

SPINAL CORD STIMULATION

Use in Patients with Complex Regional Pain Syndrome

W.C.B. Evidence Based Practice Group

By

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Compensation and Rehabilitation Services Division

Workers' Compensation Board of BC

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A. SUMMARY.

MEDICAL EVIDENCE – CONCLUSIONS

1. Twenty-five workers have had SCS implantation approved by the WCB up to October 17, 2002. Thirteen of these had CRPS, while twelve workers had other diagnoses (radiculopathies).
2. Nineteen of those twenty-five workers actually had the SCS implantation. Only ten had a successful trial.
3. Of the ten successful SCS implantations, six were in CRPS patients and four were patients with radicular problems.
4. Of the ten workers who had SCS implantation, two have RTW.
5. Of the nine “unsuccessful” SCS implantation patients, one worker has RTW.
6. An independent, critical appraisal of the literature (July 2001) on SCS in patients with CRPS does not reveal any level I quality of evidence research (Table I).
7. No high quality research or systematic reviews since August 2001 (the date of the external consultant’s review) are present in the literature that would change the conclusions reached in the WCB commissioned review on this subject.
8. 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.

CORPORATE CONCLUSIONS

1. Most workers who had the SCS implanted, do not improve significantly in terms of function and RTW rates.
2. The associated health care and rehabilitation costs with SCS is significant.
3. 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 should continue with its present position of not authorizing its use in the injured worker population.

B. WCB OF BC COMMISSIONED:

Spinal Cord Stimulation (SCS) and Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD): A Critical Review of the Published Evidence

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I. SUMMARY

The object of this review was to critically review the published evidence on the effectiveness of Spinal Cord Stimulation (SCS) on complex or chronic regional pain syndrome (CRPS), also known as reflex sympathetic dystrophy (RSD). A search of the medical literature identified 35 studies that were considered relevant to the topic. Only one of these studies represented a randomized clinical trial of sufficient quality, to be critically appraised with respect to the effectiveness of this intervention. Most studies, were of the nature of a review and not original research or were case series type of studies that lacked a control group and so were essentially descriptive in nature⁽¹⁻³⁵⁾. The one randomized trial that was identified was unblinded, had relatively subjective end points and was designed with a very small sample size that made externalization or generalization of the results difficult⁽³⁾. In addition, this study failed to detect a difference in function between the control and SCS groups. Further, the significant reduction in pain as seen in the VAS score of a 2.6 difference, is less than the 50% reduction of pain that was generally quoted as being required to demonstrate clinically significant pain differences in the literature. While it is beyond the scope of this review to undertake a health technology economic assessment, the high costs associated with the procedure are additional causes for concern as to the effectiveness of SCS, as well as the relatively high number of adverse events.

The conclusion of this review is that there is insufficient evidence to conclude that SCS is effective in treating CRPS or RSD. Further studies with larger sample sizes and better designs that include blinding and control groups are necessary to evaluate the potential harms and benefits of this technology.

II. BACKGROUND

II. a. Spinal Cord Stimulation and Chronic Regional Pain Syndrome:

The gate control theory for the control of pain involving stimulation of the spinal cord has been around for decades ⁽⁴⁾. The gate control theory is currently the most widely accepted theory and implied a central mechanism as the basis for chronic pain. However, other competing theories exist and there is strong evidence for the role of more peripheral oxidant damage as a mechanism as well. It may well be that chronic pain is a combination of central and peripheral mechanisms.

One article has suggested that the theory of spinal cord stimulation (SCS) to treat chronic pain, dates back as far back the 19th century ⁽¹¹⁾. Actual spinal cord stimulation, however, has been in use since 1967. Shealy introduced this electrical stimulation of the posterior white column to treat chronic pain at that time.

Evans defined the term reflex sympathetic dystrophy (RSD) in 1946. This symptom complex was redefined as complex regional pain syndrome (CRPS) in 1995 by the International Association for the Study of Pain (IASP) ⁽¹³⁾.

Currently accepted criteria to diagnose CRPS include:

1. Pain, allodynia, or hyperalgesia
2. Local signs or symptoms of edema, skin changes or abnormal sudomotor activity
3. Lack of other causative diagnoses
4. Usually, but not always there should be an initiating event, such as immobilization, surgery, or trauma.

Current research studies tend to use both terms, CRPS and RSD.

II. b. Appraisal criteria:

It is accepted in medical research, that the results of research studies can represent more than one state of affairs. They can represent a true set of results, or they can be due only to chance and not be true based on the type of study sample and measurements obtained. A third possibility is that

results can be false, due to various sorts of systematic error. This third possibility can be based on confounding or various biases that may arise to systematically affect results. To deal with these issues, in any current review of the literature, it is necessary to establish a set of criteria on which to make judgements about the quality of published material that is to be reviewed⁽³⁸⁾. These criteria must be able to assess the degree to which the available literature represents a true state of affairs, a possibility of chance error or the likelihood of being due to systematic error.

Fortunately, medical science has established accepted criteria that can be applied to these issues. The accepted way to deal with chance error is to reject hypotheses or study results where there is more than a certain probability of the study results being due to chance. The convention is to use p-values to assess point estimates and confidence limits to give some idea of the stability of the point estimate. If the p-value is greater than .05 or the confidence interval crosses 1 then the study results are generally accepted as being not statistically different and no conclusions can be drawn about the results.

A host of issues come into play when setting criteria to assess the potential for systematic error. The most important of which is study design. Study designs range in terms of their ability to control for systematic error, from controlled intervention trials to case series in which no control group is available.

Studies with a decreased level of sophistication in design, such as case series or retrospective studies are less able to establish causative relationships because of this propensity for systematic error to affect results. Recall bias for retrospective study designs and the inability to compare against a control group in case series are just two of many important issues to consider.

Finally, how positive the study results are (strength of the association), whether or not a dose-response relationship is seen and whether or not results are consistent across studies and outcome measurements will impact on any assessment looking at causative relationships. The exception is in the case of consistency if there is a likelihood of systematic error in the study designs. In this setting, repetitive studies may show consistent relationships that are untrue. Note that, in general, study results tend to favor positive results as negative studies tend not be published. This publishing bias tends

to increase chance error in results and artificially create consistency in study results.

In summary, the standard to accept as effective a new intervention of the type that SCS falls under requires research involving an appropriate experimental design.

The randomized clinical trial is the design that works best in this situation and is the standard for this review.

II. c. Purpose:

The purpose of this review is to evaluate the published literature on the effectiveness of SCS in the management of CRPS.

III. METHODS

III. a. Literature search:

A literature search of two available electronic databases was conducted. These were the Medline database from 1966 to 2002 and EMBASE from 1998 to 2002 using the following Key Words: spinal cord stimulation, electric stimulation therapy, neuromodulation of spine, spinal, epidural, complex or regional pain syndrome, reflex sympathetic dystrophy, causalgia. The search was restricted to human research and to articles in the English language.

In addition, a number of position papers and consensus reports were identified through the WCB librarian. Articles reviewed, were hand searched for additional references and a number of additional articles were identified for review.

III. b. Inclusion/exclusion criteria:

Controlled trials and studies with lesser designs were included if they directly addressed the topic being reviewed, namely the effectiveness of SCS in CRPS. These broad criteria became necessary due to the lack of published controlled clinical trials. This lack of higher quality or higher level of published data would have limited the review to just the 1 trial by Kemler, had the standards for review not been relaxed.

III. c. Evaluation criteria:

1. Study designs were assessed based on a hierarchy of study design. In order of importance and ability to assess a causative relationship, they were assessed as follows. The highest order looked for were controlled trials followed by retrospective studies, case series and reviews in a descending order and ability to establish causative relationships. This approach is in keeping with standard epidemiological textbooks dealing with the issue of establishing causative relationships.
2. Study outcomes were assessed in their ability to address the question of reduction in pain and increased function. Employability as an outcome was not identified.

III. c. Evaluation criteria: (con't)

3. The study period was assessed as to whether or not it was prospective, retrospective or at one point in time. The length of the study period was also assessed.
4. Results were assessed as to their statistical significance and strength of association.
5. Confounding and bias was assessed for each study.

IV. RESULTS

A search of medline and Embase identified 62 articles of which most were reviews or retrospective case series studies without control groups. 5 more studies were identified by hand searching the reviewed articles and the WCB files on this subject. On closer inspection, only 35 articles had material or content relevant to SCS and/or CRPS or RSD. Of these 19 were reviews or only contained review material relevant to this inquiry. There were 15 articles that were retrospective and/or case series. There were 2 publications on the same clinical trial.

IV. a. Other reviews

There are several good reviews of the literature looking at the volume and quality of research done in the area of SCS in the management of CRPS. M. Stanton-Hicks published a consensus report in 1998⁽¹⁶⁾. In this report he points out that only a “few investigations have attempted to determine its efficacy in the treatment of specific pain syndromes. Only one paper has prospectively looked at outcome in a small group of patients with CRPS”. The rest are retrospective studies.

J. Turner published a “systematic literature synthesis” in Neurology in 1995 on the use of SCS for chronic low back pain⁽¹⁵⁾. 39 studies, all case series studies without control groups were identified. She concluded that “the lack of randomized trials precludes conclusions concerning the effectiveness of spinal cord stimulation relative to other treatments, placebo or no treatment”.

N. Bogduk points out in his recent review published in 2001 that “Previously, SCS had been advocated as a treatment for CRPS, but only on the basis of descriptive studies”⁽⁶⁾. He went on to discuss that recently a randomized trial had been published by Kemler in 2000 that had shown some benefit in pain reduction. Bogduk concludes that “the average improvement in pain was only from 7 to 4 on a 10-point visual analogue scale, and the changes in other measures of pain and measures of functional status and health-related quality of life did not differ between treatment groups. Consequently, although welcome in a field largely devoid of evidence, that study left a quandary: are invasive and costly interventions justified when they produce modest symptomatic relief but no other attributable benefit for the patient”?

IV. a. Other reviews (con't)

Tanelian in a review published in 1996, points out some of the problems in assessing effective therapies for CRPS ⁽⁹⁾. Currently, “over 30 treatments have been reported to improve reflex sympathetic dystrophy in more than 70% of patients”. Tanelian also discusses the lack of knowledge about the natural history of the condition and the fact that despite the recommendation for early intervention, research has shown that despite 75% good initial responses to treatment, later on at 1 year nearly the same percent (66% and 69%) still have pain and are retired, disabled or have left their job. Therefore, despite optimism on the part of the clinical community about the success of various therapies the real burden of this condition may be greater and the response to therapy may be substantially less than initially anticipated.

IV. b. Case series and retrospective review research

Almost all of the existing original research on SCS reviewed involved case series studies with retrospective designs ^(3,19-33). These studies lacked control groups against which to compare outcomes and could not be accepted as evidence of effectiveness. These studies were descriptive in nature as opposed to analytical and while they did indicate a potential benefit, they were considered hypothesis generating only. Potential bias and methodological issues included small sample size, a lack of blinding with subjective outcomes and the potential for recall bias. The case series studies by Kemler and Kumar typified the problems ⁽¹⁾. Kemler studies 23 patients with RSD without a control group. Approximately half (13 patients) of the original series reported improvement in pain, while half of those with permanent implant reported complications (9/18). 5 were not implanted as they did not improve during the test phase. Investigators and subjects were not blinded. Kumar has published several case series studies ⁽²³⁻²⁷⁾. In 1991, he published on 121 subjects of whom 94 went on to receive SCS. 32 (26%) of these eventually stopped using the device. In 1998, he published again on 235 subjects of whom 59% got a good to excellent result. Again, the problem of a lack of no blinding, no control group against which to compare, and subjective assessments as to the degree of pain relief made it very difficult to interpret these results.

As discussed above, the only controlled trial that could be identified was the trial published in the New England Journal of Medicine, by Kemler in 2000.

In this case it was difficult to generalize from a study with such a small sample size (n=24 who received SCS). With no difference shown for quality of life measures and function, the modest reduction (-2.4 on a 10-point scale) in pain is also hard to interpret as this is subjective outcome and the study subjects were not blinded. One worries about a placebo effect taking place. The complication rate varied between 20 to 75%.

V. DISCUSSION

The literature on spinal cord stimulation in the treatment of complex regional pain syndrome is limited with most published material occurring in obscure or non-peer reviewed journals. The majority of the published material is review type articles. Original research is, by and large, confined to weak study designs, namely case series and retrospective research. The only clinical trial is on a very small number of subjects and did not show differences for the important outcomes of quality of life and function. Improvement in pain scores may not have been clinically significant according to accepted measures in the pain literature and may have been biased by a placebo effect in that subjects and investigators were not blinded. There appears to be a general understanding in the literature of the need for larger and better designed trials to evaluate this therapy further. This is seen as necessary before its effectiveness can be evaluated. Given the cost and complication rates studies should also assess the harm v. benefits as well as issues around the value in terms of cost.

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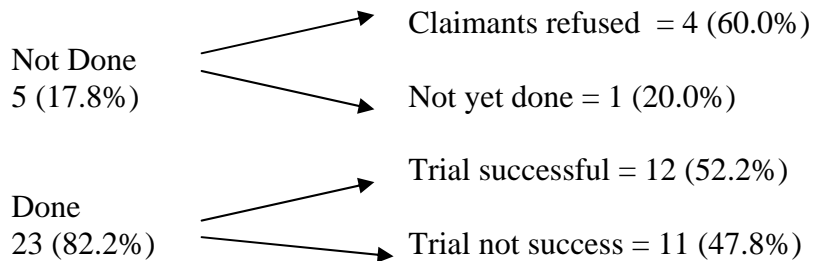
D. UPDATE ON SPINAL CORD STIMULATION AND COMPLEX REGIONAL PAIN SYNDROME AT THE WCB OF BC.

As of April, 2003, 47 claimants with chronic pain were identified as good candidates to be treated with SCS. 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).

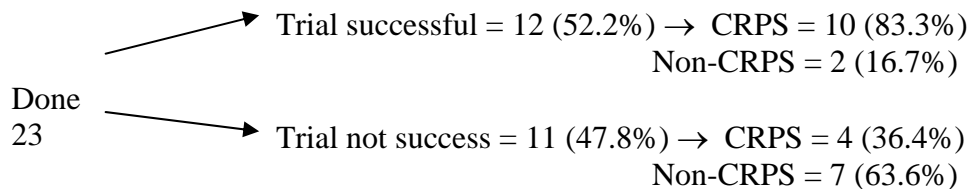
Of the original 47 claimants, 30 (63.8%) were diagnosed with CRPS, while the rest was diagnosed with chronic pain of various origins.

	WCB SCS approved	WCB SCS not approved	
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)

28 (59.6%) were approved by the WCB for (trial) implantation. Of these 28 claimants:



Of 23 implants that have been done,



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%)

Outcome:

Outcome	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%)

Based on information available on E-file, it is difficult to assess any progress due to lack of standardized measurement of progress in term of for e.g. pain score, QoL etc.

Total number of days on STD (days, mean ± SD (median)):

Those latest outcome on:	Approved 28			Not done 5	Not approved 19
	Done 23		Not success 11		
	Trial successful 12				
	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)

Total dollars paid for these claims (\$, mean ± SD (median)):

Those latest outcome on:	Approved 28			Not done 5	Not approved 19
	Done 23		Not success 11		
	Trial successful 12				
	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)

Total healthcare costs (\$, mean ± SD (median)):

Those latest outcome on:	Approved 28			Not done 5	Not approved 19
	Done 23		Not success 11		
	Trial successful 12				
	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)

Comparison between approved and not approved (mean ± SD (median))

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)