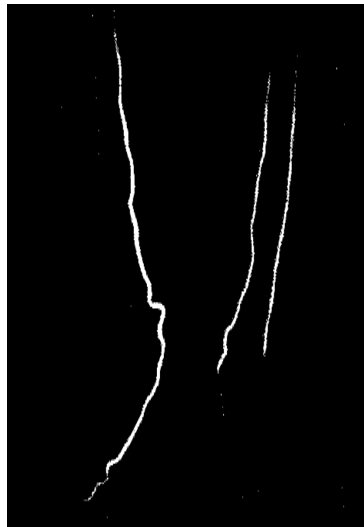


I have some disease on my legs and right hand. This disease is called Buerger syndrome whose treatment fee is supported by Government while its aspect has been authorized.

Over 4 years, I could not find the cause of my pain. When I was examined by a some MD, he found that your blood pipes had a lot of problems so he ordered me to take the MAG(Magnetic Resonance Angiography). As a result, my cause of pain had been found by only one excellent MD.



Blood pipes on my right leg are stopped, also left's pipe is only one. Both legs are typical Buerger disease. Many MDs could not find this disease but simple MRA has clarified this fact. This means that one scientific instrument is much better than a large number of highly educated MDs.



Human beings are governed by egoism.



History

- I felt painful on my leg in 1998.
- MD checked up my blood pressure of legs but failed to measure, because of no pulse on my back of right-foot.
- My waist MRI images were taken and examined, and then MD said that your problem could be recovered by muscle-building.







After that

- Hard physical training never recover my leg situation.
- Hard physical training made my legs more worse.
- In 2002 Autumn, the roots of my leg's nails became dark, and also my leg situation became serious situation.



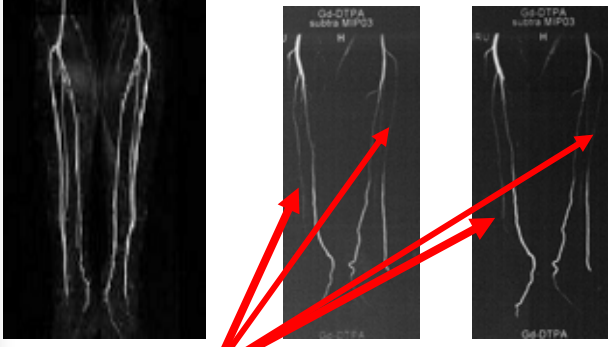
Medical Diagnosis in Major Medical Schools in Tokyo

-  MD said no problem on your legs in medical school of T university.
-  MD said there was a big problem on your right leg in medical school of N university.
-  Magnetic Resonance Angiography. Measured in 9th June 2003.




Results of Angiography


- Normal
- My Angiographies



Buerger Disease : ThromboAngiitis Obliterans



Buerger Disease : TAO



- 閉塞性血栓血管炎（ビュルガー病）
へいそくせいけっせんけっかんえん
- 四肢の主幹動脈に多くみられる慢性動脈閉塞性疾患をいいます。
- 20～40歳代の男性で喫煙者に多くみられ、とくに、下腹部、足底部に多発します。
- 症状としては、末梢部の血行障害、間欠性跛行、手指や足指の先端部に起きる疼痛などがあり、欠々に再発を繰り返します。
- 進行すると皮膚潰瘍や壊死が起こります。治療方法としては、側副血行路の拡大や交感神経節の切除などがあります。
- 悪化を防ぐためにも禁煙はたいせつな要素です。

ビュルガー病

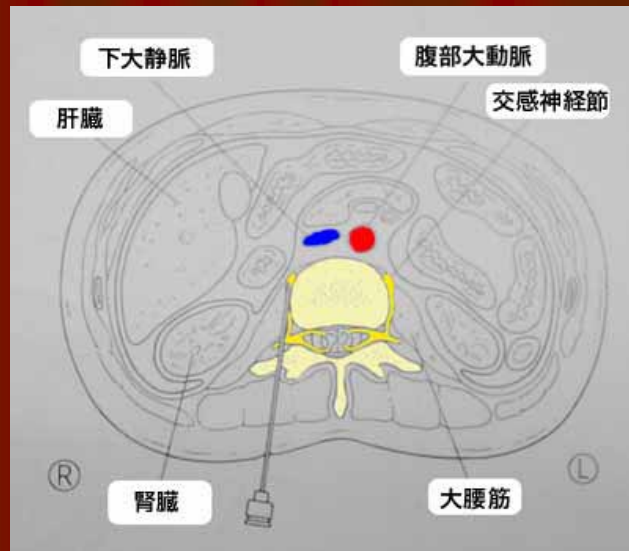


腰部交感神経節ブロック
硬膜外神経ブロック
電気刺激助痛装置

腰部交感神経節ブロック

腰椎椎体の外側に交感神経が走っています。腰部交感神経節ブロックは、慢性動脈閉塞症で下肢の血流が悪く潰瘍ができ、また痛みが強いときなどに行います。X線透視下に、背中からブロック針を刺入し、アルコールを注入して腰部交感神経節を破壊します。交感神経が遮断されると血管が拡張し血流が増え、皮膚温が上昇し、痛みが軽減し、潰瘍が徐々に治ってきます。高周波熱凝固法を用いると、より安全に行うことができます。ただし効果の持続はアルコールの方が長いようです。

腰部交感神経節ブロック

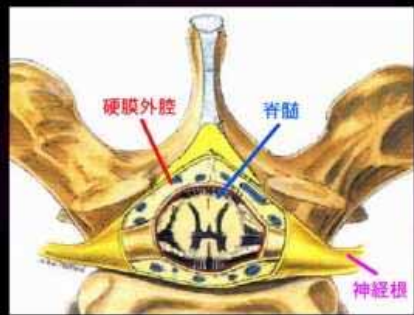


高周波熱凝固法



硬膜外神経ブロック

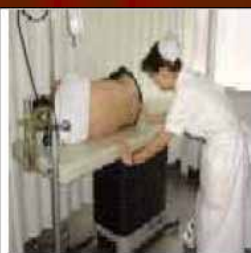
硬膜外ブロック



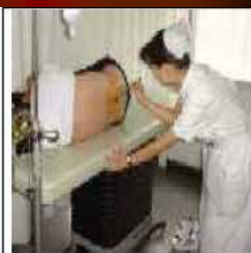
硬膜外神経ブロック手技1



ヒビテンクリーム



良く拭きます



イソジン消毒



同2回消毒



ヘキサックアルコール



同2回消毒

硬膜外神経ブロック手技2



脊髄電気刺激法による鎮痛法(spinal cord stimulation)

当科では、神経ブロック治療に対して抵抗性の難治性慢性疼痛に対し、積極的に脊髄通電法を行っています。1960年代より電気刺激による鎮痛法が試みられましたが、当教室前教授である下地恒毅(現・同名誉教授)が、世界に先駆け硬膜外腔より脊髄を通電刺激する“経皮的硬膜外脊髄通電法”を開発しました。現在では、刺激電極と植え込み型の神経刺激装置一式が開発され、日常生活に支障なく脊髄刺激が行えるようになってきました。1992年より健康保険も適応されており、実際に施行された多くの患者さんの満足を得ています。

1. 刺激装置について

完全植え込み型のバッテリー内蔵型神経刺激パルス発生器(刺激装置)、4極の硬膜外脊髄刺激電極、刺激装置の患者用コントローラー一式が市販されています。刺激装置は電極の位置、患者さんの体格や希望に応じて、前胸部や脇腹部、下腹部などに植え込みます。刺激の強さや早さは、外部からコントローラーによって変更できるようになっています。刺激装置には電池が内蔵されており、刺激の使用頻度にもよりますが、約10年もつといわれています。



The image shows the Trec 3 device, a multi-programmable microprocessor, and its packaging. To the right is an anatomical diagram of the human back and neck, illustrating the placement of the stimulation system. The diagram is labeled with three numbers: ① indicates the stimulation device (stimulator) located in the lower back; ② indicates the connection point (lead) extending from the device; and ③ indicates the stimulation electrodes (leads) that are inserted into the spinal canal.

2.適応となる疾患

- ・末梢血管障害(バージャー病など): 脊髄刺激により疼痛の緩和とともに血液の循環を改善する効果があります。
- ・帯状疱疹後神経痛: 帯状疱疹罹患後、皮疹が治癒しても強い痛みが残ることがあります。鎮痛薬や神経ブロック治療でも改善が難しい場合に、劇的な効果が得られることもあります。

具体的な刺激装置植え込みの流れは

- ① 硬膜外腔への刺激電極留置
- ② 1～2 週間の体外試験刺激による有効性の確認
- ③ 有効例では刺激システムの永久植え込みとなります。

実際には、入院して行われます。入院期間は約 3 週間前後です。



The image displays three components related to the stimulation system. On the left is a magnetic resonance imaging (MRI) scan of a human spine, showing the location of the stimulation device and leads. In the center is the external control unit, labeled 'コントローラ' (Controller), which is used to manage the stimulation. Below it is a smaller component labeled '磁力によるコントローラ' (Controller by magnetic force). On the right is a close-up of the control unit's control panel, labeled '故障' (Failure), showing several indicator lights. Text above the panel reads 'コントローラによる障害 手角筋に力が加わると息継ぎ' (Disorder by controller: when force is applied to the hand muscles, breathing is interrupted). Below the panel, text reads 'コントローラーの警報ランプが全て点灯、制御不能に。' (All warning lamps of the controller are lit, control is lost).

Spinal cord stimulation in Buerger's disease

A V Pace, N Saratzis, D Karokis, D Dalainas, G D Kitas

Ann Rheum Dis 2002;**61**:1114

Buerger's disease (BD) is characterised by segmental inflammation of medium and small size arteries, affects mainly young adult men, and is more prevalent in the southeast Mediterranean and the Far East. Its pathogenesis remains unclear, but cigarette smoking is strongly implicated. Autoimmune diseases, hypercoagulable states, diabetes, and emboli need exclusion before a diagnosis is made. The tibial and leg digital arteries are usually affected, and arteriography shows typically "corkscrew" peripheral obstructions. The best treatment is stopping smoking. Prostacyclin infusion is currently the most effective treatment for pain control and healing of ischaemic lesions.¹ In selected cases, regional guanethidine block may have good results.² Sympathectomy does not always provide longstanding benefit,³ and arterial bypass is difficult due to poor run-off in the diseased arteries.^{3,4} Limited amputations are often necessary to remove necrotic tissue.

New methods are being tested for pain relief and ulcer healing, including pedicled omental transfer⁵ and induction of angiogenesis using vascular endothelial growth factor gene transfer.⁶ Spinal cord stimulators (SCS) are used extensively in refractory peripheral atherosclerotic disease. Experience in BD is limited but suggests that SCS have favourable effects on pain and healing of digital ulcers, comparable with those noted in other arteriopathies.⁴

CASE REPORTS

We present our experience of the use of SCS in three patients with BD. They were all male, middle aged smokers, who had presented with painful ischaemic ulcers of the legs at least six years earlier, had typical angiographic appearances of BD, no evidence of other relevant diseases and had been (and still are) unable to stop smoking. Over that period, they had all required repeated admission to hospital and had unsuccessfully tried various treatments to relieve pain and promote healing of their ischaemic ulcers, including analgesics, vasodilators, antiplatelet agents, epidural analgesia, prostacyclin, and local guanethidine infusions. One patient had needed amputation of gangrenous toes and another a below-knee amputation after these treatments failed. SCS were used in all three patients to manage intractable pain, poor wound healing, and recurrence of ischaemic lesions occurring postoperatively. Within four months of treatment with SCS, the pain resolved completely and the wounds healed in all three patients and they were able to return to work. One of them requires oral analgesia after prolonged periods of standing, but none of them has required further admission to hospital.

DISCUSSION

SCS may modulate painful stimuli through several mechanisms. According to the gate control theory of pain, stimulation of large diameter, type A fibres at the posterior horns of the spinal cord by low amplitude electric current inhibits simultaneous transmission of painful stimuli through

the same spinal cord segment. Similarly, inhibition of sympathetic vasoconstriction improves the peripheral microcirculation. Nitric oxide and γ -aminobutyric acid systems in the spinal cord may be important intermediaries in SCS-induced pain relief.^{7,8} In arterial insufficiency, SCS have been shown to decrease rest pain (Fontaine class III), improve claudication distance, raise skin temperature, and increase transcutaneous oxygen tension in the forefoot, with values of >10 mmHg before treatment being associated with significantly better outcome.^{9,10}

SCS may be a useful therapeutic option in BD, particularly for pain control and wound healing and may delay the need for amputation in selected patients who have exhausted all other therapeutic options. Return to work and reduced need for repeated hospital admissions may balance the overall expense of the procedure. Further studies are required to determine the exact indications for the use of SCS in BD, while stopping smoking should continue to be emphasised as the most important treatment.

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Spinal cord stimulation for chronic pain

Richard A. Stocks BSc MCSP

Cameron T. Williams B.App.Sci. Pty MCSP

Evidence search date: June 2001

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Spinal cord stimulation for chronic pain

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None

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Spinal chord stimulation for chronic pain

Question

1. **What are the effects of spinal cord stimulation in people with chronic low back and leg pain and failed back surgery syndrome?**
2. **What are the effects of spinal cord stimulation in people with intractable ischaemic limb pain?**
3. **What are the effects of spinal cord stimulation in people with intractable angina pectoris?**

Summary

Chronic back pain and non-ischaemic leg pain: We found insufficient evidence that spinal cord stimulation improves functional disability, work status, or healthcare and medication use compared with other treatments or placebo in people with failed back surgery syndrome, other chronic back pain, or chronic non-ischaemic leg pain.

Ischaemic limb pain: Two RCTs have found no evidence that adding spinal cord stimulation to conventional analgesia improves limb survival or pain compared with analgesia alone, although the trials may have been underpowered to detect a clinically important difference. We found no evidence of effects on quality of life, functional status or healthcare use.

Intractable angina: We found weak evidence from a single RCT that spinal cord stimulation may reduce intensity and frequency of anginal symptoms and medication use in people with intractable angina pectoris. The study found that quality of life was improved, although it is unclear whether the tools assessing quality of life were valid. Further controlled trials with greater power and validated outcome measures are needed.

Background

Spinal cord stimulation has been used since the 1980s to treat patients with intractable pain syndromes including the failed back surgery syndrome (chronic low back pain which has failed to respond to surgical treatment), and ischaemic cardiac and limb pain. The technique is believed to inhibit chronic pain by stimulating large diameter afferent nerve fibres in the spinal cord. According to the pain gate theory proposed by Melzack and Wall in 1965, ascending impulses in these fibres may inhibit the conduction of pain signals to the brain.

The implantation procedure involves placing electrodes in the epidural space, along with an implantable controller that allows alteration of parameters such as pulse width, duration and intensity of stimulation. Repetitive electrical impulses are then delivered to the spinal cord.

Search Methods

Primary sources: Medline 1966 to date; Embase 1980 to date; Cochrane 2001 issue 1; NHS Centre for Research and Dissemination; Database of Abstracts of Reviews of Effectiveness; NHS Health Technology Assessment Database; NHS Economic Evaluation database; TRIPS database; Monash University database. Search date: June 2001.

Evidence found

Chronic back pain and non-ischaemic limb pain: We found one systematic review¹ and two subsequent case series^{2,3}

examining effects of spinal cord stimulation in people with chronic pain syndromes, most commonly the failed back surgery syndrome. The systematic review found no controlled trials, but identified 39 case series from a combination of Medline and hand searches and from a spinal cord stimulation manufacturers' archives. Failed back surgery syndrome was not precisely defined in the articles reviewed, but appeared to refer to chronic back or leg pain that has not responded to surgical intervention.

Ischaemic limb pain: We found one narrative review article, which was excluded because of poor methods (see below).⁴ We found two RCTs.^{5,6} The first compared spinal cord stimulation plus analgesia versus conventional analgesia alone in 51 people with atherosclerotic (n=41) or diabetic (n=10) lower limb ischaemia of more than two weeks duration, which was associated with rest pain or ulceration, or had failed to respond to bypass surgery.⁵ Main outcomes were limb amputation rates and pain relief at 18 months. The second RCT compared spinal cord stimulation plus 'best medical treatment' versus best medical treatment alone in 120 people with rest pain of more than two weeks duration, ankle systolic pressure <50mmHg, absent ankle pulses or ulceration.⁶ Main outcomes were limb survival, pain and analgesic use over a period of two years.

Intractable angina: No systematic reviews were identified. We found one small RCT⁷ and four poor quality case series.⁸⁻¹¹ The RCT

compared the effect of spinal cord stimulation with an inactive implanted stimulator on exercise capacity, quality of life and ischaemia in 25 people with angina pectoris after six weeks treatment.

Quality of Evidence Found

Chronic back pain and non-ischaemic leg pain: The systematic review examined studies concerning patients with failed back surgery syndrome who underwent spinal cord stimulation for pain relief.¹ The quality of the review was excellent, although the studies that it found were of poor quality. Search methods of the review were clearly reported, and studies were independently appraised by two investigators. The synthesis reported outcomes, methodology, patient demographic characteristics and follow up and also highlighted heterogeneity among included studies. Methodological problems with included studies were identified, and results tabulated. Dropout rates in included studies were not stated. Given the poor quality and heterogeneity of study design, it may not have been appropriate to attempt to combine study results. Combined results appear to have been calculated from mean percentages rather than individual patient data, which may skew the final results. The main combined outcome measure (proportion of patients with $\geq 50\%$ pain relief) may not be validated outcome tool for this condition.

The case series design of the included and subsequent studies is intrinsically weak, because it lacks a control group, and is prone to

selection bias. It is an even weaker design for evaluating spinal cord stimulation for chronic back and leg pain because endpoints, such as degree of pain relief, may be difficult to evaluate and because the untreated prognosis is variable. Dropout rates were high in some cases, and people who dropped out were not always accounted for in the analyses. Inclusion and selection criteria were not generally stated, and sample populations were heterogeneous for underlying diagnosis. The clinical importance of significant results is open to dispute.

Ischaemic limb pain: The narrative review did not state its search or appraisal methods, and was therefore excluded in favour of evidence from RCTs.⁴ The trials were of generally good quality.^{5,6} Both randomised treatment allocation. Treatment groups were balanced for potential confounders, and analysis was by intention to treat. Neither trial was blinded, although blinding is difficult when comparing invasive versus non-invasive strategies. The first trial only just achieved its recruitment target, and may not have had adequate power to detect a clinically important difference in outcome between groups.⁵ It was not clear whether the outcome assessment for pain, a visual analogue scale, had been previously validated. The second trial had higher power and used standard instruments such as the McGill Pain Questionnaire and EuroQol to assess subjective outcomes.⁶

Intractable angina: The RCT was of fair quality.⁷ It was unblinded but

randomised appropriately with analysis by intention to treat. There were no dropouts. Treatment groups were balanced for most relevant variables. However, there was no power calculation and the sample size was small. The reliability and validity of the outcome measures were also not reported.

The results from the case series should be viewed with caution as they lack controls or comparators, randomisation and blinding and generally have small sample sizes.⁸⁻

¹¹ There also tends to be a large dropout rate, with dropout unaccounted for in the analyses.

Study Results

Chronic back pain and non- ischaemic leg pain: The review found that there was disparity in outcome measurements, heterogeneity of patient populations and poor data presentation in the included case series.¹ Efficacy of spinal cord stimulation could not be compared with other pain treatments, placebo or no treatment because of the lack of good quality RCTs. The review concluded that there is insufficient evidence relating to the efficacy of spinal cord stimulation on patient work status, functional disability and healthcare and medication use. Complications are stated as 'surprisingly frequent,' occurring in 20-75% of patients across studies (mean frequency 42%), but were generally considered minor. The review combined data from case series, and found that $\geq 50\%$ pain relief was achieved in 59% of patients, although this average is unlikely to be reliable because methods of pain

measurement varied, and study populations were heterogeneous. The two more recent case series found that spinal cord stimulation was associated with statistically significant pain relief, functional improvement and reduced narcotic use in failed back surgery syndrome compared with baseline assessment.^{2,3} However the quality of these studies is poor and the clinical importance of these effects is not clear.

Ischaemic limb pain: Neither trial found any significant improvement in limb survival with spinal cord stimulation plus analgesia compared with analgesia alone, although power may have been inadequate to demonstrate clinically important effects.^{5,6} Both trials found that spinal cord stimulation reduced pain from baseline, although effects compared with conventional treatment were conflicting. The higher quality study found that pain was significantly reduced from baseline in both trial arms, although it found no significant difference between treatments.⁶ The smaller study found that pain assessed using a coarse visual analogue scale (rated from 1 – 5) was significantly reduced from baseline throughout the trial only in the spinal cord stimulation arm. The trial did not compare pain relief between treatments.

Intractable angina: The RCT found that, compared with control, spinal cord stimulation significantly increased exercise duration and time to angina on exercise testing (median exercise duration after 6 weeks 533s with stimulation v 447s

with control; median time to angina 319s v 246s); and decreased frequency of anginal attacks (median after six weeks 2.4 per day v 3.2 per day with control), sublingual nitrate consumption (median after 6 weeks 1.6 tablets per day v 2.6 with control), and quality of life on a linear analogue scale.⁷ It is not clear whether the subjective scales used had been previously validated, so the clinical importance of the quality of life results is not certain.

The case series found that spinal cord stimulation decreased pain from baseline in patients with chronic angina.⁸⁻¹¹

Conclusions

Chronic back pain and non-ischaemic leg pain: One high quality systematic review has found insufficient evidence on the effects of spinal cord stimulation for failed back surgery syndrome. We found insufficient evidence on the effects in people with other chronic back pain or non-ischaemic leg pain. Treatment awaits evaluation in controlled trials with well-defined inclusion and exclusion criteria, to assess efficacy and adverse effects in clinically applicable patient populations.

Ischaemic leg pain: We found two RCTs, which suggested that spinal cord stimulation plus conventional analgesia significantly improve pain compared with baseline assessment in people with chronic lower limb ischaemia unsuitable for or unresponsive to bypass surgery. However, the studies found no evidence that adding spinal cord stimulation to conventional

analgesia improved pain or limb survival compared with analgesia alone over a period of 18-24 months. Functional effects remain unclear.

Intractable angina: We found weak evidence from one small RCT that spinal cord stimulation may be effective for reducing intensity and frequency of anginal symptoms. Further trials are needed to confirm or refute this finding. Functional effects remain unclear.

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