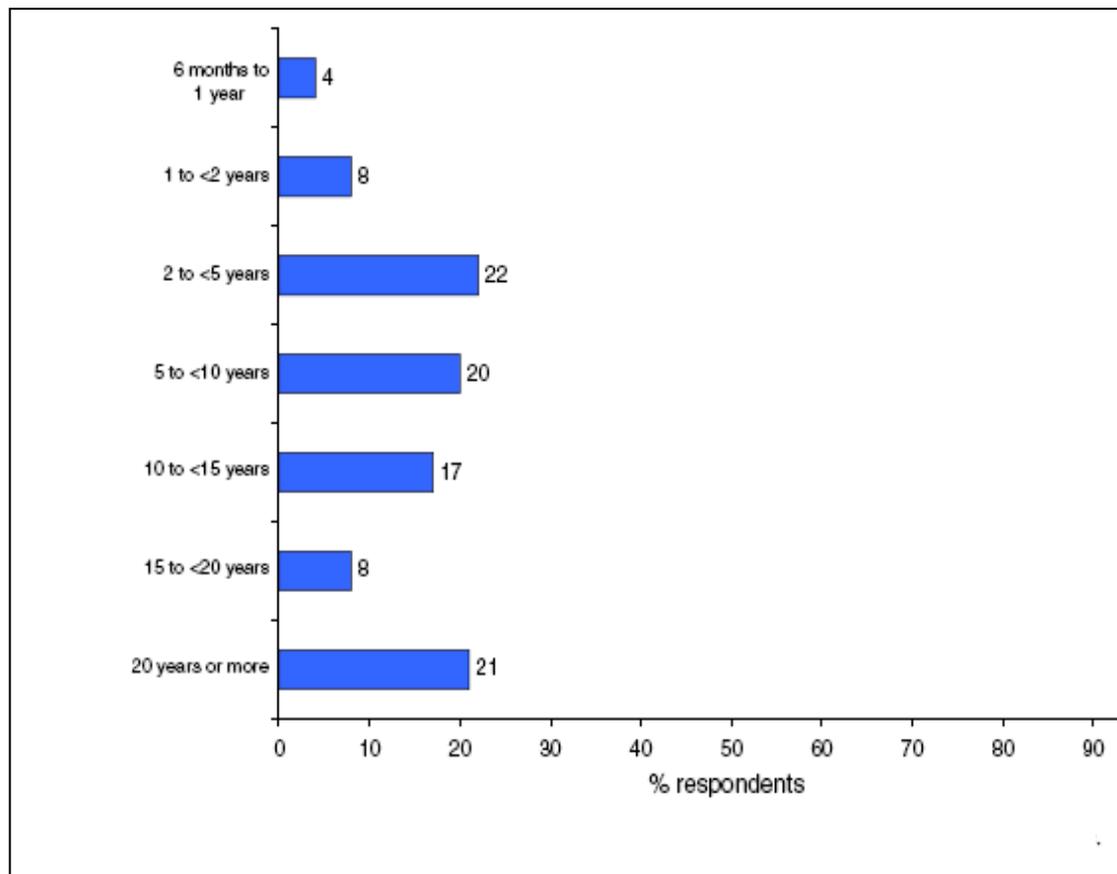


Fig 1: Duration of chronic pain of intensity > 5 on NRS pain intensity scale.

Chronic and recurrent pain has broad consequences on patients' life. Chronic pain is a complex problem, there is no hierarchy in this list,

which starts with the physical issues that maybe are the most obvious ones, making clear that the pain heavily impacts patients' behaviour:

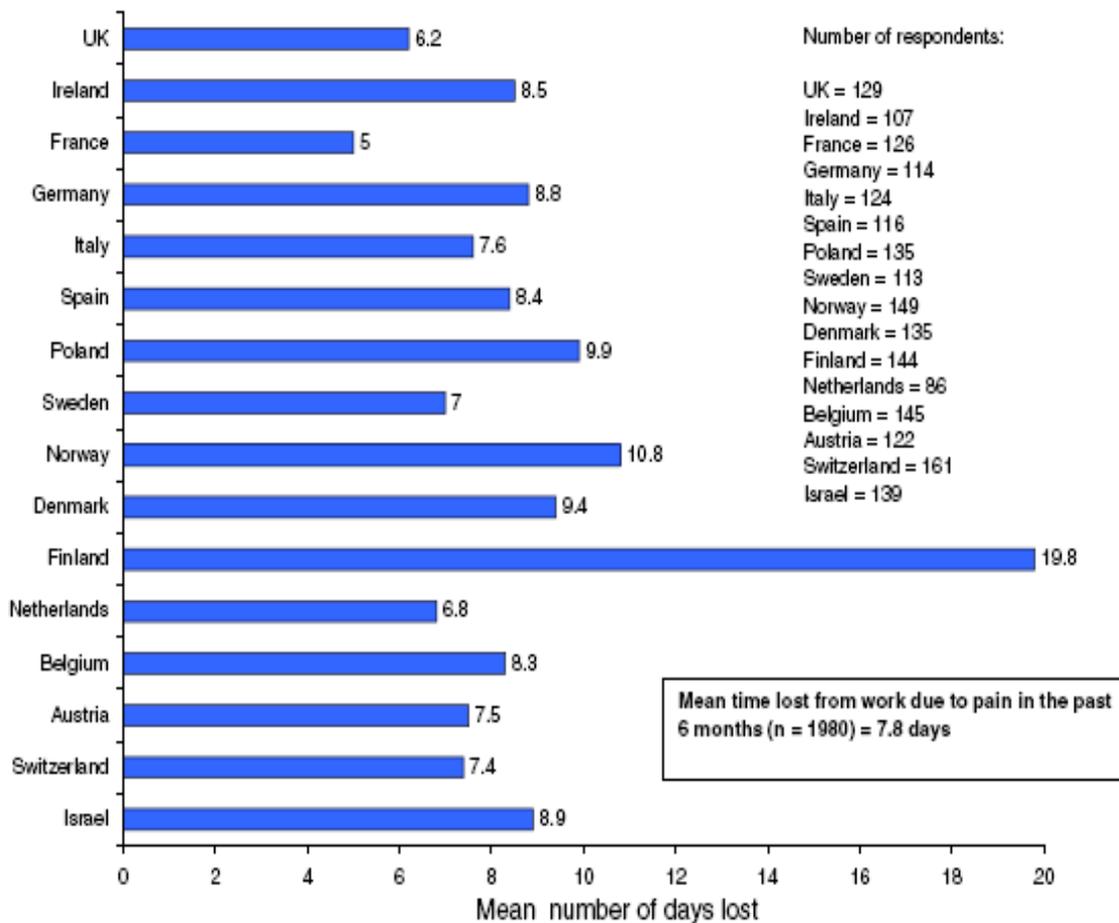
- Immobility and consequent wasting of muscle, joints, etc.
- Immune system depression and increased susceptibility to disease
- Disturbed sleep
- Poor appetite and nutrition
- Dependence on medication
- Over-dependence on family and other caregivers
- Overuse and inappropriate use of professional healthcare systems
- Poor performance on the job, or inability to work, disability
- Isolation from society and family, turning inwards
- Anxiety, fear
- Bitterness, frustration, depression, suicide

Chronic pain is associated with considerable social and economic costs:

A recent study in Finland found that, from a pool of 5,646 patient visits to primary healthcare services, 40% identified pain as the reason for their visit. One-fifth of patients reported having experienced pain for over six months. One quarter of the pain patients of active working age were receiving paid sick leave.

Chronic pain can be devastating for people's lives (Breivik, 2006):

- 20% have lost a job as a result of their pain
- 20% have been diagnosed with depression as a result of pain



Mean number of days lost during the last 6 months of full or part time employment in the 16 countries.

A study in the Netherlands found that musculoskeletal diseases are the fifth most expensive disease category regarding hospital care, and the most expensive regarding work absenteeism and disability (1.7% of GNP)³⁶. The total cost of neck pain in the Netherlands in 1996 was estimated to be US \$686 million.

A study of the socio-economic costs of pain syndromes in the UK estimates the **direct health care cost of back pain in 1998 to be £1.6 billion**. However, this direct cost is insignificant compared to the cost of informal care and the production losses related to it, which total £10.7 billion. Overall, back pain is one of the most costly of all medical conditions.

The impact of chronic pain should not, however, be viewed simply in economic terms. Chronic pain has a major detrimental effect on the quality of life of the millions of chronic pain sufferers, and their families, in Europe. **Without adequate treatment chronic pain sufferers are often unable to work or even to perform the simplest of tasks.** As a consequence, chronic pain patients often endure psychosocial as well as

physical hardship including poor nutrition and weight loss, decreased activity, sleep disturbances, social isolation, marital problems, unemployment and financial problems, anxiety, fear and depression.

Neuropathic Pain

Neuropathic pain results from a lesion in the peripheral or central nervous system. The estimated prevalence of *neuropathic* pain is 1.5% of the US population and up to 10% of all chronic pain is neuropathic in nature².

Neuropathic Pain Conditions

- 1) Failed Back Surgery Syndrome (with radicular pain)
- 2) Complex Regional Pain Syndrome (CRPS) Type I and II
- 3) Acute Herpes Zoster
- 4) Post Herpetic Neuralgia
- 5) Metabolic Peripheral Neuropathy:
 - a. Diabetes Mellitus (Type II)
 - b. Alcohol
 - c. HIV
- 6) Post surgical pain syndromes:
 - a. Post-mastectomy neuropathic pain syndrome
 - b. Post Thoracotomy pain syndrome
- 7) Occipital Neuralgia
- 8) Phantom Limb Pain
- 9) Central Neuropathic Pain
 - a. Multiple Sclerosis
 - b. Cerebrovascular Accident (Stroke)
 - c. Spinal Cord Injury

Optimal management of chronic / neuropathic pain requires a multifaceted approach using pharmacological /psychological and interventional techniques in a concerted effort to restore mental and physical function. ‘State of the Art’ medical knowledge now considers neuropathic pain to be a disease entity in its own right. As a consequence, neuromodulation by means of spinal cord stimulation, peripheral nerve stimulation, and intrathecal drug delivery have become critical components of effective management.

Persistent Cancer Pain

Goudas et al systematically reviewed the findings of epidemiological studies reporting on the prevalence and/or incidence of cancer pain published from 1982 to 2001.²¹ This review found that 2 large scale

epidemiological surveys were reported from 1996 through 2001. One study was conducted in Japan in 1987 and involved 35,683 hospitalized patients with cancer. It was found that, of **all cancer patients 32.6% were receiving some form of pain treatment. The prevalence of pain in terminal stage was in the range of 68 to 72%.**

The second large scale epidemiological survey was conducted in the US and reported by Barnabei et al.²² They studied a group of 13,625 patients with cancer aged 65 years and older and found that a total of 4,003 patients reported daily pain: In this group of patients 16% received acetaminophen or an NSAID, 32% a weak or “WHO level 2 opioid”, and **only 26% received a strong or “WHO level 3 opioid”.**

Four intermediate scale studies (from 1,000 to 10,000 subjects) were also identified by Goudas et al. Two studies were performed in the United States, one in Switzerland, and one in Germany. Cleeland et al in a US multi center study found that 36% of the 1,308 outpatients with metastatic cancer observed in the survey had pain severe enough to impair their ability to function. **42% of those with pain were inadequately managed. The survey conducted in Switzerland reported a prevalence of moderate to severe pain in 51% of the 1,640 subjects enrolled in the study.** The study completed in Germany observed 2,266 cancer patients. The majority of patients had pain caused by cancer (85%) or antineoplastic treatment (17%).

In 1997 Higginson et al reported that pain is present in 50% of cancer patients (all stages) and in 75% of patients with advanced neoplasms. (Goudas et al). **Each year more than 100,000 cancer patients experience pain at the time of death in England and Wales.**

Although cancer pain is managed better than it was 10 years ago, compelling evidence suggest that cancer patients are still not receiving adequate pain control.²⁵ **It has been reported that 5% to 15% of patients with cancer have pain refractory to medical management.**

In a prospective study of 2,266 cancer patients, localisations, aetiologies and pathophysiological mechanisms of the pain syndromes were studied.⁹

Most of the patients presented with multiple pain syndromes:

- 30% of the patients presented with 1 pain syndrome,
- 39% of the patients with 2 pain syndromes
- 31% of the patients with 3 or more distinct pain syndrome

85% of patients had pain caused by cancer. Pain was located in the following areas:

- 36% in the lower back,
- 27% in the abdominal region,
- 23% in the thoracic region,
- 21% in the lower limbs,
- 17% in the head,
- 15 % in the pelvic region.

2. Diagnostic Blocks

Low back pain is one of the most common pain complaints experienced by our population, and has become a major societal and health problem. It is the most frequent cause of activity limitation in people below the age of 45 years, the second most frequent reason for physicians' visits, the fifth most frequent cause for hospitalization, and the third-ranking for surgical procedures.¹ The overall lifetime prevalence of back pain exceeds 70% in all industrial countries. The consequences of this pain include loss of 1.4 working days per person / per year; 10-15% of all sickness absence is related to back pain.² Back problems are also responsible for 25% of all disabling occupational injuries, with an estimated 12 million people in the workforce with low back impairment, and 5 million with disability on the basis on back problems.¹

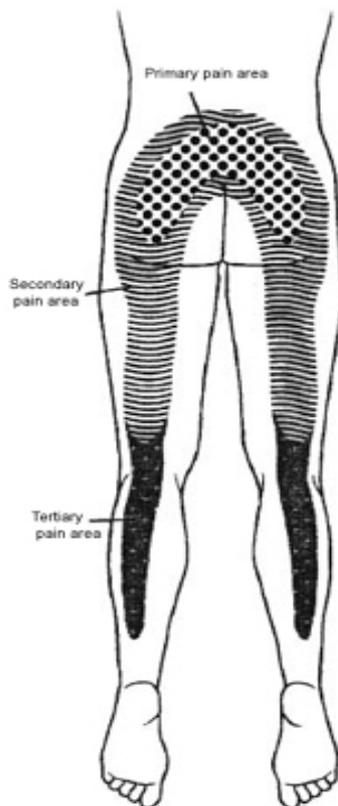
The exact etiology of low back pain is difficult to diagnose. This may be in part related to the complex structure of the spine. In the early 1900's, dislocation or distraction of the sacroiliac joint was felt to be a common etiology for pain.³ In 1911, Goldthwait postulated that "the peculiarities of the facet joints" were responsible for low back pain and instability.⁴ By the 1920's and 1930's, pathology in the facet joints was gaining ever more popularity as a possible cause of back pain, with introduction of the term "facet syndrome" by Ghormley in 1933.⁵ Many studies followed, focusing on this etiology for low back pain. In 1934, however, Mixter and Barr⁶ first described herniation of the intervertebral disc as a cause for low back pain and sciatica. This changed the entire focus of treatment for low back pain for the next 30-40 years. It was only as practitioners began to realize that lumbar laminectomy and nerve root decompression were not resulting uniformly in relief of low back pain that attention once again turned to other potential etiologies of low back pain.

Potential sources for low back pain include the supraspinous ligament, the lumbar paraspinal muscles (only after prolonged pressure or stretching,

however), the posterior longitudinal ligament, the vertebral body end plates, and the facet joints.¹ Hirsch first demonstrated in 1963 that low back pain could be produced or reproduced by injecting hypertonic saline in the region of the facet joints. Mooney and Robertson confirmed this with intra-articular injections of hypertonic saline in 1976.

Lumbar Facet Syndrome

Since the introduction of the term by Ghormley in 1933, the lumbar facet syndrome has come to be used with patients whose pain is primarily in the low back. There is frequently referred pain into the groin, hip or thigh, and occasionally even below the knee, although not into the foot. (See Figure 3) Patients characterize the pain as a dull, deep ache which may be difficult to localize. There may be a history of sudden "catching" or "locking" of the back, and many patients report increased symptoms with lumbar extension. Pain is usually aggravated by prolonged standing, and occasionally by prolonged sitting. There is no clear diurnal pattern to the pain. Some patients experience their pain as worse in the morning, associated with stiffness, while others feel worse at the end of the day, after prolonged activity. This pattern is usually typical for each patient, however. There is typically no change in pain with Valsalva manoeuvres.



Physical examination frequently reveals tenderness in the paraspinal region, presumably over the facet joints. Range of motion may be decreased in all planes, but typically extension and extension with rotation are most affected, and these movements will frequently reproduce a portion of the patient's pain. Neurological findings are typically absent, and straight leg raising does not produce radicular stretch signs, although it may increase low back pain.

Radiographic evidence is of equivocal utility. Degeneration of the facet joints may be noted on plain films or magnetic resonance images, but

often there is no obvious pathology at all. Interestingly, those joints appearing most degenerating on such films may actually be least responsible for pain production, which may be secondary to the fact that movement is completely restricted at that segment.

Procedure:

The primary diagnostic test for determining if facet joint pathology is causing or contributing to low back pain has been the injection of local anesthetic into the joint or onto the medial branch of the dorsal primary ramus. Typically, 1-2 ml of local anesthetic is instilled into the joint in questions; larger volumes will cause rupture of the joint capsule, with subsequent extravasation of solution to other potential pain-generating tissues, which makes interpretation of the injection results problematic. The dorsal ramus medial branch is typically blocked with 1 ml of local anesthetic at the superior aspect of the root of the transverse process at the level in question. Blockade of the nerve root may occur with larger volumes or improperly positioned needles.

3. Radiofrequency Facet Denervation (RF Rhizotomy)

Lumbar zygoapophyseal (facet) joints are considered to be responsible for 15-40% of chronic back pain. Each joint has dual innervation from the dorsal rami that pass immediately above and below each joint. Cervical facet mediated pain may present as localised cervical pain or as cervicogenic headache. Accurate diagnosis of facet mediated pain should be established by means of double blind block of the medial branch of the dorsal rami prior to performing RF neurotomy.

Procedure:

This technique utilises a radiofrequency generator system to generate a low energy, high frequency alternating current to produce a small heat lesion surrounding the non-insulated electrode tip. It also has a nerve stimulator to localise the nerve. The lesion is generally ellipsoidal and the dimensions vary depending on the length of the non-insulated tip, current and time of use. Once the needle is advanced to the target neural tissue guided by fluoroscopy, sensory (50 Hz) and motor (2Hz) testing is performed to further ensure proper needle tip positioning. Then, a small volume of local anaesthetic is injected for local anaesthesia before the tip is heated to 80° for 60 seconds to generate the lesion. Appropriate patient selection is of paramount importance, it is reported that with controlled

nerve blockade as a diagnostic tool, over 80% of treated patients can expect in excess of 60% pain relief at 12 months following RF lesion.

3. Spinal Cord Stimulation (SCS)

Introduction

Spinal cord stimulation (SCS) or peripheral nerve stimulation delivers a low-voltage electrical stimulation to block the sensation of pain. SCS treats pain that is neuropathic in origin. Neuropathic pain results from actual damage or altered function of nerves due to trauma, scar tissue, disc diseases, and nerve entrapment syndromes. The spinal cord stimulation system consists of three major devices: the lead, the extension and the power source. Available equipment varies by system. The goal of stimulation therapy is to reduce chronic pain by as much as possible. Stimulation therapy can be tailored non-invasively to meet changing patient needs. Patients require their own unique stimulation parameters to suppress pain, and stimulation requirements may change over time. The therapy is reversible and nondestructive.

Clinical Applications of Spinal Cord Stimulation (SCS)

A wide range of neuropathic pain conditions respond well to SCS in carefully selected patients refractory to other therapies. Pain relief in the order of 50% has been demonstrated in a range of conditions including failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), peripheral nerve and plexus injuries, segmental pain post spinal cord injury and post-amputation pain (North and Wetzel, 2002).

Failed Back Surgery Syndrome (FBSS)

Case-control studies suggest in response rates of varying between 40 and 88% for FBSS. A review of 39 case control studies over a 28 year period demonstrated 59% response rate (range: 15%-100%). Complications were reported in 42% of patients mostly due to problems with early SCS systems. It was identified that the majority of patients treated with SCS for FBSS are satisfied with the procedure and would recommend it to others suffering from the same condition ⁶. It is also suggested that SCS may be superior to re-operation in FBSS⁷.

In a series of reports, North et al have described their use of SCS in persistent back and leg pain. Recently, they published a prospective randomised trial comparing SCS to re-operation in 50 patients with persistent radicular pain following lumbo-sacral spine surgery⁸. When assessed by an independent third party, SCS was found to have greater “success” (>50% pain relief and satisfaction with treatment), in 47% of those randomised to SCS vs 12% in those randomised to surgery. Crossover to alternative therapy was more common in the surgical group than those who received SCS initially. While significant methodological issues are evident in this trial, it does represent a common clinical dilemma, namely radicular pain persisting after lumbosacral spine surgery. These patients commonly elect to undergo further surgery and this trial demonstrates their poor response to such a strategy. This patient population form the basis for the clinical diagnosis of Failed Back Surgery Syndrome (FBSS), the most commonly cited indication for SCS implantation. Possible pathology in this group includes arachnoiditis, epidural fibrosis, and ischaemic neuropathy, while they also commonly describe persistent low back pain (axial pain) in addition to the radicular component (which is commonly the target of SCS).

The Australian perspective is given in a prospective study of 29 patients followed up over a two year period⁹. Pre-operative psychological evaluation was recommended (not essential) and analgesia (>50%) in response to trial stimulation was required for permanent implantation, with the majority of patients having back pain and/or radicular leg pain (n=23). 56% reported marginal to excellent analgesia at two years. Functional improvements were noted for sleep, sitting, and home and occupational duties.

Complex Regional Pain Syndrome Type I (CRPS-I)

The efficacy of SCS in cases of Complex Regional Pain Syndrome Type 1 (CRPS-1) has been examined in a systematic review¹⁰, with the paucity of well controlled trials notable. Only one randomised controlled trial and one prospective case series were considered relevant, but both demonstrated benefit in terms of pain relief. Patients with CRPS of greater than 6 months duration were randomised 2:1 to a trial of SCS plus physiotherapy or physiotherapy alone, with results reported on an intention to treat basis¹¹. Permanent implantation only occurred in two thirds of trial recipients, and required >50% reduction in self-reported pain scores on a VAS scale or “much improved” on a perceived benefit scale. Results at 6 months were reported, with 20 of 36 classified as successful (56%), with 18 of these having a >50% VAS pain score reduction. However, if one only considers those who had a successful

trial, the results are impressive with 20 of 24 gaining benefit at 6 months post-implantation. The quite stringent SCS trial criteria with resultant relatively low permanent implantation rates in this study contribute to the observed efficacy of permanent implantation. Although quality of life measures demonstrated improvements in those randomised to SCS, there were no functional improvements reported. Those receiving physiotherapy alone reported an increase in their VAS pain scores, with longer-term follow-up of those randomised to this trial reporting maintenance of benefit in those receiving SCS and further increases in pain score in those not receiving the therapy¹⁰. Number needed to treat (NNT) for “much improved” with SCS was calculated as 3. Similar efficacy was identified at one year post-implantation¹². On average, 34% of patients in the population studies suffered a stimulator-related adverse occurrence. The authors conclude that further studies are required to fully assess the efficacy of SCS relative to other therapies in chronic pain states. Nevertheless the consensus of pain clinicians is that SCS has a valuable role in properly selected patients as part of a multimodal approach¹³.

Cardiovascular Disease

Since 1985, SCS has emerged as an effective modality for the treatment of refractory angina pectoris. SCS has been demonstrated to significantly reduce the frequency of angina episodes, nitro-glycerine consumption and Canadian Cardiovascular Society angina class¹⁴. It has also been shown to reduce the duration of hospitalisation and cost of hospital care. The total cost of SCS implantation was recoverable within 16 months. Recently, the long-term efficacy of this modality in the management of refractory angina pectoris has been demonstrated with SCS reducing the severity and frequency of angina attacks, increasing exercise tolerance and walking duration.

Peripheral Vascular Disease

SCS was first utilized in the management of peripheral vascular disease (PVD) in 1976 and was demonstrated to facilitate the healing of chronic leg ulcers. Multiple retrospective studies have demonstrated efficacy in terms of improved exercise tolerance, reduced pain and limb salvage¹⁵. The prospective evidence available to date displays trends towards limb salvage but does not reach statistical significance. The authors suggest that this modality offers significant potential benefit to patients with PVD however further studies are warranted to clarify the role of SCS in pain relief and functional improvement.

Microvascular Disease

The role of SCS in microvascular ischemic syndromes remains unclear, although there is case series evidence suggesting benefit in a diverse range of conditions including Raynaud's disease / phenomenon and thromboangiitis obliterans.

Miscellaneous Pain Conditions

Electrical stimulation of sacral nerves has developed over the last decade, with several reports of efficacy in a range of pelvic conditions. Prospective case series suggest that benefit can be attained for urinary incontinence secondary to detrusor hyperreflexia (eg multiple sclerosis), interstitial cystitis, and faecal incontinence, and also in refractory pelvic pain ¹⁶. Technically, these techniques utilise nerve root stimulation, predominantly the 3rd sacral root (S3) however some stimulation of S2 and S4 may be indicated. Both trans-sacral (electrode placed at the anterior S3 foramen) and more recently retrograde epidural (stimulating electrode placed in the sacral epidural space near the S3 foramen) approaches have been described. It appears that stimulation of the S3 nerve root activates both somatic and visceral afferent fibres, with resultant decrease in reflex urinary and colonic muscle activity. A prospective case series reported in patients screened for sacral nerve root stimulation Retrograde stimulation has been demonstrated to be associated with significantly reduced urinary frequency, increased voiding volumes and significantly reduced pain scores in the setting of Interstitial Cystitis ¹⁷.

In addition to assessing the therapeutic efficacy of this modality in FBSS and CRPS, Kavar also reviewed efficacy in a diverse group of conditions including spinal cord injury and post-amputation / phantom limb pain ⁹. Only one of 6 patients in this group received benefit. No benefit was identified with stump and phantom pain. These results are similar to those reported by Kumar et al in a retrospective analysis of their 15-year experience in 235 patients. Long term benefits were noted in 59% in those receiving permanent implantation, with the best results in those with failed back surgery syndrome, CRPS, peripheral vascular disease, multiple sclerosis and peripheral neuropathy, whilst response was poor for patients with spinal cord injury pain, amputation pain syndromes, and primary bone or joint pain ¹⁸. Spinal cord stimulation (SCS) suppresses visceral response to colon distension in an animal model. In humans, it may be an effective therapy for chronic pain of pelvic origin, irritable bowel syndrome, and persistent unspecified abdominal pain. Recent studies have demonstrated efficacy in chronic pancreatitis (Kapural et al, 2008)

Pre-Implant Trial

Of all the therapies available to treat chronic pain, SCS has one, unique property that maximizes both its clinical and cost effectiveness: the pre-implant trial. Only when stimulation has shown to be effective will a system be fully implanted. No other therapy offers this degree of precision at a stage of care when most alternative treatment interventions have been exhausted. During the trial, a lead system is tunneled in the epidural space of the spinal cord. Determining who is a good candidate for SCS involves expert opinion and a successful screening procedure. Full implantation is recommended if the patient achieves 50% pain relief during the trial. In the event that they do not achieve 50% pain relief, the screening trial can be extended. The SCS screening procedure is an effective diagnostic. Differentiating neuropathic pain from nociceptive pain can be extremely difficult; however, the screening process associated with SCS can effectively distinguish the two. The patient suffering from neuropathic pain will realize paraesthesia covering the pain site(s) and thus, will be a good candidate for full implantation of the device. Percutaneous trial may be performed as a day case, the patient being discharged home for 5-7 days to evaluate the benefit obtained. Percutaneous trial **significantly reduces in-patient bed days** and also optimizes benefit from full implantation.

Clinical Outcomes Associated with Spinal Cord Stimulation

Spinal cord stimulation has been extensively studied in clinical literature. Many systematic reviews have been published, targeting all or selected therapeutic indications. Since 2002, three thorough Health Technology Assessments (HTAs) have been published (from Australia, Spain and the UK). Results of these HTAs are summarised below.

Health Technology Assessments

Source of Publication	Search strategy	Clinical studies incl	Economic Review?	Summary of conclusions
ASERNIP (2004); Australia Accelerated Review	Medline, Pre-medline, CCTR	FBSS: #1 RCT CRPS: #1 RCT	Yes	Evidence of safety and efficacy; need for more evidence
Catalan HTA Agency (2004), Spain	Medline, Embase, Cochrane Library, NHS EED	FBSS: #1 RCT And #14 CS	No	Good quality evidence, although small sample size; "A" Recommendation
Taylor et al (2004) United Kingdom	Medline, Embase, Cochrane Library, NHS EED	FBSS:#1 RCT and 72 CS; CRPS: #1 RCT and 25 CS	Yes	FBSS: evidence of clinical effectiveness; CRPS: evidence of clinical and cost effectiveness

RCT: Randomised Control Trial; CS: Case Series

NHS EED: [National Health Service Center for Reviews and Dissemination Economic Evaluation](#)

Randomized Control Trial (2005)

Since the publications of the HTA reviews listed above, the level of evidence for SCS has increased because a second Randomised Control Trial (RCT) was published in early 2005 by North et al.¹ This RCT scored a 4/5 on the Jadad scale for assessing trial quality. The RCT compared two treatment options for FBSS patients: SCS and re-operation (back surgery) in 50 patients. After a 3-year follow-up, 45 patients (90%) were available to assess the success of each treatment alternative defined as at least 50% pain relief and patient satisfaction with the treatment.

- Pain relief of >50% was achieved in 47% of the patients of the SCS treatment group, $p < 0.01$

¹ North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomised, controlled trial. *Neurosurgery* 2005; 56: 98-107.

- As patients were allowed to crossover, based on latest treatment, 52% of SCS patients were successful versus 19% of re-operated patients, $p < 0.05$
- Patients using SCS significantly reduced their intake of opioids; whereas, patients who were re-operated required increased opioids after the intervention.

Meta-analysis of Case Series, 2004

Spinal Cord Stimulation alleviates pain in 62% of FBSS implanted patients according to Taylor et al case series analysis². In addition to this primary outcome, patients' physical ability and daily life are improved by suppressing the use of opioids in 53% of them. These data were pooled together in order to: 1. assess a global outcome; and 2. assess phase prognostic factors of pain relief.

	Study Number	Cases/Sample size*	Percentage
Pain relief >50%	65	1992/3313	62%
No analgesics	16	324/681	53%
Return to work	15	405/1133	40%
Satisfaction	6	147/220	70%

The Process Study

Since patients with neuropathic pain secondary to failed back surgery syndrome (FBSS) typically experience persistent pain, disability, and reduced quality of life, this study hypothesised that spinal cord stimulation (SCS) is an effective therapy in addition to conventional medical management (CMM) in this patient population. 100 FBSS patients with predominant leg pain of neuropathic radicular origin were randomised to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group) for at least 6 months. The primary outcome was the proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were improvement in back and leg pain, health

² Taylor RS, Taylor RJ, Van Buyten JP, Buchser E, North R, Bayliss S. The cost-effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. *Journal of Pain and Symptom Management*, 2004; 27(4): 370-379.

related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6 months, 24 SCS patients (48%) and 4 CMM patients (9%) ($p < 0.001$) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction ($p \leq 0.05$ for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications. In selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.

Clearly, a review of these studies illustrates that the use of SCS is not investigational. Spinal cord stimulation (SCS) has been in use for over 25 years. And in recent years, the technology and the profession's understanding of the appropriate target populations for its use have dramatically improved. Additionally, the studies indicate that the use of SCS has been shown to offer good to excellent long term relief (as defined as $>50\%$) from pain in chronic pain patients. It is unlikely that there are any alternative procedures for chronic pain that have been documented over such a period of time with such successful results. Clearly the use and associated outcomes for the patients receiving the spinal cord stimulation are evidence based.

Cost Effectiveness of Spinal Cord Stimulation

Studies have shown that SCS compares favorably to re-operation and other conventional pain therapy in terms of efficacy and cost. An extensive review of cost-effectiveness evidence on Spinal Cord Stimulation was published in 2004 by Taylor et al². 99 abstracts from medical and economic databases were retrieved; 14 articles met the inclusion criteria. The evidence presented illustrates that Spinal Cord Stimulation is economically favorable in comparison to other therapies in 1 to 3 years, in patients with FBSS, CRPS and angina pectoris. The initial acquisition costs are offset by a reduction in other medical direct costs such as medications, physician visits and hospitalisations. A number of factors influence the length of the “pay back” period, including relative efficacy of SCS, the battery longevity that is related to the pain severity, and the way the patients use SCS.

A cost effectiveness analysis of SCS vs Conventional Pain Therapies (CPT) was performed on 104 consecutive FBSS patients treated in a major Canadian pain centre (Kumar K, Malik S, Demeria D., 2002). Patients were monitored for 5 years and all direct medical costs were collected. Monthly drug intake was reduced in the SCS group from 78 Canadian dollars before SCS to 25 Canadian dollars after SCS. In the CPT group, the monthly cost after 5 years was 3 times higher than the SCS group. Total costs after 5 years were in favour of SCS, showing an average saving of 8,906 Canadian dollars during the 5-year period.

Actual annual cost of spinal cord stimulation and conventional pain therapy for 5 years*

Year	Actual costs (\$)		Cumulative costs	
	SCS	CPT	SCS	CPT
1	18,028	8865	18,013	8865
2	1092	7291	19,120	16,156
3	1092	7291	20,212	23,447
4	7819	7291	28,013	38,738
5	1092	7291	29,123	38,029
Total	29,123	38,029		
Average per year	5825	7606		

* SCS, spinal cord stimulation; CPT, conventional pain therapy

The costs of SCS are higher than CPT in the first 2 years, mainly because of the cost of the implant (device costs, implant procedure costs, etc). However, after 2.5 years, SCS is dominant over CPT.

The authors of this study conclude, “Spinal Cord Stimulation is cost effective in the long-term. Spinal Cord Stimulation can achieve significant cost savings, compared with a control group. Additional benefits may include an increase rate of work rehabilitation, increased pain control, and a better quality of life.”

Published Guidelines for SCS

FBSS Guidelines

A European interdisciplinary team of neurosurgeons, anaesthetists, and orthopaedic surgeons met in 2001 and 2002 in order to establish a treatment algorithm for FBSS, including the role of Spinal Cord Stimulation.³ Their consensus states:

If pain persists or recurs after successful surgeries, repeated surgery or conservative therapy is often not successful, then, neuromodulation needs to be considered. The clinical evidence has shown that Spinal Cord Stimulation results in a significant reduction of the pain in these therapy-resistant or refractory patients. The approach is based on a very careful diagnosis in order to detect cases when re-operation is indicated.

For predominant leg pain: if pain is persisting after surgery and structural causes are eliminated (in this case, re-operation is indicated), a SCS trial is recommended.

For predominant back pain: if pain relief after a fusion operation is unsuccessful and no structural damage can be demonstrated, a SCS trial is recommended. The positive criteria for implant are more than 80% paraesthesia coverage and at least 50% reduction in pain.

CRPS Guidelines

Guidelines on CRPS management were published by an expert panel in 2002⁴. They believe treatment success can be achieved through a multidisciplinary approach (rehabilitation, pain management and psychological treatment). The goal of treatment is the minimisation of pain and optimisation of function. On the psychological side, interventions such as counseling, relaxation, hypnosis, coping skills may be used. When it comes to medical interventions, they consider a grading approach in 3 steps. When satisfactory pain relief is not reached after 12 to 16 weeks of a treatment, the next step is recommended:

- 1st step: Medications: Anti-convulsants, TCAD's, NSAID's, Opioids
- 2nd step: Blocks / Rhizotomy

3 Gybels J, Linderoth B, Le Huec JC, Vanden Berghe L, Van Buyten JP. A treatment algorithm for Failed Back Surgery (FBSS): focus on neurostimulation. Submitted to Neuromodulation – 2005.

4 Stanton-Hicks MD, Burton AW, Bruehl SP, Carr DB, Harden RN, Hassenbusch SJ, Lubenow TR, Oakley JC, Racz GB, Prithvi Raj P, Rauck RL, Rezaei AR. An updated interdisciplinary clinical pathway for CRPS: Report of an expert panel. Pain Practice, 2002; 2(1): 1-16.

- 3rd step: Neurostimulation, in addition to medications

Clinical Requirement for SCS in Ireland

Utilising a variety of epidemiological sources it is evident that there is a significant requirement for SCS in Ireland. Extrapolating data from the Ontario Health Technology Advisory Committee (OHTAC) 2005 SCS recommendations it is estimated that in Ireland, 2016 people per-annum will develop neuropathic pain from failed back surgery syndrome, complex regional pain syndrome type I and post herpetic neuralgia. Approximately 10-15 % will develop intractable pain. An estimated 70% of these will proceed to test stimulation after psychological testing of which on average 84% or **177** people per-annum will be eligible for permanent implantation.

Across Western Europe, more than 700 Pain Centres, composed of multidisciplinary teams, are trained to perform Spinal Cord Stimulation implants. In 2004, a total of 6,252 patients benefited from Spinal Cord Stimulation therapy in Europe. However, across these countries patients' access to SCS varies widely, as shown by a simple calculation of number of implants per million inhabitants:

Country	Population* (in million)	Average number of implants per million inhabitants
Austria	8.1	21
Belgium	10.3	>30
Finland	5.2	21
France	59.5	17
Italy	57.5	23
Norway	4.5	21
Sweden	8.9	41
Switzerland	7.3	44
UK and Ireland	63.5	7

*OECD Figures – population in 2003

The huge variability in the number of implants per million is reflective partly of different pain management pathways; but it also illustrates the severe limitations to treatment access (e.g. reimbursement, funding challenges), underlying the fact that pain management is neither consistent nor optimal across countries. The low implant rate for the UK and Ireland is evidence to suggest that there are many patients here who are not getting access to this treatment as they may deserve.

Spinal Cord Stimulation is a well-established therapy in the management of refractory neuropathic pain for FBSS and CRPS patients. Published clinical evidence has demonstrated SCS is an efficient and safe therapy, minimally invasive and reversible. SCS can be adjusted to each individual's pain and functional needs. SCS alleviates pain successfully in more than 60% of implanted patients (62% in FBSS, and 65% in CRPS, from case series analysis). Spinal Cord Stimulation is a cost-effective therapy for FBSS and CRPS patients suffering from refractory neuropathic pain. When relieved of their pain with SCS, healthcare resource demand dramatically decreases, because patients' drug intake and number of physician visits reduces, leading to a substantial reduction in overall medical costs.

3. Peripheral Field Stimulation (PFS)

Peripheral Nerve or Peripheral Field Stimulation procedures are becoming increasingly popular for the treatment of many causes of nerve related pain and peripheral neuralgias. This revolutionary treatment works by placing electrodes along the course of painful peripheral nerves to control pain. The stimulation blocks pain perception from travelling from the nerve to the brain. It involves a small device that is placed near the involved nerve that delivers low-level electrical impulses that interfere with the perception of pain, especially chronic nerve pain. Recent papers have referred to PFS as “ a pacemaker for pain” ^{22, 23, 24}.

Syndromes that may benefit from PFS include:

- Back and Neck Pain
- Post-Surgical Pain
- Occipital Neuralgia
- Trigeminal Neuralgia
- Traumatic Nerve Injuries
- Diabetic Peripheral Neuropathy
- CRPS
- Lateral Femoral Cutaneous Neuropathy
- Peripheral Vascular Disease Neuropathy
- Post-amputation Pain
- Herpetic Neuralgia
- Refractory Angina
- Post Surgical Pain Syndromes.

Procedure

Peripheral Nerve or Field Stimulation an electrical current to the source of chronic pain. Under local anaesthetic and IV sedation a stimulator lead is placed along the painful nerves. Patients typically undergo a trial for 5-7 days to see if they feel better and have increased activity with the device. If pain improves, a permanent electrode and battery can be placed.

The trial procedure is typically performed as an outpatient. Full implantation requires overnight admission.

Benefits

The implanted device produces a low voltage current which creates a sensation that blocks the brain's ability to sense the previously perceived pain. It interferes with the perception of pain by creating a pleasant sensation that replaces the pain. The intensity of the stimulator can be changed, and the system can be turned on and off as necessary to provide optimal pain relief as experienced by the patient.

Treatment of chronic neuropathic pain in the region of the face, neck, and head are challenging for pain specialists to treat. The pain is typically refractory to many of the conventional treatment options.

Recently PFS has become increasingly common in difficult to treat neuropathic facial pain.

Risks

Most peripheral nerve stimulation procedures are performed on an outpatient basis. As expected with any surgical procedure, there are potential risks. Side effects that may occur include bleeding, infection, scar tissue deposition, electrode failure, inadequate pain surface area coverage, and nerve damage.

Patients with the following conditions should not receive peripheral nerve stimulation:

- Cardiac pacemaker
- Systemic infection

- Pregnancy or lactating

Outcomes:

Peripheral nerve stimulation is reported to be an effective pain treatment by the inhibition of nociception (pain perception) and pain from the peripheral nervous system (Ristic 2007). In a clinical investigation of patients receiving peripheral nerve stimulation for craniofacial pain, 73% of the patients experienced significant improvement in pain intensity (Konstantin 2006). With the improvement of pain symptoms after treatment, you may be able to decrease pain medications and increase your daily activities.

The number of centers using peripheral nerve stimulation for craniofacial pain and other peripheral nerve syndromes is increasing. In the future there will be a wider acceptance of this treatment because it is minimally invasive, can be tested, is reversible in effect, and has adjustable settings. These unique qualities may eventually make peripheral nerve stimulation the preferred modality for otherwise intractable conditions (Konstantin 2006).

Peripheral nerve stimulation can be very effective in reducing chronic pain from certain painful conditions; however it is ineffective for some patients. A trial with a temporary device ensures optimal benefit and successful outcome.

Trigeminal and Occipital Peripheral Nerve Stimulation for Craniofacial Pain: A Single-institution Experience and Review of the Literature Konstantin V. Slavin, M.D.; M. Efkan Colpan, M.D.; Naureen Munawar, M.D.; Christian Wess, M.D.; Hrachya Nersesyan, M.D., Ph.D. *Neurosurg Focus*. 2006;21(6)
2006 American Association of Neurological Surgeons

Analgesic and antinociceptive effects of peripheral nerve neurostimulation in an advanced human experimental model. Ristić D, Spangenberg P, Ellrich J. *Eur J Pain*. 2007 Sep 17

4. Intrathecal Drug Delivery (ITDD)

Introduction

The spinal cord is a key target for modulating both acute pain processes and the interlinked mechanisms underlying persistent nociception including oncogene expression and spinal neuronal reorganization. A number of systems exist that allow direct administration of analgesic drugs directly into the patient's spinal canal. Spinal administration of opioids such as morphine is now one of the most frequent methods of controlling severe pain due to cancer or advanced disease. In cancer related pain, intrathecal opioid administration has been demonstrated to provide superior analgesia with fewer side effects and a trend towards increased survival relative to other. First line agents for intrathecal infusion in pain management are morphine and the related synthetic opioid hydromorphone. If adequate analgesia is not achieved with the maximum dosage of first line agents, the addition of an adjuvant agent may be considered. Potential combinations include the addition of local anaesthetic agents such as bupivacaine, the α 2-adrenoceptor agonist clonidine, NMDA receptor agonists including ketamine, and midazolam. In instances where neuropathic pain predominates it may be appropriate to commence with combination therapy. As our understanding of the complex processes involved in spinal modulation of nociception continues to increase, novel agents directed more specifically to the patho-physiological processes underpinning persistent pain will continue to be added to the armamentarium of IT therapies. Potential agents include conopeptides such as ziconotide and antibodies directed against nerve growth factors intimately involved in the spinal processing of nociceptive information. Ziconotide mediates its analgesic effects via an inhibition of neurotransmitter release in the dorsal horn of the spinal cord and recent studies support its efficacy in the management of intractable AIDS or cancer related pain.

Target population for Intrathecal Drug Delivery

Patients with chronic pain that cannot be controlled by well-tailored drug regime and/or spinal cord stimulation and/or suffer intolerable side-effects are the target group (Erdine, 2006). There are two distinct patient groups eligible for spinal infusion:

- i) Patients with long life expectancy, but with resistant pain;
- ii) Cancer patients with limited life expectancy and intractable pain that is resistant to all other treatments.

Patient selection for long-term IDD requires a careful evaluation of the candidate. Initially, an accurate description of the pain characteristics should be established, to allow a diagnosis and establish a treatment algorithm. **Patients who respond best to IDD include those with nociceptive, neuropathic and mixed types of pain that cannot be controlled by a well-tailored oral drug regime and/or spinal cord stimulation (SCS).** There are slightly different selection criteria for malignant pain versus non-malignant pain (see next table).

Malignant pain	Non-malignant pain
<ul style="list-style-type: none"> •Life expectancy greater than 3 months (due to cost of initial treatment) •Inadequate pain relief and/or intolerable side effects from systemic agents •Favourable response to screening trial 	<ul style="list-style-type: none"> •Objective evidence of pathology (important because of the psychological issues that surround pain of unknown aetiology) •Psychological clearance •Inadequate pain relief and/or intolerable side effects from systemic agents •Lack of drug-seeking behaviour •Favourable response to screening trial

Patients with psychiatric illness, depression, senility, alcohol or opioid abuse and associated severe physical conditions are not eligible for implantation.

Patient selection criteria for long term IDD

Clinical Benefits of Intrathecal Drug Delivery Therapy

This section presents first, a summary of the clinical experience with intrathecal drug delivery therapy for chronic/persistent non malignant pain. The second part describes the evidence focussing on the benefit of a programmable pump for those patients who experience pain due to cancer or its related treatment.

There is a growing acceptance for the use of opioids in the management of chronic non-malignant pain. While the efficacy of intrathecal morphine is well accepted for post-operative or cancer pain, its use for chronic non-malignant pain remains less well defined. There is uncertainty about long-term efficacy, safety, and opioid tolerance associated with this treatment.

The literature on intrathecal opioids for non-malignant pain includes prospective and retrospective studies, none with comparison or control groups. This lack of comparative trials is most probably due to the difficulty of comparing intrathecal drug delivery with other means of administration of pain medication such as oral treatments. However, most studies published in the literature have reported a positive effect of the treatment.

Systematic Review

In 2003 the Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) published a systematic review on Implantable Spinal Infusion Devices for Chronic Pain and Spasticity.⁴⁸ The search completed by ASERNIP-S queried a wide range of databases from inception up to April 2003. The objective of this review was to assess the safety and efficacy of implantable spinal devices for treating chronic pain and spasticity.

Of the 79 studies identified, the authors included one Randomized Controlled Trial (level 2) and 6 case series (level 4).

Randomized Controlled Trial (Smith et al 2002).

This international study compared Intrathecal Drug Delivery to Conventional Medical Management in advanced cancer and refractory pain patients. 202 patients were enrolled in 21 centres, suffering from an average superior or equal to 5 on a VAS (Visual Analogue Scale), despite 200mg per day of oral morphine or the equivalent. Patients were followed during 12 months. Clinical success was defined as at least 20% reduction in the VAS pain score from baseline to 4 weeks regardless of toxicity or equal pain scores with at least 20% reduction in toxicity.

ASERNIP-S concluded that **infusion of drugs via implantable spinal infusion devices appears efficacious, with significant reductions in pain measured via visual analogue scales for pain.** Pain measured by VAS was reduced by at least 20%, or pain was equal with at least 20% reduction in toxicity, in more of the Intrathecal delivery group ($p=0.05$). The randomized controlled clinical trial included in their review also showed **a reduction in toxicity, when compared to medical management ($p=0.02$), and this reduction in toxicity impacted on the cumulative survival of the group implanted with the spinal infusion.**

ASERNIP-S also concluded that the **use of implantable spinal infusion appears safe.** Drug related adverse events do occur, as they do when chronically administered, via systemic route, although perhaps less than

for systemic administration. Device related adverse events occur with replacement and revision rates ranging from 3 to 17% and the explantation rate varying from 0 to 21% in the reviewed literature.

Chronic Persistent Non-malignant Pain

Thumineur et al published in 2004, a 3 year prospective study evaluating long-term outcomes of intrathecal opioid treatment and included two comparative groups to improve understanding of selection criteria and relative severity of intrathecal pump recipients.⁴⁹ The study subjects included 38 pump recipients while the comparative groups included 31 intrathecal candidates who either had an unsuccessful trial, or declined the therapy, and another group of 41 newly referred patients. The following data were analysed at study entry and at 6 monthly intervals for a 3-year period:

- Symptom Check List 90 (SLC-90),
- SF-36 Health survey,
- Beck Depression Inventory,
- McGill Pain Questionnaire (short form),
- Oswestry Disability Index,
- Pain Drawings and Pain rating on visual analogue scale.

Drug combination is common in pain treatment: most patients were on more than one intrathecal medication, for instance, morphine with clonidine or hydromorphone and fentanyl.

Three groups of patients were enrolled: PR for implanted patients, NR for non recipient group, and others as newly recruited patients (NP). Results are displayed for the 3 groups. Mean baseline scores on all pain measures were significantly lower in the NP group.

Results showed that pain, measured by a VAS, was significantly reduced in the pumps recipients, while it worsened in the NR group as shown in the table below.

	Baseline	36 months	P-value
Recipients	8.4 (1.4)	6.1 (0.6)	<0.000001
Non-recipients	7.4 (1.5)	7.9 (1.2)	<0.01
Other	6.5 (1.5)	4.2 (1.6)	<0.000001

VAS at baseline and 36 months for the 3 groups

Other parameters were significantly improved in the implanted patients:

- Quality of life, measured by VAS and Mc Gill Pain Questionnaire

- Function, measured by ODI [Oswestry Disability Index]
- Mood, measured by SCL90 depression and anxiety scales, Beck Depression Inventory
- Quality of life, measured by SF-36.

These same parameters improved among new referrals (less severe patients receiving conservative pain management) while non-recipients significantly worsened. Although pump recipients improved, they were still worse off at 36 months than new referrals were at baseline. **The study showed that when patients with extremely severe pain problems are selected as pump candidates, they will likely improve with the therapy, but their overall severity of pain and symptoms still remains high.**

Other studies:

- A retrospective multicenter study involving over 400 patients with pump implants (mean follow-up of 14 months) found that **two-thirds of patients were very satisfied with the therapy**, 57% having at least moderate increases in activities of daily living, and an average pain relief of 50%.
- In a retrospective study of 120 implanted patients, Vinkelmuller et al. reported a **92% rate of patient satisfaction, an average pain reduction of almost 60%, and large improvements in mood and function** during a follow-up period that varied between 6 months and 6 years.

Variability among pain management clinicians regarding the provisions of pain treatment prior to pump implant, and criteria used to choose patients for implanted devices cloud the outcomes of the studies mentioned above. Patients with the most severe and refractory problems have poorer outcomes with any treatment, including intrathecal (IT) opioid therapy, while the opposite is true of patients with lesser severity. Differences among study populations in prior studies may explain the variations noted in outcomes.

Chronic/Persistent Cancer Pain

Intrathecal drug delivery systems have been in general use in patients with chronic refractory cancer pain since 1991, until recently many small, open-label, cohort studies had been published. In 2002, Smith et al conducted a prospective, multicenter, randomized study designed to enroll 202 patients with advanced cancer and refractory pain, with pain scores superior or equal to 5 on a 0-10 scale. Patients were randomly assigned to comprehensive medical management (CMM) or intrathecal drug delivery

system (IDDS) delivered by a programmable infusion system. Data were recorded at baseline, every 2 weeks up to 12 weeks, and then monthly through 6 months. The data collected at the scheduled visits were identical for both study groups, and were recorded at routine visits. Clinical success was defined as at least 20% reduction in VAS scores, or at least 20% reduction in toxicity.

Sixty of 71 IDDS patients (84.5%) achieved clinical success compared with 51 of 72 CMM patients (70.8%, p= .05). IDDS patients more often achieved $\geq 20\%$ reduction in both pain VAS and toxicity (57.7% [41 of 71] v 37.5% [27 of 72], p= .02). The mean CMM VAS score fell from 7.81 to 4.76 (39% reduction); for the IDDS group, the scores fell from 7.57 to 3.67 (52% reduction, P = .055).

The increased analgesic effectiveness of small doses of opioid administered intrathecally, accompanied by reduced systemic exposure, resulted in a reduction in the frequency and severity of opioid side effects. The mean CMM toxicity scores fell from 6.36 to 5.27 (17% reduction); for the IDDS group, the toxicity scores fell from 7.22 to 3.59 (50% reduction, P = .004). The IDDS group had significant reductions in fatigue and depressed level of consciousness (P < .05).

Outcome	Comprehensive Medical Management (CMM) Group	Intrathecal Pain Therapy (IDDS)	P value
Clinical success ($\geq 20\%$ ▼ VAS)	70.8% of patients	84.5% of patients	P=0.05
$\geq 20\%$ ▼ VAS and toxicity	37.5% of patients	57.7% of patients	P=0.02
Mean VAS pain score	39% ▼ (reduction)	52% ▼ (reduction)	P=0.055
Toxicity scores	17% ▼ (reduction)	50% ▼ (reduction)	P=0.004
6 month survival	37.2%	53.9%	P=0.06

Summary of results from Study Smith et al. 2002

IDDS patients had improved survival, with 53.9% alive at 6 months compared with 37.2% of the CMM group (P = .06). Deep analyses on the

2 populations suggest that **the improved mortality in the IDDS group is partially explained by the larger average reduction in toxicity score.**

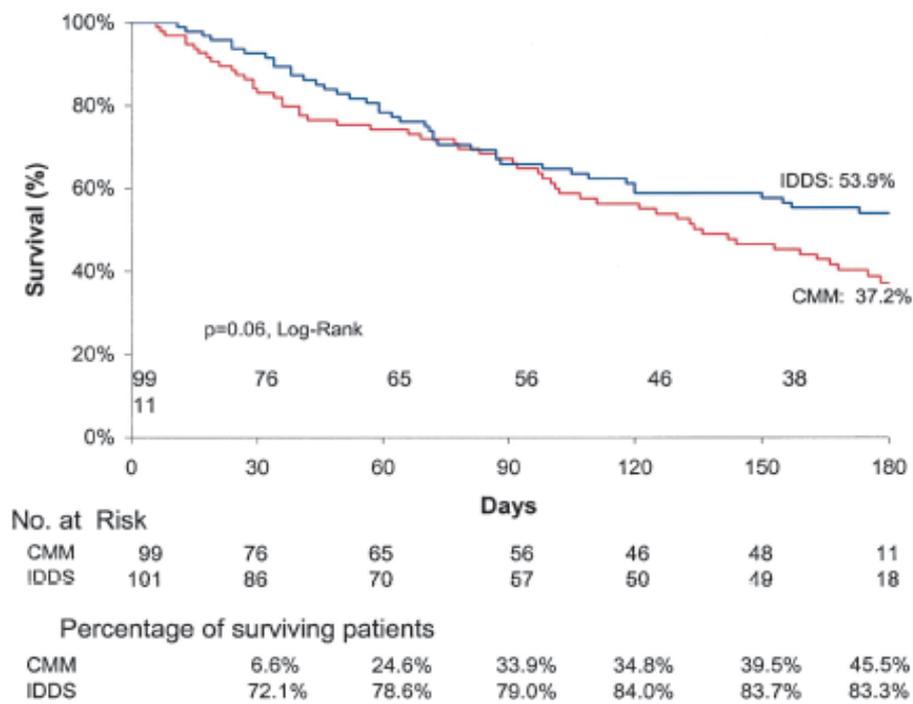


Fig 5. Kaplan-Meier survival curve of the IDDS and CMM groups, as randomized. Survival was higher in the IDDS group (P = .06, log-rank test).

Kaplan-Meier survival curves in both groups

In 2003, the results of a prospective, multicenter, international, open-label study of an investigational, patient-activated, intrathecal morphine delivery system in patients with cancer pain revealed superior analgesia and fewer opioid related side effects compared to systemic opioid therapy after 1-13 months of follow up.

Cost Effectiveness of ITDD

This section presents the cost-effectiveness studies of Intrathecal Drug Delivery for chronic pain treatment.

In their accelerated review of spinal infusion devices for spasticity and pain, the Australian systematic review concludes that **intrathecal drug delivery is less costly than conventional medical management in the long-term.** Their conclusion is based on literature which shows consistent findings. Three studies have been performed so far to assess the cost-effectiveness of IDD versus conventional management.

Kumar et al, 2002: The cost-effectiveness performed by Kumar et al

compared 2 groups of pain patients, one undergoing intrathecal drug therapy or IDT (21 patients) and the other conventional pain therapy or CPT (44 patients) (54). Both groups are Failed Back Surgery Syndromes patients (non malignant pain) followed by this Canadian center during 5 years for whom Spinal Cord Stimulation did not achieve a satisfactory pain relief. The control group, i.e. the CPT group, have similar age and sex distribution than the IDT group. Costs are actual costs, based on the year 2000 Canadian dollars, averaged for a 5-year period.

While the first year costs are higher in the IDT group, due to the upfront costs of the implant, this strategy is less costly on the long-term, resulting in a lower average annual cost.

Annual cost comparison: IDT compared with CPT during a 5-year period

Year	IDT (\$)	CPT (\$)
1	16,785	8,848
2	1,055	6,533
3	1,055	8,043
4	1,055	6,533
5	9,460	8,043
total cost	29,410	38,000
mean annual cost	5,882	7,600

5 year cost comparison between the 2 groups

Differences are explained by the higher number of physicians visits and referrals, as well as the higher level of pharmacotherapy required in the CPT group. **The break even cost is at 28 months on average.** A worst case scenario [i.e. patients experience at least one complication] was performed to calculate cost-effectiveness for patients experiencing at least one complication. IDT remains cost-effective under sensitivity analysis. Authors also assessed therapy effectiveness by using the Oswestry Disability Index that showed a 27% improvement in the IDT group versus 12% only in the CPT group.

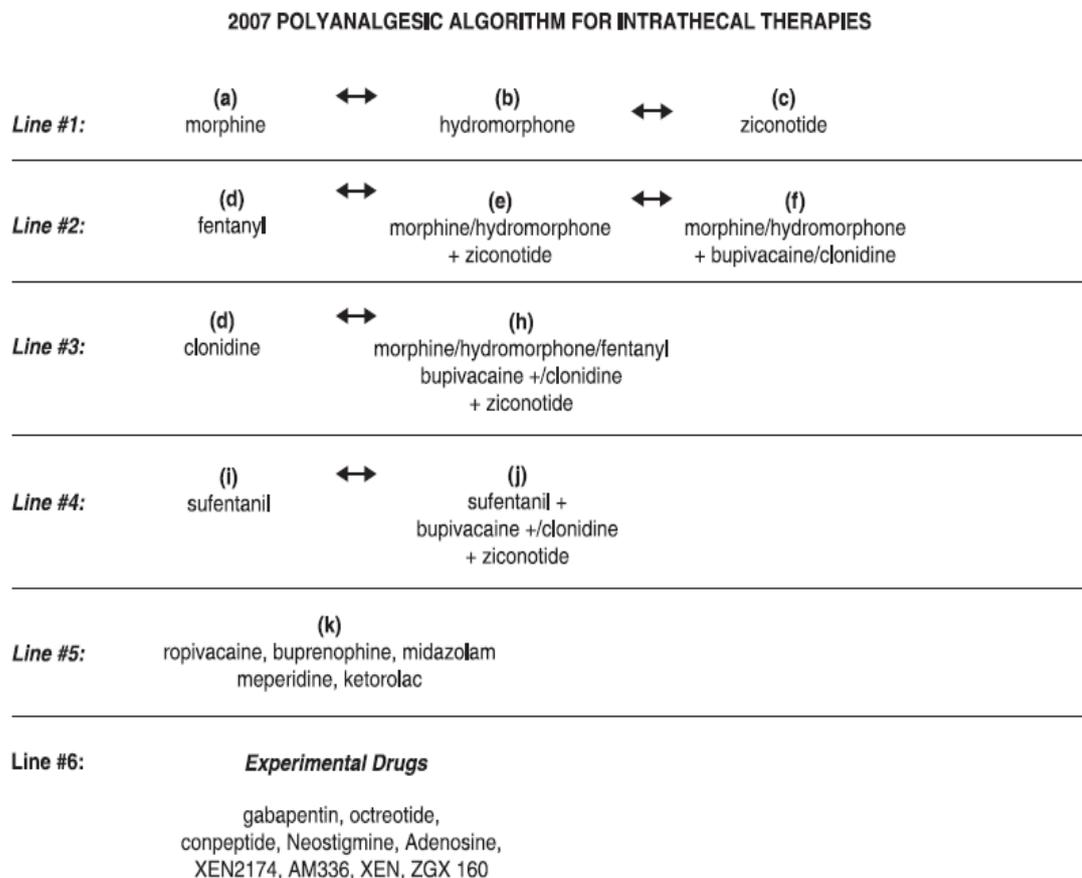
On the 23 patients who underwent IDT, 2 who had been working with intermittent time loss prior to implantation continue to work with increased comfort and without disruption. 2 other who were unemployed before implant were able to find part-time employment.

Mueller-Schwefe et al, 1999: With the increasing number of

administration routes, Mueller-Schwefe et al reviewed the evidence of cost-effectiveness of various ways to administrate opioids in malignant and non-malignant pain. Among those, there is the De Lissovoy publication.

Cost analyses of alternate routes of opioid administration indicate that IDD is the most cost-effective route of opioid administration for patients who require long-term management of cancer ($\geq 3-6$ months) or non-malignant pain ($\geq 11-22$ months). The upfront cost of implantation is offset by the maintenance costs of treatments over time.

De Lissovoy et al, 1997: This US study is based on a model, comparing conventional medical management and IDD in FBSS patients over 60 months on a cohort of 1000 patients. A sensitivity analysis was performed on the variability of adverse events. Effectiveness data come from literature and costs are physicians fees and hospital charges from 1994 (Medicare). The total costs of Intrathecal Morphine Therapy ranges from 53,468 USD to 125,102 USD over 60 months. The cost of conventional management was estimated to be 85,186 USD. They conclude that one year of pain relief costs between 7,212 to 12,276 USD.



Clinical Requirement for ITDD in Ireland

ITDD is considered in patient's refractory to all other medical and therapeutic interventions. In Germany there are on average 220 IT pumps implanted for the management of chronic pain (Figure X). There is a significant disparity between this number and that seen in the United States. In an attempt to identify the incidence of IT pump implantation in the US a group from the University of Utah conducted a retrospective review of a medical claims database. MEDSTAT'S MarketScan databases which reflect the healthcare experience of employees and dependants covered by health benefit programs of large employers was used. The claims data in this database is collected from approximately 100 different insurance companies and third party administrators (160 million Americans or 57% of total population). The database does not include Medicaid or worker's compensation (120 million Americans). The years queried included 2000 and 2001 or 1.75 years. First, we identified all unique patients that experienced a procedure related to an implantable infusion pump. A total of 3,269 patients were identified and represented a total of 291 unique diagnoses. We then focused on diagnoses related to neuropathic pain which made up 84 of the 291 original diagnoses identified. These 84 diagnoses represented 2,809 unique patients with an implantable infusion pump. The total of 2,809 patients over 1.75 years represents 1,605 patients per year or 0.0004% of the total number of patients in the database (4 million). Therefore, 0.0004% of the 160 million Americans represent 64,200 patients with neuropathic pain requiring an implantable infusion pump. If an equivalent prevalence is assumed for the other 120 million Americans, then the total would be approximately 112,000 patients per annum. Extrapolating the US data would suggest that a country with the population of Ireland would expect to have 1800 requiring IDD systems implanted for the management of chronic pain and annually. Extrapolating the German data suggests a figure closer to 20, in Ireland the clinical experience of St Vincent's University Hospital would suggest a figure of 50 new cases per annum.

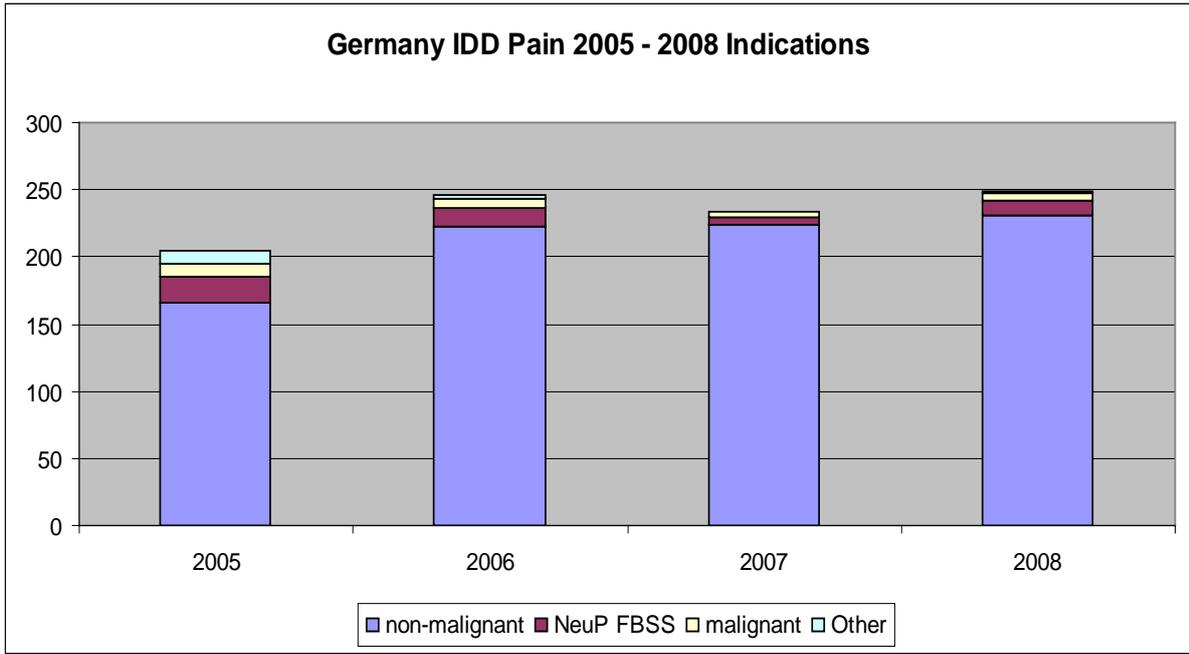


Fig X: Implantable pump rates Germany 2005-08. (Courtesy Medtronic Ltd.)

5. Intrathecal Baclofen (ITB) in the management of spasticity.

Introduction

Severe spasticity is a devastating motor disorder characterised by a velocity-dependent increase in muscle tone and tendon reflexes caused by a hyperactive stretch reflex. A consequence of either an injury or a neurological disorder, severe spasticity is regularly associated with spasms and pain, often resulting in substantial impairments in activities of daily living such as sleep, walking, cleaning, dressing and sitting. Severe spasticity is a common symptom of cerebral palsy, multiple sclerosis and stroke, and often results in high direct costs (i.e. medical costs) due to the increased level of healthcare resource utilisation.

Spasticity can be treated with physiotherapy and oral medications such as baclofen, but these are sometimes ineffective or have unacceptable side effects. Intrathecal treatment involves injecting medication into the cerebrospinal fluid which surrounds the spinal cord. A pump implanted in the abdomen injects baclofen into the cerebrospinal fluid, increasing the drug's effectiveness and reducing adverse events. Intrathecal baclofen (ITB) therapy has demonstrated a dramatic improvement in severe spasticity together with and long-term safety.

An economic model has been developed which demonstrates the cost effectiveness of ITB therapy in patients with cerebral palsy, multiple sclerosis and stroke suffering from severe spasticity.

Incidence and prevalence

Severe spasticity is a common symptom of cerebral palsy, multiple sclerosis and stroke. Using published estimates, the number of patients with severe spasticity suitable for ITB was calculated (Table 1, Table 2).

Table 1. Epidemiology of severe spasticity

	Incidence		Prevalence	
	% of pts	No. of pts	% of pts	No. of pts
Cerebral palsy	0.003% ¹	110	0.050% ¹	2,120
Multiple sclerosis	0.003% ¹	148	0.100% ¹	4,240
Stroke	0.250% ²	10,600	0.800% ²	33,919
Spinal cord injury	0.002% ¹	72	0.070% ¹	2,968
Brain injury	0.250% ²	10,600	1.200% ²	50,878

* excluded from subsequent results

Table 2. Number of patients considered for ITB

	% pts considered for ITB	No. of pts considered for ITB	
		Incidence	Prevalence
Cerebral palsy	10.0% ¹	11	212
Multiple sclerosis	3.5% ¹	5	148
Stroke	6.3% ²	668	2,137
Spinal cord injury	7.5% ¹	5	223
Brain injury	1.7% ²	180	865
Total		870	3,585

* excluded from subsequent results

Costs

Assuming an intrathecal pump will last for 7 years, the per patient costs for this period are outlined in Table 3, Table 4 and Table 5 (screening, pump implantation and aftercare).

The per patient, total cost is **€26,935** over 7 years, equivalent total cost of **€3,848** per year.

Table 3. Screening costs associated with ITB

Pre-screening	No. of units	Unit cost
Test dose		€3,363 ³
In-patient stay	1	€95 ⁴
Total cost		€3,758

Table 4. Implantation costs associated with ITB

Pump implantation	No. of units	Unit cost
Pump		€1,500 ³
Intrathecal catheter		€500 ³
Surgery		€4,831 ³
Inpatient stay	6	€2,370 ³
Total cost		€19,201

Table 5. Aftercare costs associated with ITB

After care	Unit cost
Pump refill (annual cost)	€68 ³
Total cost	€3,976

Potential cost offsets

There are several potential cost offsets to be considered with ITB therapy:

- Since patients will receive baclofen intrathecally they will no longer require oral baclofen medication. Thus, assuming an average daily dose of 58mg and an average cost of €0.68 per mg for oral baclofen⁵, this would save **€14,323** per patient every year.
- The reduction in the severity of spasticity has also been shown to reduce the hospital inpatient stay associated with management of

these patients⁶. This would lead to a cost saving of **€6,770** per patient per annum (Table 6).

- Since patient's mobility is often improved, a reduction in pressure sores will be achieved which can lead to a potential cost saving of **€733** per patient per annum (Table 7).

Table 6. Hospital bed day savings associated with ITB

Reduction in bed days / patient / year	17.14 ⁶
Inpatient bed day	€95 ⁴
Potential savings per annum per pt	€6,770

Table 7. Pressure sore treatment savings associated with ITB

Pressure sores	Average cost	% of pts
Grade 1	€1,343 ⁷	50% ¹
Grade 4	€3,320 ⁷	50% ¹
Average cost of treating a pressure sore	€7,332	
% of patients who will avoid a pressure sore of 5 years	50% ¹	
Potential cost savings over 5 years per pt	€3,666	
Potential cost savings per annum per pt	€733	

Efficacy of ITB

ITB use has been shown to improve flexibility measured using the Ashworth score (Appendix A) and reduce the incidence and severity of spasms, measured using the spasm frequency scale (Appendix A); Table 8 and Table 9.

It has also been demonstrated that ITB use increases mobility, reduces pain and can improve skin integrity and urinary function; see Table 10.

Table 8. Ashworth score pre- and post-ITB

Condition	pre-ITB	post-ITB	p
CP	3.1 ⁸	1.7 ⁸	<0.005 ⁸
MS	4.2 ¹	1.3 ¹	<0.001 ¹
SCI	4.0 ¹	1.7 ¹	<0.001 ¹
Other	4.3 ¹	1.7 ¹	<0.001 ¹
All patients	3.9¹	1.6¹	<0.001¹

Table 9. Spasm score per- and post-ITB¹

Condition	pre-ITB	post-ITB	p
CP	-	-	-
MS	3.2	0.4	<0.001
SCI	3.4	0.8	<0.001
Other	3.2	0.8	<0.001
All patients	3.2	0.6	<0.001

Table 10. Improved mobility and urinary function following ITB treatment¹

	% of patients
Bedridden patients becoming able to sit in wheelchair	66%
Improved ability to sit comfortably	86%
Improved wheelchair mobility	72%
Improved ability to transfer	96%
Activities of daily living improved	73%
Reduction in spasm related pain	89%
Improvement in skin integrity	83%
Improved urinary function	82%

Quality of life

At present none of the aforementioned measures of clinical efficacy have been directly correlated to utility scores (quality of life). However, based on case studies and videos demonstrated in the model, the user has estimated the following utilities using the EQ-5D instrument⁵ (Table 11).

⁵ EQ-5D is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D was originally designed to complement other instruments but is now increasingly used as a 'stand alone' measure. <http://www.euroqol.org/>

Table 11. User-defined EQ-5D estimates for a patient with severe spasticity

Domain	Patient with severe spasticity	
	Current therapy	ITB
Mobility	Some problems	Some problems
Self Care	Some problems	Some problems
Usual Activities	Some problems	Some problems
Pain / Discomfort	Moderate	Moderate
Anxiety / Depression	Moderate	Moderate
Utility score	0.516	0.516
Utility gain	0	

Conclusion

- Although the initial cost of ITB therapy results in an incremental cost, the potential cost savings through medication avoided, reduced inpatient stay and a reduction in pressure sores leads to a net budget impact of **€17,978 saved** per patient per annum.
- When this is combined with the estimated utility (quality of life) gain, the use of ITB therapy in patients with severe spasticity becomes a **dominant treatment strategy (i.e., cost saving and more effective)**.
- Guidance from NICE recommends that the use of intrathecal baclofen is considered in people with multiple sclerosis and severe spasticity unresponsive to other treatments. This analysis suggests that ITB therapy may also be a cost-effective option for patients with cerebral palsy and stroke affected by severe spasticity.
- Although not included in the economic model, there are other potential benefits associated with ITB therapy and, if these were taken into consideration, may mean ITB therapy is even more cost-effective than first thought.
 - Patients with conditions such as scoliosis, may have a reduced requirement for corrective surgery and orthotic aids following ITB therapy.
 - Post-ITB therapy, patients' improved mobility and improvement in activities of daily living will also reduce the societal burden normally associated with treating these

patients. Patients will be more likely to be able to work, thereby potentially improving productivity.

7 Pain Management Programme (PMP)

A PMP is an intensive, cognitive behavioural program which teaches active coping skills for improving quality of life despite persistent pain. It is appropriate for anyone who has had pain on a persistent basis for more than six months which is interfering with their ability to carry out their normal activities e.g. working, socialising, doing housework, hobbies and so on. It is also particularly useful in the process of functional restoration in patients who have undergone major interventional pain procedures. Participants attend the program in groups of no more than 10. The course runs for five days per week from 9am to 5pm, over three weeks (15 days in total). The Pain Management Team consists of clinical psychologists, physiotherapists, exercise physiologist, nurse-rehabilitation counsellor, occupational therapist and medical specialists with expertise in chronic pain. Input may also come from employment placement consultants specialising in injured workers, and a volunteer speakers who are actively managing their own pain. After the program itself finishes, participants' progress is closely monitored for the next 12 months, to ensure that they are continuing to put the strategies they have learned into practice. It is recommended that an effective PMP should be carried out on an out-patient basis and last for a minimum of 100 hours. All patients who undergo spinal cord stimulation or IT pump implantation must commence a PMP 6 weeks post implantation to ensure optimal benefit.

Participants in a Pain Management Program should expect to see positive changes in a number of different areas of their lives, including:

- Increased strength, flexibility and fitness
- Improvements in daily activities such as standing, walking, sitting, lifting, typing and so on
- A significant reduction in the use of pain medications, a decreased reliance upon passive treatments (hydrotherapy, massage) and a decrease in the use of aids such as walking sticks, back supports, braces and so on
- Improvements in mood (less depression, less anxiety, greater self-confidence in the ability to manage pain)
- Improvement in relationships with partner, family members, work colleagues and others in the social environment
- Not all of these changes will occur in the first four weeks, but as with any health regime (e.g. new diet, exercise program), with time and practise the results get better.

Research clearly indicates that individuals with chronic pain who work are physically and mentally better off than those who don't work because of their pain (e.g. Kuijer et al. 2006). Research also shows that most people who suffer from chronic pain are also employed (Blyth et al. 2001). Therefore, although getting back to work with pain is often a challenge, the evidence strongly indicates that it is important and therefore we make returning to work a key objective of the program.

8 Pain Medicine Services; St Vincent's University Hospital

St Vincent's University Hospital is the only fully multi-integrated pain and largest medicine service in Ireland.

Patient Assessment

All patients at initial evaluation are assessed by a multidisciplinary team comprising a pain specialist (Dr D O' Keeffe / Dr P Murphy), a clinical psychologist and a physiotherapist. All patients complete a range of psychometric evaluation tools prior to assessment in order to help identify the physical and psychological impact of pain on each individual. Following evaluation an individualised management plan is devised for each patient comprising medication optimisation, diagnostic procedures, psychological intervention, functional rehabilitation (physiotherapy and occupational therapy) and interventional therapies.

Patient Population

The Department of Pain Medicine, St Vincent's University Hospital is the largest centre in Ireland. Figures from 2007 reveal in excess of 60 new patient referrals per month. Approximately 20% of all referrals are from Pain Medicine Consultants in other institutions.

Diagnostic Procedures

A range of diagnostic procedures are performed including, cervical and lumbar facet medial branch blocks, intravenous lignocaine / ketamine infusions, coeliac plexus blocks, lumbar and cervical sympathectomy. Intrathecal testing is performed on patients being considered for IT pump implantation and trial electrodes are placed in patients being considered for SCS/PFS. New innovations in per-cutaneous trialling of SCS systems will enable more patients to be evaluated and treated in coming years.

Interventional Procedures

Approximately 150 major implants were performed in St Vincent's University Hospital including SCS, occipital nerve stimulation, ITDD and ITB. This accounts for over 80% of all major interventions performed in Ireland in 2007. As a result, this unit has developed a national and international standing as a centre of excellence in the provision of neuromodulation and advanced pain management therapies. The pain department closely collaborates with the Department of Neurology, SVUH and the National Rehabilitation Hospital, Dun Laoighaire in providing ITB therapy for patients with uncontrolled spasticity and pain resulting from multiple sclerosis and spinal cord injury.

Pain Management Programme

The PMP in St Vincent's University Hospital is the largest programme in Ireland and ran 11 programmes in 2007 treating 99 patients.

Research

The Department of Pain Medicine, St Vincent's University Hospital is actively involved in a number of collaborative studies with national and international institutions and also with industry. Ongoing studies are being conducted in conjunction with the University of Sydney, Oxford University and the Conway Institute UCD. Industry partners including Valiant, Medtronic, Pfizer and the IDA are involved in ongoing research projects. In conjunction with Eisai / Icon, The Department of Pain Medicine is currently leading a Europe wide study on the use of novel intrathecal agents including Ziconotide.

Summary

- 1) There is a significant need for a **specialist neuromodulation centre of excellence** for the management of chronic neuropathic pain in the Republic of Ireland. Approximately **177 full SCS implants** are estimated to be required per-annum in Ireland. To achieve adequate screening, approximately 205 percutaneous trial procedures per-annum are thus required. The added requirement for Peripheral Nerve Stimulation (PNS), Sub-cutaneous Nerve Stimulation (SENS) and IT pump implantation increase the caseload to in excess of 350 cases per-annum. The Department of Pain Medicine, St Vincent's University Hospital is uniquely placed to take on the role of specialist neuromodulation/ pain medicine centre of excellence.
- 2) A neuromodulation centre requires a **minimum of 2 specialists** actively involved in implantation in order to provide continuous cover.
- 3) US recommendations indicate that a **minimum of 25 implants per specialist per annum** is required to ensure competence and optimal patient outcomes (i.e. minimum 50 implants per-centre per annum.)
- 4) In order to ensure optimal outcomes in terms of pain control, functional restoration, return to work and psychological status, all patients undergoing neuromodulation must also receive an **effective pain management programme** (cognitive behavioural therapy).
- 5) In a recent key publication the authors conclude *'... because pain management is the subject of many initiatives within the disciplines of medicine, ethics and law, we are at an "inflection point" in which unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right.'*

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Appendix 1: Protocols for Interventional Pain Procedures

ST VINCENTS UNIVERSITY HOSPITAL

DEPARTMENT PAIN MEDICINE

MEDIAL BRANCH BLOCK

Nursing And Medical Care Protocols

Devised December 2007

Dr P Murphy

MEDIAL BRANCH BLOCK (ALSO KNOWN AS FACET JOINT BLOCK)

A diagnostic block used for patients experiencing neck or back pain

Indications

- Chronic non-malignant pain

Contraindications

- Coagulopathy
- Sepsis (local or systemic)

Preadmission Preparation

Medical Practitioner's Responsibilities Whilst Patient is at Clinic:

- Obtain informed consent from the patient
- Instruct the patient to visit their local medical practitioner one-week prior to admission to have: Full blood count; urea, electrolyte and creatinine attended. If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.
- Instruct the patient to cease:

Aspirin	10 days prior to admission
NSAID's	7 days prior to admission
COX-2 inhibitors (Vioxx, Celbrex)	2 days prior to admission
Heparin / Warfarin	As per consultant's direction.
- Check that patients have all medical imaging to hand..

Preadmission Preparation

Nurse Manager Responsibilities

- Receive booking form
- Contact patient per telephone and arrange admission date and provide preadmission instructions
- Book procedure according to waiting list, clinical condition and patient requirements.
- Send preadmission letter and a patient education sheet to the patient per mail
- Record procedure date and details in procedure book
- See Appendices for copy of preadmission letter and patient information sheets

On admission

- Complete pain history / admission
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score, and pulse oximetry.
- Check that a consent form has been signed
- Check blood, urine, wound swab, coagulation status results
- Check for any open wounds or signs of cellulitis
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- Insert IV cannula
- The assessing doctor must document the suspected levels and sides.
- The final decision on which diagnostic blocks are to be performed should only be made after examination on the day of the procedure. This should include a subjective assessment (ie. pain scores) and an objective of assessment of the movement that the patient has in their lumbar spine. For example, how far can they reach on forward flexion – to knees, mid shin, etc.
- For diagnosis it is inappropriate to block more than two joints at any one session.
- Consideration must be given to comparative local anaesthetic or placebo control for the repeat blocks.

Intraoperative Management

Staffing:

- +/- Theatre assistant
- Consultant
- Scout nurse

Equipment / Set up

- See Appendices for theatre set up sheet
- Air conditioning on to ensure air circulation in theatre
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO₂

Post-operative Care

Anticoagulation:	Prophylactic anticoagulation not required
Analgesia:	Patients may need supplemental oral analgesia
Bladder care:	Nil special care required
Diet:	As tolerated
IV fluids:	Nil. Remove IV cannula prior to discharge
Medications:	Give normal medications.
Mobility:	May mobilise.
Observations:	BP, pulse, pulse oximetry, and pain score every 15 minutes x 3 then hourly until discharge
Oxygen:	Not normally required
Wound care:	Check site for bleeding
Discharge:	After 1 hour and following review by Medical Officer.

Observe for possible complications

- Infection
- Transient radicular pain

DEPARTMENT PAIN MANAGEMENT

RADIOFREQUENCY LESIONING

Nursing And Medical Care Protocols

Devised October 2007

Dr Paul Murphy

RADIOFREQUENCY LESIONING

Radiofrequency denervation of facet joints is a destructive procedure and commits the patient to repeated and prolonged sessions of procedural therapy. This is particularly a problem if the diagnostic blocks have been inadequate, and the patient returns because there is in fact pain from other structures.

Indications

- Chronic non-malignant pain back and neck pain

Contraindications

- Coagulopathy
- Sepsis (local or systemic)

Preadmission Preparation

Medical Practitioner's Responsibilities Whilst Patient is at Clinic:

- Obtain informed consent from the patient
- Instruct the patient to visit their local medical practitioner one-week prior to admission to have: Full blood count; urea, electrolyte and creatinine attended. If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.
- Instruct the patient to cease:

Aspirin	10 days prior to admission
NSAID's	7 days prior to admission
COX-2 inhibitors (Vioxx, Celebrex)	2 days prior to admission
Heparin / Warfarin	As per consultant's direction.

- Check that patients have all medical imaging to hand.
- See Appendices for copy of OP16 and consent form.

Preadmission Preparation

Practice Manager Responsibilities

- Receive booking from consultant
- Contact patient per telephone and arrange admission date and provide preadmission instructions
- Book procedure according to waiting list, clinical condition and patient requirements.
- Send preadmission letter and a patient education sheet to the patient per mail
- Record procedure date and details in procedure book
- See Appendices for copy of preadmission letter and patient information sheets

On admission

To Theatre:

- Complete pain history / admission
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score and pulse oximetry
- Check that a consent form has been signed
- Check blood, urine, wound swab, coagulation status results
- Check for open wounds or signs of cellulitis
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- Insert IV cannula
- The suspected levels and sides must be documented by the assessing doctor.
- The final decision on which diagnostic blocks are to be performed should only be made after examination on the day of the procedure. This should include a subjective assessment (ie. pain scores) and an objective of assessment of the movement that the patient has in their lumbar spine. For example, how far can they reach on forward flexion – to knees, mid shin, etc.
- For diagnosis it is inappropriate to block more than 4 joints at any one session.
- If there is any doubt about the patients response, it is far easier to repeat diagnostic blocks than to commit to a possibly unnecessary session of radiofrequency. Consideration must be given to comparative local anaesthetic or placebo control for the repeat blocks.
- The decision to proceed to radiofrequency must be made by a member of the Specialist staff.

Intraoperative Management

Staffing:

- +/-Theatre assistant
- Consultant
- Scout nurse

Equipment / Set up

- Position the patient prone with a pillow under the head, abdomen and feet
- Air conditioning on to ensure air circulation in theatre
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO2

Post-operative Care

Anticoagulation: Prophylactic anticoagulation not required

Analgesia: Patients may need supplemental oral analgesia

Bladder care: Nil special care required

Diet: As tolerated

IV fluids: Nil. Remove IV cannula prior to discharge

Medications: Give normal medications.

Mobility: May mobilise

Observations: BP, pulse, pulse oximetry and pain score every 15 minutes x 3
then hourly until discharged

Oxygen: Not usually required

Wound care: Check site for bleeding

Discharge: After one hour and following medical review

Observe for possible complications

- **Infection**
- Bleeding
- Pain

DEPARTMENT OF PAIN MEDICINE
ST VINCENTS UNIVERSITY HOSPITAL

INTRATHECAL TESTING

Nursing And Medical Care Protocols

Formulated December 2007

Dr P Murphy / Dr D O' Keefe

INTRATHECAL TESTING

Intrathecal testing is the administration of differing drug agents into the intrathecal space (in a blinded fashion) to determine analgesic efficacy. Intrathecal testing is **imperative** prior to the implantation of intrathecal drug pumps.

Intrathecal testing is performed over a number of days and may be administered as a single shot technique or via an intrathecal catheter (see relevant protocols for more information).

Intrathecal testing should **only** be performed when the patient is experiencing pain.

Indications

- Chronic non-malignant pain
- Cancer pain management
- Severe muscle spasms
-

Contraindications

- Coagulopathy
- Sepsis (local or systemic)
- Hypovolaemia
- Allergy to specific drug(s)

Preadmission Preparation

- Obtain informed consent from the patient
- Arrange for the patient to have: full blood count; urea, electrolyte and creatinine; coagulation studies attended (if required). If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.
- Instruct the patient to cease:

Aspirin	10 days prior to admission
NSAID's	7 days prior to admission
COX-2 inhibitors (Vioxx, Celebrex)	2 days prior to admission

Heparin / Warfarin

As per consultant's direction.

- Check that patients have all medical imaging to hand.

Preadmission Preparation

On admission

To Ward:

- Complete pain history / admission
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score and pulse oximetry
- Check that a consent form has been signed
- Check blood, urine, wound swab, coagulation status results
- Check for open wounds or signs of cellulitis
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- Insert IV cannula

Intraoperative Management

Staffing:

- Pain specialist
- Registered nurse

Equipment / Set up

- Position the patient sitting on the side of the bed with their bottom as far back as possible and their feet resting on a chair. Place a pillow on the patient's lap for them to rest their arms on. Alternatively, the patient may be positioned prone with a pillow under the head, abdomen and feet or lateral.
- Air conditioning on to ensure air circulation in theatre (if injection performed under Image Intensifier)
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO₂

Post-operative Care

- Analgesia:** Patients may need supplemental oral analgesia

Opiate analgesia is to be withheld from 12 midnight each night prior to testing.
- Bladder care:** If no indwelling catheter insitu, the patient is to have a bladder scan performed 6 hours after the procedure.
- Diet:** As tolerated. To fast from 12 midnight the night prior to testing.
- IV fluids:** Nil. Remove IV cannula prior to discharge
- Medications:** Give normal medications (withhold opiate analgesia from 12 midnight each night prior to testing).
- Mobility:** May mobilise
- Observations:** BP, pulse, pulse oximetry and pain score every 5 minutes x 3 then every 15 minutes x 3 then hourly until transferred to the ward.
- Ward observations:** Hourly BP, pulse, pulse oximetry, respiratory rate, pain score and sedation score for 6 hours then every second hour (do not wake the patient for a pain score if sleeping normally).
- Oxygen:** Not usually required
- Wound care:** Check site for bleeding
- Discharge:** Transferred to the ward following medical review

Observe for possible complications

- **Infection (catheter track if intrathecal catheter used, insertion site, meningitis)**
- Epidural or spinal haematoma
- Spinal headache
- CSF leak around insertion site
- Pain and discomfort
- Hardware problems such as kinking, dislodgment if a catheter system is used.

- Adverse drug effects:
- **Opiate induced** (drowsiness and increased sedation, nausea and vomiting, pruritus, urinary retention, respiratory depression, euphoria, dysphoria, diaphoresis)
- **Clonidine induced** (drowsiness and sedation, hypotension, bradycardia, dry mouth, nausea and vomiting, urinary retention, anxiety)
- **Baclofen induced** (drowsiness and increasing sedation, dizziness, hypotension, hypertension, bradycardia, bradypnoea, respiratory depression, muscle weakness, nausea and vomiting, dry mouth, slurred speech, agitation, confusion, disorientation)
- **Local anaesthetic induced** (vasovagal response, toxicity or motor weakness)

DEPARTMENT OF PAIN MEDICINE
ST VINCENTS UNIVERSITY HOSPITAL

INTRATHECAL PUMP IMPLANTATION

Nursing And Medical Care Protocols

Devised October 2007

Dr Paul Murphy

INTRATHECAL DRUG PUMP IMPLANTATION

A pump implanted into the body that delivers intrathecal drugs to the spinal cord to treat uncontrolled pain or muscle spasm (Cousins and Bridenbaugh 1998: Chapter 29)

Indications

- Cancer pain management
- Chronic non-malignant pain management, which is non-responsive to more conservative methods of treatment eg. Failed back surgery, Complex Regional Pain Syndrome
- Severe muscle spasm following spinal cord injury, cerebral palsy and Multiple Sclerosis (baclofen +/- opioids and clonidine)
- Where the side effects of medication administration are intolerable when given via alternate routes (Krames 1996:333-352, Cousins and Bridenbaugh 1998: Chapter 29)

Contraindications

- Unsuccessful pain relief trial
- Coagulopathy
- Sepsis (local or systemic)
- Where the pump cannot be implanted 2.5 cm or less from the surface of the skin or where the patient's body size is not sufficient to accept the bulk and weight of the device (Cousins and Bridenbaugh 1998: Chapter 29)

Preadmission Preparation

Medical Practitioner's Responsibilities Whilst Patient is at Clinic:

- Carefully document the results of intrathecal testing
- Obtain informed consent from the patient
- Arrange pre-operative full blood count; urea, electrolyte and creatinine; coagulation screen; FSH / LH; testosterone level (males); oestradiol level (Females) attended. If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.
- Instruct the patient to cease:
Aspirin 10 days prior to admission

NSAID's	7 days prior to admission
COX-2 inhibitors (Vioxx, Celebrex)	2 days prior to admission
Heparin / Warfarin	As per consultant's direction.

- Complete the prescription for the first pump syringe, double checking to be performed at this time.
- Check that patients have all medical imaging to hand and schedule these for Radiology Review prior to implant.

Preadmission Preparation

Practice Manager Responsibilities

- Contact patient per telephone and arrange admission date and provide preadmission instructions
- Book procedure according to waiting list, clinical condition and patient requirements.
- Send preadmission letter and a patient education sheet to the patient per mail
- Record procedure date and details in procedure book
- Order implantable device from manufacturer / supplier
- Arrange admission with Bed Management for required date. The patient is admitted on the morning of surgery unless the patient has specific medical needs (if so, admit the evening prior to surgery)
- Ensure that a prescription for the first pump fill has been completed.)

Preadmission Responsibilities

- Pain Fellow to:
Review pre-operative test results

Check informed consent has been obtained

If seen the day prior to surgery, mark the surgical site with an indelible marker, including previous scar

On admission

To ward:

- Perform ward test / dip-stick urinalysis for protein, nitrites and blood (any indication of an urinary tract infection). Notify the pain management consultant or team immediately if positive results are obtained.
- Check for any open wounds or signs of cellulitis
- Pre-operative shower or wash using povidone-iodine solution and dress in theatre gown
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score, and pulse oximetry.
- Check that a consent form has been signed and a patient admission attended
- If admitted the night prior to surgery, to fast from 12 midnight.
- If admitted the night prior to surgery, may have their normal, routine analgesia.
- Complete pain history / admission
- Check blood, urine, wound swab, coagulation status results
- Ensure that implantable device is available for use
- Ensure that the first pump fill syringe has been prepared by pharmacy and available for use
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- If not previously attended, mark the pump pocket site with indelible marker
- Insert IV cannula
- Consider the need for a urinary catheter
- Pre-operative antibiotics
- Apply TED stockings

Intraoperative Management

Staffing:

- Theatre (scrub) nurse
- Scout nurse
- Anaesthetic nurse
- Theatre assistant
- Anaesthetist
- Consultant

Equipment / Set up

- See Appendices for theatre set up sheet
- Supine position for induction of general anaesthesia then usually turned to right lateral position
- Air conditioning on to ensure air circulation in theatre
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO₂, ECG

Post-operative Care

Anticoagulation: Prophylactic anticoagulation not required

Analgesia: IV PCA for post-operative analgesia

Intrathecal drug pump to be commenced the day after implantation (patient to be transferred to 9C at 0800 hours for commencement and monitoring)

Priming bolus calculations are to be made on the priming bolus work sheet and to be checked by another staff member (See appendices)

All dose changes must be clearly noted in the progress notes and pump printouts are to be kept in the patient's notes (a photocopy is to be taken and filed in the Pain Centre notes)

Patients may need supplemental oral analgesia

Bladder care: If the patient does not have a urinary catheter in situ, a bladder scan is to be attended 6 hours post-operatively

Diet: As tolerated

IV fluids: Maintain IV fluids for 24 hours

Medications: Give normal medications. May need to withhold oral baclofen if being administered intrathecally. Do not rapidly withdraw benzodiazepines if they have been used for muscle spasm.

- Mobility:** Bed rest with toilet privileges on the first post-operative day
then to be encouraged to mobilise as tolerated
- Patients are not to use “monkey bars”
- To lie flat and log roll (not to sleep in the prone position)
- TED stockings
- Observations:** Hourly BP, pulse, pulse oximetry, respiratory rate, pain score
and sedation score for 6 hours following return to ward (more
frequently if required) then BP, pulse, pain score and pulse
oximetry as per PCA protocol
- Neurological observations to be attended 4th hourly
- Temperature to be recorded 4th hourly for 48 hours
- Oxygen:** To be administered as per the PCA protocol for the first 24
hours post-operatively and for 24 hours after the intrathecal
pump has been started.
- Wound care:** Abdominal binder to be used as requested by the consultant
- Dressings to be kept dry and intact and should not be changed
unless the dressings are soaked. If so, a wound swab is to be
taken at the time of redressing.
- Wound drains to be maintained on suction unless otherwise
instructed
- Sutures or staples should be removed 8-10 days post-
operatively.

Observe for possible complications

- Infection (pump pocket, catheter track, spinal wound, spinal abscess, meningitis)
- Epidural or spinal haematoma
- Spinal headache
- CSF hygroma
- CSF leak around catheter insertion site
- Bleeding
- Pain and discomfort
- Pump pocket seroma or haematoma
- Hardware problems such as intrathecal catheter kink, dislodgement, disconnection or leaks, intrathecal catheter obstruction, pump failure.
- Programming errors
- Adverse drug effects
- Weight gain
- Fluid retention
- Decreased libido
- Endocrine dysfunction

Long Term Care

- An intrathecal drug history sheet is to be placed on the inside cover of the patient's pain file. It is to be updated whenever a change is made to drug dose, type, bolus doses are administered or if the side port is accessed.
- Endocrine function is to be monitored regularly
- Dose changes, especially those involving a combined bridge bolus, change in drug concentration and dose, are to be calculated by 2 medical staff members.
- **Nursing staff to be accredited to perform pump refill procedures.** Staff are encouraged to seek assistance from more experienced staff or to request that refills be performed under Image Intensifier

DEPARTMENT PAIN MEDICINE
ST VINCENTS UNIVERSITY HOSPITAL

SYNCHROMED INTRATHECAL

DRUG PUMP REFILLS

Nursing And Medical Care Protocols

December2007

Dr P Murphy / Dr D O'Keeffe

INTRATHECAL DRUG PUMP REFILL

What it is

Accessing an implanted drug pump with the intention to refill the pump reservoir with the prescribed volume of medication

Indications

- When the alarm volume of the intrathecal sounds, indicating low volume remaining in the pump
- To prevent medication withdrawal and rebound pain which will arise from the abrupt cessation of medication administered intrathecally

Contraindications

- Sepsis (local)
- Untrained staff

Equipment / Set up

- See Appendices for set up sheet
- Position the patient comfortably in a supine position or upright in wheelchair

Pre-refill care

- Assemble equipment
- Palpate pump site to determine location of refill port
- Interrogate the pump using the Medtronic scanner to determine expected return volume.
- Check pre-prepared syringe with a second registered nurse
- Don personal protective equipment
- Perform surgical scrub and don gown and sterile gloves
- Cleanse skin over the pump with antiseptic solution eg povidone-iodine or chlorhexidine and alcohol solution. Allow solution to dry on the skin (3 minutes)
- Using the appropriate refill kit access the centre port and remove remaining medication from the pump and compare with the expected return volume
- Refill pump
- Remove needle, clean the skin and apply dressing if required.

- Re-interrogate the pump and with a second registered nurse, reprogram pump to show correct residual volume, low alarm volume, drug concentration, infusion rate and estimated refill date. Make any changes to the program at this time.
- Make an appointment with the patient for pump refill.

Post-refill Care

Observations: If the patient is presenting for a routine pump refill with no changes to pump programming, no observations are required.

If an intrathecal bolus dose is to be administered via the intrathecal drug pump, baseline BP, pulse, pulse oximetry and pain score is to be recorded. Following pump refill and bolus dose programming the patient is to have BP, pulse rate, pulse oximetry and pain score recorded every 10 minutes for one hour (more frequently if unstable)

Wound care: Apply Band-aid type dressing if required

Discharge: Outpatients may be discharged immediately following the procedure if no technical difficulties were encountered with the procedure and there are no signs of accidental subcutaneous injection of medication

Observe for possible complications

- **Accidental injection of medication into the pump pocket (ie subcutaneously) or via the side port of the pump.**
- **Signs of medication overdose include:**

Agitation and restlessness

Increasing sedation

Respiratory depression, hypotension, bradycardia

DEPARTMENT OF PAIN MEDICINE

St Vincent's' University Hospital

SPINAL CORD STIMULATION (TRIAL)

Nursing And Medical Care Protocols

Devised May 2008

Dr Paul Murphy/ Dr Declan O'Keeffe

SPINAL CORD STIMULATION (TRIAL)

At treatment therapy that delivers a low voltage electrical stimulation to the spinal column to disrupt pain signals (Cousins and Bridenbaugh 1998: Chapter 32).

Indications

- Failed back syndrome
 - Complex Regional Pain Syndrome
 - Post-herpetic neuralgia
 - Arachnoiditis
 - Radiculopathies
 - Phantom limb or stump pain
 - Peripheral neuropathy
 - Intractable angina
 - Peripheral vascular disease
 - Successful trial screening
- (Cousins and Bridenbaugh 1998: Chapter 32; Waldman and Winnie 1996:483-499)

Contraindications

- Patient refusal
- Coagulopathy
- Sepsis (local or systemic)
- Inability of patients to successfully use the device
- The patient has a pacemaker or defibrillator
- Those patients who require frequent MRI's

Preadmission Preparation

Medical Practitioner's Responsibilities Whilst Patient is at Clinic:

- Complete booking form
- Obtain informed consent from the patient
- Arrange: full blood count; urea, electrolyte and creatinine levels and coagulation screen pre-procedure. If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.
- Instruct the patient to cease:
Aspirin 10 days prior to admission

NSAID's	7 days prior to admission
COX-2 inhibitors	2 days prior to admission
Heparin / Warfarin	As per consultant's direction.

- Check that patients have all medical imaging to hand

Preadmission Preparation

Practice Manager Responsibilities

- Receive booking from consultant
- Contact patient per telephone and arrange admission date and provide preadmission instructions
- Book procedure according to waiting list, clinical condition and patient requirements. If the patient lives locally, the patient is admitted on a day only basis; if the patient is frail or lives regionally, they are admitted for 3- 5 days
- Send preadmission letter and a patient education sheet to the patient per mail
- Record procedure date and details in procedure book
- Order device from manufacturer / supplier
- Arrange admission with Bed Management for required date (if short stay patient)

Preadmission Clinic Responsibilities

- Ensure bed booked for appropriate area post-operatively
- Flag any patient unable to attend preadmission clinic
- Check preoperative blood test results and urine or wound swab results
- Screen patient for an anaesthetic review (review may be attended by Pain Fellow)
- Weigh patient and check vital signs
- Perform ward test / dip-stick urinalysis for protein, nitrites and blood (any indication of an urinary tract infection). Notify the pain management consultant or team immediately if positive results are obtained.
- Resident Medical Officer to:

Admit the patient including specific questions regarding bladder function, pressure areas and perform a neurological assessment of upper and lower limbs.

Prescribe normal medications including usual opioid drugs

Contact the Pain Fellow and inform them about the patient

Check coagulation status if clinically required

Arrange for an ECG to be attended on males aged 40 years or more, females aged 50 years or more or if any cardiac history.

- Pain Fellow to:
Review pre-operative test results

Check informed consent has been obtained

On admission

To ward:

- Perform ward test / dip-stick urinalysis for protein, nitrites and blood (any indication of an urinary tract infection). Notify the pain management consultant or team immediately if positive results are obtained.
- Check for any open wounds or signs of cellulitis
- Pre-operative shower or wash using povidone-iodine solution and dress in theatre gown
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score, and pulse oximetry.
- Check that a consent form has been signed and a patient admission attended
- If admitted the night prior to surgery, to fast from 12 midnight.
- If admitted the night prior to surgery, may have their normal, routine analgesia.

To Theatre:

- Check pain history / admission
- Check blood, urine, wound swab, coagulation status results
- Ensure that the trial lead is available for use
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- Insert IV cannula
- Consider the need for a urinary catheter
- Apply TED stockings

Intraoperative Management

Staffing:

- Theatre (scrub) nurse
- Scout nurse
- Anaesthetic nurse
- Theatre assistant
- Anaesthetist
- Pain specialist

Equipment / Set up

- Lateral or prone position for lead placement
- Appropriate air circulation in theatre
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO₂, ECG

Post-operative Care

Anticoagulation: Prophylactic anticoagulation not required

Analgesia: Stimulation to be commenced the after implantation

Patients may need supplemental oral analgesia

Bladder care: If the patient does not have a urinary catheter in situ, a bladder scan is to be attended 6 hours post-operatively (inpatients)

Diet: As tolerated

Hygiene: To have sponge baths, being careful not to wet the dressing

IV fluids: Not usually required. Remove IV cannula prior to discharge if day only patient

Medications: Give normal medications.

Mobility: To be encouraged to mobilise as tolerated

Patients are to be encouraged to maintain good body mechanics
- to log roll rather than sliding on the surface of the bed; to keep their back straight when mobilising; not to lie prone; not to reach overhead (patients are not to use “monkey bars” or to sleep with their arms above their head) and to avoid rotation of the trunk to prevent lead movement)

TED stockings

Observations: Hourly BP, pulse, pulse oximetry, respiratory rate, pain score and sedation score for 6 hours following return to ward (more frequently if required)

Neurological observations to be attended 4th hourly – monitor for signs of new neurological deficit +/- severe central back pain.

Temperature to be recorded 4th hourly for 48 hours.

Monitor the patient for signs of infection (chills, fever, redness or swelling at the insertion site)

Oxygen: Not usually required

Wound care: Dressings to be kept dry and intact.

Observe for possible complications

- Bleeding
 - Headache (from CSF leak)
 - Infection
 - Failure to relieve pain
 - Allergic or immune system responses to the implanted materials
 - Loss of pain relief
 - Spinal cord injury
 - Paralysis following epidural haematoma or abscess
 - Hardware problems eg lead migration, loose electrical connections, lead or extension fractures
 - Seroma at the receiver site
- (Cousins and Bridenbaugh 1998: Chapter 32; Waldman and Winnie 1996:483-499)

Long Term Care

Patients with dorsal column stimulators should avoid:

- MRI (however, urgent MRI is possible if the magnetic switch in the stimulator is turned off)
- Demand driven pacemakers
- Therapeutic X-rays (radiotherapy). Radiation therapy may cause damage to the electrical components if delivered directly over the receiver.
- High output ultrasound such as lithotriptors (scanners can damage the implanted neurostimulator)
- Ultrasound scanning (may cause mechanical damage to the neurotransmitter)
- Use of defibrillators
- Diathermy in the region of the neurostimulator (Medtronic 2000:2)

Discharge Instructions

- Do not raise arms above the head during trial period
- To avoid twisting, bending and lifting during trial period
- Not to lie on their stomach during trial period
- To avoid prolonged sitting during trial period
- Patients should not drive or operate dangerous equipment during stimulation – if going to drive or operate machinery, the stimulator must be turned off.
- Do not operate the stimulator whilst flying in an aircraft (to avoid interference with aircraft communication systems)
- Keep the control magnet away from the neurotransmitter when not in use
- Keep spare 9 volt batteries for the patient programmer
- The numbness and tingling sensation felt may alter with movement and increased activity

- To advise medical staff if they have a stimulator prior to any procedure being performed

Report to the Pain Management and Research Centre if they experience any redness or pain.

DEPARTMENT OF PAIN MEDICINE
ST VINCENTS UNIVERSITY HOSPITAL

Spinal Cord Stimulator

(Implantation)

Nursing And Medical Care Protocols

Devised January 2008

Dr P Murphy

SPINAL CORD STIMULATION

At treatment therapy that delivers a low voltage electrical stimulation to the spinal column to disrupt pain signals (Cousins and Bridenbaugh 1998: Chapter 32).

Indications

- Failed back syndrome
- Complex Regional Pain Syndrome
- Post-herpetic neuralgia
- Arachnoiditis
- Radiculopathies
- Phantom limb or stump pain
- Peripheral neuropathy
- Intractable angina
- Peripheral vascular disease
- Successful trial screening

(Cousins and Bridenbaugh 1998: Chapter 32; Waldman and Winnie 1996:483-499))

Contraindications

- Patient refusal
- Unsuccessful pain relief during trial stimulation
- Coagulopathy
- Sepsis (local or systemic)
- Inability of patients to successfully use the device
- The patient has a pacemaker or defibrillator
- Those patients who require frequent MRI's

Preadmission Preparation

- Carefully document the results of trial stimulation
- Arrange for the patient to have: full blood count; urea, electrolyte and creatinine levels and coagulation screen performed. If the patient has a history of urinary tract infections, a midstream urine specimen is to be collected for culture and sensitivity also. If the patient has open wounds present, a wound swab is to be attended.

- Instruct the patient to cease:

Aspirin	10 days prior to admission
NSAID's	7 days prior to admission
COX-2 inhibitors (Vioxx, Celebrex)	2 days prior to admission
Heparin / Warfarin	As per consultant's direction.
- Check that patients have all medical imaging to hand.

Preadmission Preparation

- Order device from manufacturer / supplier
- Arrange admission with Bed Management for required date. The patient is admitted on the morning of surgery unless the patient has specific medical needs (if so, admit the evening prior to surgery)
- Check preoperative blood test results and urine or wound swab results
- Weigh patient and check vital signs
- Resident Medical Officer to:

Admit the patient including specific questions regarding bladder function, pressure areas and perform a neurological assessment of upper and lower limbs.

Prescribe normal medications including usual opioid drugs

Contact the Pain Fellow and inform them about the patient

Check coagulation status if clinically required

Arrange for an ECG to be attended on males aged 40 years or more, females aged 50 years or more or if any cardiac history.

- Pain Fellow to:
 - Review pre-operative test results

Check informed consent has been obtained

If seen the day prior to surgery, mark the surgical site with an indelible marker, including previous scar

- Check for any open wounds or signs of cellulitis
- Pre-operative shower or wash using povidone-iodine solution and dress in theatre gown
- Perform and record observations including temperature, pulse, respiratory rate, blood pressure, pain score, and pulse oximetry.

To Theatre:

- Complete pain history / admission
- Check blood, urine, wound swab, coagulation status results
- Ensure that implantable device is available for use
- If not previously attended, anaesthetist to conduct a pre-operative assessment
- If not previously attended, mark the pocket site with indelible marker
- Insert IV cannula
- Consider the need for a urinary catheter
- Pre-operative antibiotics
- Apply TED stockings

Intraoperative Management

Staffing:

- Theatre (scrub) nurse
- Scout nurse
- Anaesthetic nurse
- Theatre assistant
- Anaesthetist
- Pain specialist

Equipment / Set up

- Lateral or prone position for lead placement then may be turned to the supine position for induction of general anaesthesia
- Air conditioning on to ensure air circulation in theatre
- Warm blankets or warming blanket to maintain patient temperature

Monitoring

- As per anaesthetist requirements, usually non-invasive blood pressure monitoring, SpO₂, ECG

Post-operative Care

- Analgesia:** IV PCA for post-operative analgesia
- Stimulation to be commenced the after implantation
- Patients may need supplemental oral analgesia
- Bladder care:** If the patient does not have a urinary catheter in situ, a bladder scan is to be attended 6 hours post-operatively
- Diet:** As tolerated
- Hygiene:** Not to shower until sutures are removed (to have sponge baths, being careful not to wet the dressing)
- IV fluids:** Maintain IV fluids for 24 hours
- Medications:** Give normal medications.
- Mobility:** Rest in bed for 24 hours (may have toilet priveledges) with head of bed elevated 20 degrees then to be encouraged to mobilise as tolerated
- Patients are to be encouraged to maintain good body mechanics
- to log roll rather than sliding on the surface of the bed; to keep their back straight when mobilising; not to lie prone; not to reach overhead (patients are not to use “monkey bars” or to sleep with their arms above their head) and to avoid rotation of the trunk to prevent lead movement)
- TED stockings
- Observations:** Hourly BP, pulse, pulse oximetry, respiratory rate, pain score and sedation score for 6 hours following return to ward (more

frequently if required) then BP, pulse, pain score and pulse oximetry as per PCA protocol

Neurological observations to be attended 4th hourly – monitor for signs of new neurological deficit +/- severe central back pain.

Temperature to be recorded 4th hourly for 48 hours.

Monitor the patient for signs of infection (chills, fever, redness or swelling at the insertion site)

Oxygen: To be administered as per the PCA protocol for the first 24 hours post-operatively

Wound care: Dressings to be kept dry and intact and should not be changed unless the dressings are soaked. If so, a wound swab is to be taken at the time of redressing.

Wound drains to be maintained on suction unless otherwise instructed

Sutures or staples should be removed 8-10 days post-operatively

Observe for possible complications

- Bleeding
- Headache (from CSF leak)
- Infection
- Failure to relieve pain
- Allergic or immune system responses to the implanted materials
- Loss of pain relief
- Spinal cord injury

- Paralysis following epidural haematoma or abscess
 - Hardware problems eg lead migration, loose electrical connections, lead or extension fractures
 - Seroma at the receiver site
- (Cousins and Bridenbaugh 1998: Chapter 32; Waldman and Winnie 1996:483-499)

Long Term Care

Patients with dorsal column stimulators should avoid:

- MRI (however, urgent MRI is possible if the magnetic switch in the stimulator is turned off)
- Demand driven pacemakers
- Therapeutic X-rays (radiotherapy). Radiation therapy may cause damage to the electrical components if delivered directly over the receiver.
- High output ultrasound such as lithotriptors (scanners can damage the implanted neurostimulator)
- Ultrasound scanning (may cause mechanical damage to the neurotransmitter)
- Use of defibrillators
- Diathermy in the region of the neurostimulator (Medtronic 2000:2)

Discharge Instructions

- Do not raise arms above the head for 6 – 8 weeks following implant
- To avoid twisting, bending and lifting for 6 – 8 weeks
- Not to lie on their stomach for 6 – 8 weeks
- To avoid prolonged sitting for 6 – 8 weeks
- Patients should not drive or operate dangerous equipment during stimulation – if going to drive or operate machinery, the stimulator must be turned off.
- Do not operate the stimulator whilst flying in an aircraft (to avoid interference with aircraft communication systems)
- Keep the control magnet away from the neurotransmitter when not in use
- Keep spare 9 volt batteries for the patient programmer
- The numbness and tingling sensation felt may alter with movement and increased activity
- To advise medical staff if they have an implanted stimulator prior to any procedure being performed
- Report to the Pain Management and Research Centre if they experience any redness or excessive pain around the stimulator pocket or back wound.