THE EFFECTIVENESS OF SPINAL CORD STIMULATOR IN TREATING COMPLEX REGIONAL PAIN SYNDROME IN INJURED WORKERS

Martin CM[1], Noertjojo K[1], Dunn CT[1], McNestry A[1], Chamber GK[2]
[1]Evidence-Based Practice Group, Workers' Compensation Board of BC, Richmond, BC.
[2]Centre for Clinical Epidemiology, Vancouver Hospital, Vancouver, BC.

Summary / Conclusion.

- An independent, critical appraisal of the literature on SCS in patients with CRPS does not reveal any level I quality of evidence research[36-39].
- No high quality research or systematic reviews since August 2001 (the date of the external consultant's review) up to May 2003, are present in the literature that would change the conclusions reached in the WCB commissioned review on this subject.
- The one randomized trial available in the world literature suggested there was a significant complication rate (20 - 75%) associated with use of the implantable spinal cord stimulator.
- Claimants who were approved for SCS (trial and permanent implant) had relatively shorter days on STD. However, these claimants had relatively higher median total claim costs and health care costs.
- Most claimants who had the SCS implanted, do not improve significantly in terms of function and RTW rates.
- Incorporating the lack of high level medical research on this subject, along with its significant potential adverse effect rate and poor compensation outcome measures when SCS are used, the WCB of BC should continue with its present position of not authorizing its use in the injured worker population.

Background.

- The WCB of BC spends almost $ 200 million, annually, on health care benefits (Figure 1 and Figure 2).

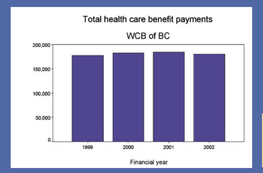


Figure 1. Total annual health care benefit costs at the WCB of BC

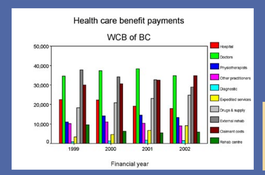


Figure 2. Description of annual health care benefit costs at the WCB of BC.

- In recent years, the WCB of BC has received increasing requests for the implantation of spinal cord stimulators to treat patients with complex regional pain syndrome.
- Complex Regional Pain Syndrome (CRPS) is characterized by continued pain which is disproportionate to the inciting event and is characterized by various signs and symptoms involving sensory, vasomotor, sudomotor and motor functions. It usually affects one or more extremities
- Spinal cord stimulation is one of a neurostimulation device that delivers low-voltage electrical stimulation to the spinal cord to block the sensation of pain.
- The goal of spinal cord stimulation is to reduce rather than to eliminate pain.
- Neurostimulation was developed based on the Gate Control Theory of pain developed by Melzack and Wall in 1965.
- Melzack and Wall proposed that neurostimulation activates the body's pain inhibitory system. According to the Gate theory, there is a gate in the spinal cord that controls the flow of noxious pain signals to the brain. The theory suggests that the body can inhibit these pain signals or "close the gate" by activating certain non-noxious nerve fibers in the dorsal horn of the spinal cord.
- The spinal cord stimulation system, implanted in the epidural space, stimulates these pain-inhibiting nerve fibers, masking the sensation of pain with a tingling sensation (paresthesia).
- Typically, a spinal cord stimulator consists of (Figure 3):
  - A. One or two leads which deliver electrical stimulation to the spinal cord with extension wire which conducts electrical stimulation from the power source to the lead
  - B. A power source which generates the electrical stimulation
  - C. A programmer to turn the stimulator on and off and to make adjustments in the amplitude, rate, and pulse width of the electrical stimulation.

Figure 3. Components of spinal cord stimulator (Medtronics).

- The spinal cord stimulation system is typically implanted in a two-stage procedure. Stage 1 involves implantation of a lead for a trial screening for about 1 - 10 days. Stage 2 involves permanent implantation of the complete spinal cord stimulation system.
- Figure 4 shows an x-ray picture of permanent spinal cord stimulation in place

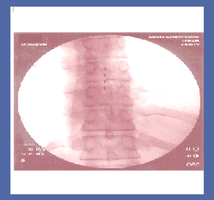


Figure 4. Fluoroscopy of in-situ midline spinal cord stimulation.

Objectives.

1. To describe the outcome of a systematic review on the effectiveness of Spinal Cord Stimulator (SCS) in treating patients with CRPS
2. To describe the outcome of WCB of BC claims associated with SCS and CRPS.

Methods.

1. Systematic review on the SCS in treating CRPS or reflex sympathetic dystrophy (RSD)
   - the WCB of BC commissioned GK Chambers Consulting Inc. to conduct a standard systematic review on SCS and CRPS or RSD in the early 2001.
   - electronic databases search, restricted to human research and to articles in the English language, was done on the Medline database (1966 to 2002) and Embase (1998 - 2002).
   - keyword: spinal cord stimulation, electric stimulation therapy, neuromodulation of spine, spinal, epidural, complex or regional pain syndrome, reflex sympathetic dystrophy, causalgia.
   - the electronic search was then followed by manual searches.
   - inclusion/exclusion criteria: any studies that addressed the effectiveness of SCS in CRPS patients
   - assessment of each individual research was based on the type of study design, type of outcome including reduction in pain and increased function, study length and period, statistical significance and the strength of the association of the results. How confounding and potential bias was assessed in each study was also reviewed.
2. Outcome of treatment with SCS at the WCB of BC
   - During the period January 2000 - March 2002, clinical staffs, who were asked to approve SCS on advice from pain specialists treating injured workers, were asked to submit the claim number of these claimants to the Senior Medical Advisor.
   - Reviews on the medical records and invoices related to these claimants were undertaken by the WCB of BC Evidence Based Practice Group. Data were extracted and Microsoft Access database was created to monitor the progress of these claimants using numerous variables and outcomes.
   - Data were then translated and analyzed in SPSS for Windows ver. 10.0.

Results.

Spinal Cord Stimulation and Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy: a Critical Review of the Published Evidence

Search results:

- Medline and Embase search identified 62 articles - mostly expert review articles or retrospective case series. Five more articles were identified by manual searching
- 35 (of 67 articles) had material content relevant to the objective of this review.
- 19 (of 35 articles) were expert review articles. 15 (of 35 articles) were retrospective case series. One clinical trial was published in two different journals (2 of 35 articles).

Research results:

- Kemler et al[1,2] reported a case series of 23 patients with CRPS who were treated with SCS, 18 (78.3%) of whom had permanently implanted SCS. Five (21.7%) did not receive permanent implantation due to no improvement during the trial period. 13 (of 23; 56.5%) patients reported improvement in pain. 9 (of 18; 50%) patients with permanent SCS implanted reported complications due to the device.
- Kumar et al[23-28] updated their case series several times. In their latest update[28], they reported on 235 chronic pain patients of various origins. Thirteen were diagnosed with CRPS and all were considered to have successful long-term pain control. Overall, 59% were considered to have good or excellent results.
- The only randomized controlled trial on SCS and CRPS was published by Kemler et al[3] in 2000. 54 patients with CRPS were randomized to received SCS and physical therapy (36 patients) or physical therapy alone (18 patients). 24 of 36 patients (66.7%) were permanently implanted with SCS. Kemler et al showed that there was a modest reduction in pain score (-2.4 on a 10 point scale) with no difference in term of quality of life and functional measurements at 6 months follow-up.

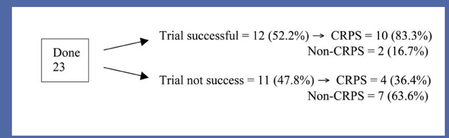
Outcome on treatment of chronic pain with SCS at the WCB of BC

- 47 claimants with chronic pain were referred for SCS implantation. 32 (68.1%) were males. The average age was 39 ± 9 year old. Males (38.5 ± 10.0) were younger than females (40.1 ± 8.6).
- Table 1. Distribution of cases.

	WCB SCS		
	Approved	Not approved	Total
CRPS	18 (64.3)	12 (63.2)	30 (63.8)
Not CRPS	10 (35.7)	7 (36.8)	17 (36.2)
	28 (59.6)	19 (40.4)	47 (100.0)

Thirty (63.8%) of the claimants were diagnosed with CRPS. 28 (59.6%) of the claimants were approved for SCS.

Of the 28 claimants approved for SCS, 23 (82.2%) had trial implant.12 (52.2%) of these had successful trial.



Of 23 implants that have been done, 14 (60.9%) patients were diagonsed with CRPS.

- Complication of surgery:
  - Infection 1 (4.3%)
  - Occipital headache (relief after SCS removal) 1 (4.3%)
  - SCS needed repair/replacement of electrode 3 (13.0%)
- It was not possible to assess any clinical progress based on the available data. Clinical progress could not be done due to lack of standardized measurement such as pain score, quality of life or functional measurements
- Tables 2 through 6 show other clinical and claim outcomes including return to work rates in the injured workers previously described. Significant observations are described below each table.

Table 2. Treatment outcome (as of March, 2003):

Outcome (n, %)	Approved 28 (59.6)				Not approved 19 (40.4)
	Done 23 (82.2)			Not done 5 (17.8)	
	Trial successful 12 (52.2)		Not success 11 (47.8)		
	CRPS 10 (83.3)	Not CRPS 2 (16.7)			
Wage Loss	2	1	2	3	5
Vocational Rehabilitation	3	-	4	1	7
Partial Permanent Disability	2	1	4	-	5
Return to Work	3 (30.0%)	-	1 (9.1%)	1 (20.0%)	2 (10.5%)

- 3 of 12 (25%) claimants who had successful trials returned to works compared to 1 (20%) that SCS trial was not done and 2 (10.5%) of claimants who were not approved (not good candidate) for SCS.
- Of those 3 with successful trial who returned to work, all had CRPS.

Table 3. Total number of days on short term disability (STD).

Those latest outcome on: n Mean ± SD (median)	Approved 28				Not approved 19
	Done 23			Not done 5	
	Trial successful 12		Not success 11		
	CRPS 10	Not CRPS 2			
Wage Loss	698 ± 272 (698)	891	1251 ± 426 (1251)	1356 ± 421 (1290)	1165 ± 418 (1272)
Vocational Rehabilitation	681 ± 586 (709)	-	933 ± 216 (858)	1233	960 ± 365 (787)
Partial Permanent Disability	1815 ± 448 (1815)	430	2071 ± 543 (1865)	-	1254 ± 437 (1154)
Return to Work	1465 ± 731 (1121)	-	765	895	617 ± 215 (617)
Overall STD	1147 ± 690 (1045)	660 ± 326 (660.5)	1390 ± 658 (1244)	1239 ± 358 (1233)	1055 ± 409 (1154)

- The median STD of this particular chronic pain patient was about 1000 days.
- Among those who had SCS permanently implanted, claimants without CRPS had shorter STD compared to those with CRPS

Table 4. Total claim costs ($).

Those latest outcome on: Mean ± SD (median)	Approved 28				Not approved 19
	Done 23			Not done 5	
	Trial successful 12		Not success 11		
	CRPS 10	Not CRPS 2			
Wage Loss	144779 ± 4480 (144779)	121094	218298 ± 81857 (218298)	102511 ± 42376 (113443)	158833 ± 74601 (151501)
Vocational Rehabilitation	119608 ± 130358 (74806)	-	280660 ± 132618 (259296)	180545	195543 ± 168553 (152518)
Partial Permanent Disability	585371 ± 274969 (585371)	944980	603244 ± 421972 (603397)	-	412063 ± 292820 (271770)
Return to Work	296156 ± 134115 (224446)	-	55451	123222	168797 ± 114067 (168797)
Overall claim cost	270759 ± 222552 (218794)	533037 ± 582575 (533037)	366151 ± 314322 (262430)	122260 ± 44239 (123222)	240046 ± 204620 (153655)

- Among those who had SCS permanently implanted, mean claim costs were relatively cheaper for CRPS claimants
- Largest median claim costs incurred among those who were granted pension

Table 5. Total health care costs only ($).

Those latest outcome on:	Approved 28				Not approved 19
	Done 23			Not done 5	
	Trial successful 12		Not success 11		
	CRPS 10	Not CRPS 2			
Wage Loss	31802 ± 3486 (31802)	36647	62707	29240 ± 14156 (25565)	38270 ± 25500 (28505)
Vocational Rehabilitation	106005	-	600821 ± 847116 (148849)	23528	24993 ± 10760 (25328)
Partial Permanent Disability	34549	51762	43292 ± 12290 (37956)	-	26286 ± 19142 (21041)
Return to Work	60358 ± 8182 (59924)	-	21947	17156	32824 ± 24578 (32824)
Overall healthcare cost	55034 ± 26858 (52401)	44204 ± 10688 (44204)	252125 ± 537185 (60029)	25681 ± 11359 (23528)	29838 ± 18128 (25833)

- As it was expected the most costly health care was incurred by those who had trial or permanently implanted SCS.
- Those on which SCS was not successfully implanted had the highest median health care cost

Table 6. Comparison between claimants that were approved and not approved

Those latest outcome on:	Days on STD (days)		Total claim cost ($)		Total health care cost ($)	
	Approved	Not approved	Approved	Not approved	Approved	Not approved
Wage loss	1107 ± 417 (961)	1165 ± 418 (1272)	144348 ± 61772 (138953)	158834 ± 74601 (151501)	35812 ± 14712 (34268)	38270 ± 25500 (28505)
Vocational rehabilitation	876 ± 393 (858)	960 ± 365 (787)	207751 ± 137352 (218353)	195542 ± 168552 (152518)	386400 ± 667727 (106005)	24993 ± 10761 (25328)
Partial Permanent Disability	1764 ± 736 (1830)	1254 ± 437 (1154)	646957 ± 344924 (776090)	412063 ± 292820 (271770)	43238 ± 10610 (37956)	26286 ± 19142 (21041)
Return to Work	1211 ± 625 (969)	617 ± 215 (617)	213428 ± 149666 (213141)	168797 ± 114067 (168797)	44035 ± 23149 (52401)	32824 ± 24578 (32824)
Overall	1224 ± 615 (1046)	1055 ± 409 (1154)	300451 ± 279167 (196843)	240046 ± 204620 (153655)	119047 ± 327333 (41415)	29839 ± 18129 (25833)

- Claimants who were approved for SCS (trial and permanent implant) had relatively shorter days on STD. However, these claimants had relatively higher median total claim costs and health care costs.

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