

## Advanced Pain Therapies for Failed Back Surgery Syndrome

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## Types of pain

- É Nociceptive (conventional analgesic)
- É Neuropathic (Adjuvant analgesics)
- É Mixed (Failed Back surgery syndrome)
  
- É Acute/subacute/chronic

## Definition of Neuropathic Pain

IASP version: Neuropathic pain is pain due to a lesion or dysfunction in the somatosensory nervous system.

Can be very difficult to treat (Dworkin et al 2007)

## What is failed back syndrome?

- É Poor response to surgery
  - ó Disc surgery (fibrosis)
  - ó Spinal fusion
- É Pain
  - ó Radicular/referred
  - ó Axial spinal pain

## Advanced therapies

- É Spinal cord stimulation (SCS)
- É Intrathecal drug delivery systems (IDD)

Pain management programme/CBT

These need to be delivered with in context of skilled multidisciplinary team

## É What is Spinal cord stimulation (SCS)?

## SCS leads and Pulse generator



Patient feels tingling sensation in affected area and hence pain relief. So if numbness in affected area, no pain relief.

## NICE and SCS 2008

É Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who:

- ó É continue to experience chronic pain for at least 6 months despite appropriate conventional medical management
- ó É who have had a successful trial of stimulation as part of the assessment specified in recommendation 1.3.

Kumar et al Pain 2007; North et al. Neurosurgery 2005

## Indications for advanced pain therapies

### Spinal cord stimulation

- É Radicular pain
- É Plus lower back pain on the side of radicular pain
- É No numbness in affected area
- É Leg pain >>> back pain
- É Better Evidence

### Intrathecal drug delivery

- É Nociceptive back and leg pain
- É Back pain >>> leg pain
- É More diffuse pain
- É May be OK for patients not suitable for SCS
- É Poor evidence

## Patient Selection Checklist

- ✓ Failure of pharmacotherapy/ side effects
- ✓ More conservative therapies have failed (Cognitive Behaviour Therapy)
- ✓ Further surgery not indicated
- ✓ Psychological evaluation

Cole AJ. In *Low Back Pain Handbook*, 2nd ed. 2003; pg 362

## Benefits of SCS

- É An effective method of pain control for many patients with neuropathic pain
- É Non-destructive and less invasive than surgical alternatives
- É Reversible

Kumar K, Nath RK, Toth G. Deep Brain Stimulation for Intractable Pain: A 15-year experience. *Neurosurgery*. 1997

## SCS Trial

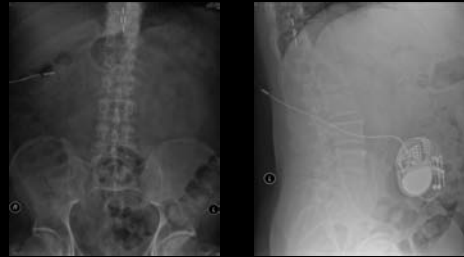
- É SCS Trial provides an opportunity
  - ó Gauge patient response
  - ó improve therapy cost-effectiveness
- É The goal is at least a 50% reduction in pain and better function

Kumar K, et al. *Neurosurgery*. 2006;58:481-486

## SCS Trial for FBSS



## SCS Permanent Implantation



## Some Risks of SCS

- É Lead migration resulting in loss of pain relief
- É Intermittent or uncomfortable stimulation
- É Stimulation in the wrong location
- É Neurological damage during procedure
- É Risk of infection at implantation

North R, Kidd D, Zahurak M, et al. *Neurosurgery*. 1998;32:384-395.

## SCS stimulation Clinical Evidence

Does it work?

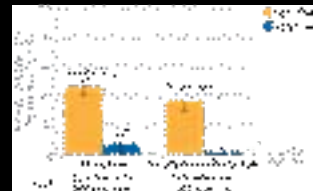
50-60% chance of 50% pain relief at 5 yrs

## Medtronic PROCESS Study

- É **Primary outcome**
  - ó Patients with >50% leg pain relief at 6 months (>50% reduction in leg VAS)
- É **Secondary outcomes evaluated at 1, 3, 6, 9, 12, 18 and 24 months**
  - ó Pain relief (leg and axial back VAS)
  - ó Quality of life (SF-36 and EQ-5D)
  - ó Function (Oswestry Disability Index)
  - ó Patient satisfaction
  - ó Need for drug or non-drug therapy for pain
  - ó Time away from work
  - ó Adverse events

Kumar, et al. *Pain* 2007

## Clinically Significant Leg Pain Relief



Key Findings:  
>50% leg pain relief at 24 months, continued greater effect with SCS\* in the per treatment/ITT analyses over 24 months

Kumar, et al. *Pain* 2007; n = 100

## Secondary outcome

- É Better function
- É More patient satisfaction
- É Improved QOL measures
  - ó SF36
  - ó EQ 5D

## Intrathecal Drug Delivery (IDD) Therapy

- É Delivery of pain medicine in the intrathecal space
- É The pump is connected to a thin, flexible catheter; both are implanted under the skin
- É Smaller doses of medication are needed for effective pain relief



## Intrathecal Drug Delivery (IDD) Therapy

- É Explanation
- É Trial
- É Back-up
- É Communication
- É Equipment



## Drugs used in Intrathecal Drug Delivery

- É Morphine/Hydromorphone
- É Bupivacaine
- É Clonidine
- É Baclofen
- É Ziconotide

## Approximate Equivalent Daily Doses of Morphine

Route of Administration	Relative Potency (mg)*
Oral	300
Intravenous	100
Epidural	20
Intrathecal	1

Lamer D. *Mayo Clin Proc.* May 1994;69(5):473-80.

## Benefits of IDD Therapy

- É Pain relief for patients with refractory pain
- É Reduction in adverse effects
- É Decreased or elimination of oral analgesics
- É Increased ability to perform activities of daily living

Lamer D. *Mayo Clin Proc.* May 1994;69(5):473-80. Paice JA, et al. *J Pain Symptom Manage* 1996;11(7):71-80

## IDD therapy Trial

- É To assess the efficacy and side effects of intrathecal morphine
- É Trialing methods include
  - ó Continuous epidural
  - ó Continuous intrathecal
  - ó Bolus epidural
  - ó Bolus intrathecal
- É 50% reduction in pain may be indication for long-term therapy

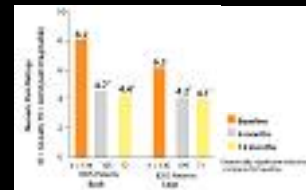
## IDD Therapy Risks

- É Programming error
- É Drug concentration error
- É Surgical complications, such as infection
- É Catheter could become dislodged or blocked
- É Immune suppression
- É Endocrine problems

Oncifio B, Myklebust T. J Neurosurg 1990;72:200-209; Winkelmueller M, Winkelmueller W. J Neurosurg 1996;85:458-467; Paice JA, Penn RD, Shotts J. J Pain Symptom Manage 1996;11(2):74-80

## Intrathecal Drug Delivery Clinical Evidence

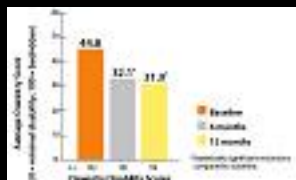
## Back and Leg Pain Relief



**Key Findings:**  
 Numeric back pain ratings decreased >48%, and leg pain ratings decreased by 32% at 12-month follow up

Deer, et al. Pain Medicine 2004; n=56

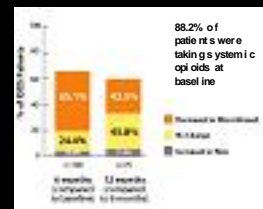
## Successful Disability Reduction



**Key Findings:**  
 Successful disability reduction was reported in 60% of patients at 6 months and in 66% at 12 months

Deer, et al. Pain Medicine 2004; n=56

## Decreased Use of Pain Medications



**Key Findings:**  
 At 6 months, 65% of patients decreased their use of systemic opioids from baseline  
 At 12 months, 42% of patients decreased their usage compared with the 6-month follow up

Deer, et al. Pain Medicine 2004; n=56

É Thanks