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# Spinal Cord Stimulation for Chronic Visceral Abdominal Pain

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#### Abstract

Background. Spinal cord stimulation (SCS) may reduce pain scores and improve function in patients with chronic visceral abdominal pain. We thus present our large clinical experience in SCS for visceral abdominal pain.

Methods. We trialed spinal cord stimulation in 35 patients, each of whom was shown by retrograde differential epidural block to have either visceral pain (n = 32) or mixed visceral and central pain (n = 3). SCS trials lasted 4 to 14 days (median 9 days). SCS lead tips were mostly positioned at T5 (n = 11) or T6 (n = 10).

Results. Thirty patients (86%) reported at least 50% pain relief upon completion of the trial. Among these, pretrial visual analog scale (VAS) pain scores averaged 8.2  $\pm$  1.6 (SD) and opioid use averaged 110  $\pm$ 119 mg morphine sulfate equivalents. During the trial, VAS pain scores decreased to  $3.1 \pm 1.6$  cm (P < 0.001. Mann-Whitney Rank Sum Test) and opioid use decreased to 70  $\pm$  68 mg morphine equivalent a day (P = 0.212). Five patients failed the trial, one was lost to follow-up, and 19 were followed for the whole year. Seven patients were either followed for less than a year (n = 3) or the SCS system was removed due to infection or lead migration (n = 4). One patient despite the successful trial felt no improvements at 6 months after the implant and requested an explant of the SCS device. Among the 28 patients who received permanent implant, 19 were followed at least a year. Their VAS pain scores remained low  $(3.8 \pm 1.9 \text{ cm})$ ; P < 0.001) at 1 year, as did opioid use (38 ± 48 mg morphine equivalents; P = 0.089).

Conclusions. Spinal cord stimulation may be a useful therapeutic option for patients with severe visceral pain.

### Key Words. Anesthesia; Visceral Pain; Abdominal Pain; Spinal Cord Stimulation

#### Introduction

Chronic visceral pain is a devastating condition. Current treatments, including various blocks and radiofrequency treatments [1], rarely produce prolonged pain relief. Recent basic-science studies suggest that spinal cord stimulation (SCS) may have a role in the treatment of visceral abdominal and pelvic repeated distension and hyperalgesia [2–4]. And in fact, there are several potential mechanisms by which electrical stimulation of the spinal cord might suppress visceral pain. But which—if any—are clinically important, remains to be determined [5].

SCS has been used for many years to treat chronic pain syndromes such as complex regional pain syndrome [6], failed back surgery syndrome [7], and peripheral neuropathy in diabetes [8]. However, there is so far only limited published material regarding SCS for treatment of chronic visceral pain and there is no level 1 evidence that it works. Previously published small case series studies of SCS for abdominal and pelvic visceral pain have shown encouraging improvements in pain scores [9–13], improved functional capacity [9], and reduced opioid use [9,11,13].

Interpreting the limited available published experience is further complicated by the fact that there is considerable variability in patient selection, lead positioning, and type of hardware used in these reports. Consequently, it remains unclear from these reports what fraction of patients will have a successful trial of SCS for visceral pain, and whether a reasonable fraction of the patients may have long-term benefit from stimulation. We thus present our extensive experience with SCS as a treatment for chronic visceral pain.

#### Methods

#### Sample

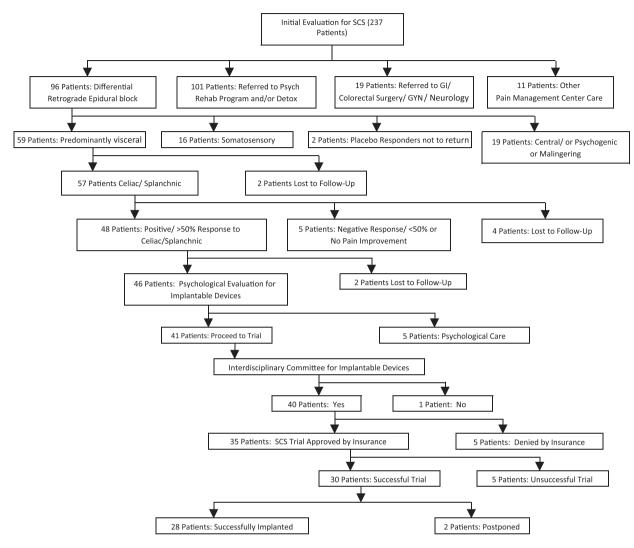
With the Institutional Review Board approval, we reviewed our experience in of 35 consecutive patients who were trialed with SCS for chronic visceral abdominal chronic pain over the period from January 2002 to May 2008. All had received an epidural retrograde differential block, the results of which suggested that the origin of the pain in majority of the patients was clearly visceral (Table 1, Figure 1; [14]). Also, most patients had a  $\geq$ 50% pain reduction in response to splanchnic, celiac, or superior hypogastric visceral blocks. Qualifying patients underwent

Response to Sympathetic Block (%)	100	80	30	40	100	100	50	NA	100	NA	100	100	NA	50	80	100	80	NA	100	0	80	100	0	80	100	100	100	100	100	80	50	100	100	30	NA
Type of Pain (Diff.)	Visceral	Visceral	Mixed	Mixed	Visceral .	Visceral .	Visceral	Visceral	Visceral .	Visceral	Visceral .	Visceral .	Visceral	Visceral	Visceral		Visceral		Visceral .	Visceral	Visceral	_	Visceral	Visceral	Visceral	Visceral	Visceral	Visceral	ceral	NA	Visceral	Visceral	Visceral	Visceral	Visceral
h/o Drug Abuse			Yes												Yes																				
h/o Alcohol Abuse			Yes							Ι				I		Yes		Yes		Yes									Yes		Yes				Yes
h/o Depression	I	1	Yes	Yes	I	Yes	I	Yes	Yes	I	I	Yes	I	I	Yes	Yes	I	Yes	1	Yes	I	I	1	1	Yes	Yes	1	Yes	Yes	Yes	Yes	I	I	Yes	Yes
Location of Pain	LLQ; stabbing	EPI: stabbing	EPI; aching	DIFF; aching	EPI; stabbing	EPI; dull	EP; shooting	EPI; sharp	LQ; burning	RLQ; aching	EPI; throbbing	EPI; sharp	EPI; sharp	RLQ; stab	RUQ; sharp	EPI; aching	RUQ; sharp	-LQ; sharp	LUQ; aching	EPI; aching	EPI; aching	-UQ; aching	RUQ; aching	LUQ; sharp	EPI; aching	LUQ; sharp	EPI; sharp	EPI; sharp	EPI; aching	EPI; aching	EPI; aching	LUQ, RUQ, LLQ; sharp	LLQ, RLQ; sharp		
Years of Pain Lo	13 LI		е В	25 DI					5 LI			Ш Ю		2	_	_		7 LI	С  8		10 EI	_	_	-		5 Ll	- -	<del>п</del>	7 EI	Ξ		18 LI			5
Diagnosis	Adhesions	Mesenteric ischemia, gastroparesis	Pancreatitis		Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Adhesions	Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Pancreatitis	Adhesions	Pancreatitis	Adhesions, mesen isch	Adhesions	Pancreatitis	Pancreatitis	Pancreatitis	Adhesions	Adhesions	Postgastric surgery syndrome	Pancreatitis							
Sex	ш	Σ	Σ	Σ	ш	Σ	Σ	ш	ш	ш	ш	ш	-	2	2	2	2	2	2	-	-	2	2	N	N	N	-	2	-	2	2	2	2	-	-
Age	61	46	50	59	35	46	87	29	36	52	41	35	50	22	21	52	21	52	37	44	35	22	59	22	58	49	17	30	55	59	49	61	49	43	54
Patient	-	2	* സ	4*	5†	9	4	8	<b>0</b>	10*	11	12	13	14	15	16	17	18	19	20	21	22	23*	24	25	26	27	28	29*	30	31	32	33	34	35

Characteristics of the patients trialed using SCS for the abdominal visceral pain Table 1

\* Data on five patients who failed SCS trial. <sup>†</sup> Two patients with successful trial, but who did not receive implant of SCS thereafter. SCS = spinal cord stimulation; LLQ = left lower quadrant; LUQ = left upper quadrant; RLQ = right lower quadrant; RUQ = right upper quadrant; EPI = epigastrium; DIFF = diffuse; NA = not applicable.

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**Figure 1** Algorithm: patients selection for spinal cord stimulation. Please note that initially there were 237 candidates who underwent evaluation for possible treatment with spinal cord stimulation. Of those only 28 were successfully implanted with spinal cord stimulation (SCS) system. Out of 59 patients who were thought to have predominantly visceral source of pain based on an epidural retrograde differential block, 48 had positive response to visceral sympathetic block (either celiac or splanchnic) and underwent psychological and interdisciplinary committee evaluation for implantable devices, and only 35 were approved by their respective insurance providers to have the SCS trial. Finally, 30 out of 35 patients had a successful trial and 28 of them decided to have an implant while two postponed such decision.

psychological evaluation and then their case was discussed by the Cleveland Clinic Interdisciplinary Committee for Implantable Devices (Figure 1). This committee, consisting of various subspecialists and in place for over 10 years at the Cleveland Clinic Main Campus, deliberates every single case being considered for an implant to determine if the patient is an appropriate candidate for the particular implantable device and if there are other less-invasive or even surgical alternatives. Notably, only about half of the patients we evaluated for chronic

visceral pain went on to receive an epidural retrograde differential block prior to even being considered for inclusion in this series by the Committee (Figure 1).

#### Measures

Visual analog scale (VAS) pain scores (0–10 cm) and opioid use (in mg of morphine sulfate equivalents) were determined at baseline (office visit just before the trial), at the end of the SCS trial, and at office visits 6 and 12

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months after implantation. Data that was evaluated included such demographics as the patients' age and gender and clinical data such as years of chronic pain, type of abdominal pain, location of the pain, diagnosis as a possible source of chronic pain if established, retrograde differential epidural block result, and visceral block type and its result (Table 1).

SCS trial data included the type of the lead used, number of leads used, final position of the lead/leads tip/tips, lead/ leads position (i.e., midline or paramedian), and trial duration. Similar data were obtained when an SCS system was implanted, along with any associated complications.

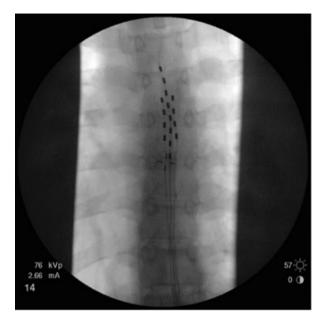
To evaluate differences between the various values obtained, the Mann–Whitney Rank Sum Test was used. Statistical tests and graphs were produced using Sigma Plot software (Systat Software Inc., San Jose, CA). Results are presented as means  $\pm$  standard deviations from the mean, unless otherwise specified.

#### Results

Thirty-five patients with chronic severe visceral abdominal pain underwent SCS trials lasting 4-14 days (median of 9 days). There were 23 women and 12 men: their average age was  $44 \pm 15$  (median 46) years. They had chronic abdominal pain for an average of  $8 \pm 5$  years with a range of 2-25 years. Nineteen patients had pain located to the epigastrium, five to the left upper guadrant, four to the right upper guadrant, and six to the left lower guadrant. Typically, patients characterized their pains as sharp, shooting, stabbing, aching, throbbing, or dull. While six patients had past history of alcohol abuse (>3 years before the trial heavy alcohol use causing chronic pancreatitis), only one patient had also remote history of drug abuse. During differential retrograde epidural block, all patients were shown to have clear visceral pain including three who had predominantly visceral pain with a central component (Table 1; [14]).

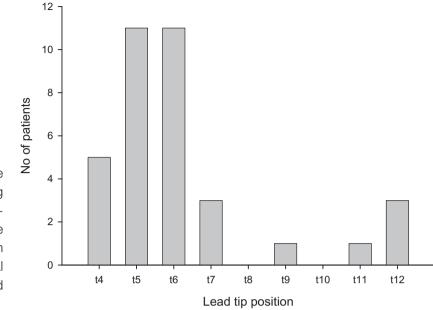
In most patients, the leads (quatrodes and/or octrodes; St. Jude Medical, Plano, TX or Boston Scientific, Natick, MA) were positioned for the SCS trial with the tips at the level of the T5 vertebral body (11 patients; see Figures 2 and 3) or T6 vertebral body (10 patients). For patients with lower abdominal quadrant pains, lead tips were positioned at T11 [1] or T12 (three patients) using an anterograde approach (Figure 3). In each case, 1–3 leads (one octrode or dual octrodes or transverse tripol using one octrode and two quatrodes) were positioned midline (see Figure 2). There were no paramedian lead placements. We considered the trial to have succeeded when patients reported ≥50% pain relief at the return office visit. There were no infections or any other complications during the trial.

Five patients failed a trial of SCS: their average baseline VAS pain score was  $6.6 \pm 0.9$  cm and did not improve at conclusion of the trial ( $5.8 \pm 1.78$  cm; P = 0.4; Figure 4). They were later trialed on alternative therapies. Pain relief exceeded 50% in 30 of 35 patients (86%). Among the 30



**Figure 2** Characteristic position of spinal cord stimulation (SCS) leads for the treatment of upper abdominal pains. Leads are carefully positioned midline with tip at about T5-T6 for generalized, epi-gastric, or periumbilical abdominal pain and T11-L1 for lower quadrant and pelvic pains. We inserted one, two, or three (as shown here) leads into the posterior epidural space for the SCS trial.

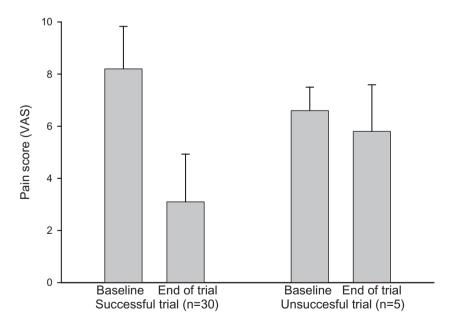
patients in whom the trial was successful, VAS pain score before the trial averaged  $8.2 \pm 1.6$  cm and opioid use averaged  $111 \pm 119$  mg morphine equivalents (median of 80 mg). During the trial, VAS pain scores decreased to  $3.1 \pm 1.6$  cm (P < 0.001) and opioid use decreased to  $70 \pm 68$  mg of morphine sulfate equivalents a day (median of 40 mg; P = 0.21). To objectively measure therapeutic effects of the SCS, we calculated improvements in the pain scores and changes in opioid use during the trial for all of the 35 patients. Baseline average pain scores were  $7.9 \pm 1.6$  and decreased to  $3.5 \pm 2$ (P < 0.001). Opioid use did not decrease significantly (there was no attempt to wean patients to much lower doses during the trial) and it changed from 138.3  $\pm$  134 to  $116.0 \pm 121$  (*P* = 0.377). There were 22 patients who received one lead for the SCS trialing (octrode leads), eight patients had two (octrode leads), and five patients had three leads placed (each received one octrode and two quatrodes). Pain scores were similar when one, two, or three leads were used for trialing (see Figure 5). Twentyeight of the patients in whom the trial was successful proceeded to implantation, one did not because their insurance company denied coverage, and one decided to postpone the implant. Three out of five nonresponders to the SCS trial had less than 50% improvement in pain scores after sympathetic block, one had no sympathetic



**Figure 3** Final position of the tip of the leads inserted during the trial where optimal paresthesias to cover the area of the patients pain were achieved. In most of the patients, optimal lead tip position was at T5 and T6 level.

block, and one had full response (Table 1). In the responder group, only 2/27 patients had less than 50% improvement after prior sympathetic block (three patients did not undergo sympathetic block; see Table 1).

Among the 28 patients who received a permanent implant, one was immediately lost to follow-up, three patients had their SCS systems removed because of infection, and one was removed because of lead migra-



**Figure 4** Improvements of the pain scores during trial of the spinal cord stimulation (SCS) for visceral abdominal pain. Group on the left side of the graph (n = 30) are those patients who received more than 50% improvements in their visual analog scale (VAS) pain scores. Right is a group of the patients who had unsuccessful SCS trial (n = 5). The average pain score in the first group improved significantly (P = 0.003), while the group of nonresponders did not have improvement in their VAS pain scores (P = 0.4).

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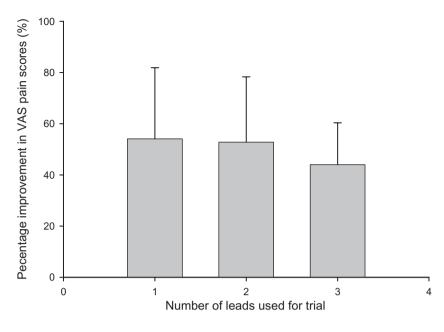
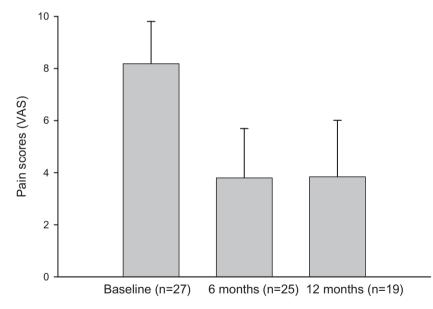
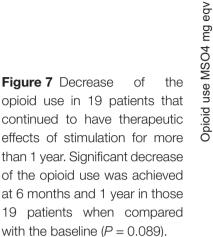


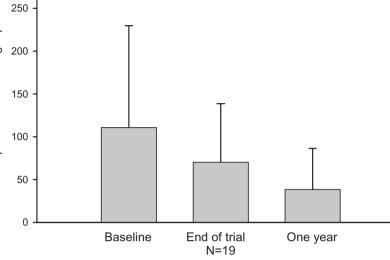
Figure 5 Relevance of the number of epidural leads inserted during the spinal cord stimulation trial to the pain relief achieved. We could not detect any differences regarding the improvements in patients pains when one, two, or three leads were used.

tion. One patient requested an explant of the SCS system at about 6 months after an implant because she did not find it effective. Among the remaining 22 patients, 19 were followed for more than a year (see Figure 6). The number of leads implanted permanently differed from the number of the leads trialed individually in 19 patients who were trialed with one and received two leads for the permanent implant (octrodes). One patient who was



**Figure 6** Long-term improvements in visual analog scale pain scores in patients who received spinal cord stimulation (SCS) implant. Please note that there were 27 patients who had long-term follow-up after the successful trial (one patient was lost to follow-up immediately after the implant and two never received an implant after the successful trial). At 6 months we recorded 25 scores as two patients had an infection requiring removal of the system. At 1 year, 19 patient pain scores were recorded as another one patient had an infection requiring system removal, one patient had lead migration with consequent loss of pain relief and had no revision yet, one was dissatisfied with long-term pain relief with SCS, and three patients still are followed for less than a year.





trialed with two leads received a three-lead permanent implant (two quatrodes and one octrode).

300

The average VAS pain scores were  $3.8 \pm 2.2$  cm 1 year after SCS implant and opioid use was low:  $38 \pm 48$  mg morphine sulfate equivalent (median of 25 mg; Figure 7). Twenty-seven patients who received and kept an implant were followed for a median of 60 weeks of stimulation. Complications were limited to three infections resulting in an explant and one lead migration. Two patients had to have their generator changed as the part of regular maintenance (generators' end of life).

#### Discussion

We describe here treatment by neuromodulation of 35 patients with severe chronic visceral abdominal pain from various causes including: nonalcoholic, idiopathic, and alcoholic chronic pancreatitis; long-standing abdominal adhesions from multiple abdominal surgeries; mesenteric ischemia; and gastroparesis and postgastric surgery syndrome. All had failed multiple conservative and surgical treatments to alleviate their pains before undergoing SCS trial. All patients were uniformly on large amounts of oral or transdermal opioids and multiple other medications prescribed for the treatment of their chronic pain. It is encouraging to note that 30 out of 35 patients responded well to a trial of SCS (>50% of the pain relief) and 28 proceeded to implantation of a permanent SCS system.

Although about 14% of the patients failed to improve during the SCS trial, such ratio is still much better than the trialing results in patients with other chronic pains such as post-laminectomy syndrome [15], chronic radiculopathy [16], or CRPS [7]. All patients, except one, who underwent successful trial improved in pain scores and function after the implant demonstrating rather longterm therapeutic effect of SCS (Figures 6 and 7). These patients were also able to reduce their opioid use.

Spinal Cord Stimulation for Chronic Visceral Pain

Patient selection may be a key factor for the success of SCS for chronic visceral pain. Patients who complain of chronic abdominal pain come from rather heterogeneous patient populations including not only those with the history of chronic pancreatitis, various motility disorders, and patients with extensive intra-abdominal adhesions following multiple surgical procedures, but also those with somatization disorders and opioid misuse. Psychological factors, unexplained sources of abdominal pain, and opioid dependence/tolerance all may be negative predictors of treatment success for chronic abdominal pain. Approximately 50% of the patients who came for an initial evaluation of their chronic abdominal pain to our outpatient clinic are redirected to chronic pain rehabilitation programs, detoxification, or other alternative treatments (Figure 1). Reviewing the data of five patients who failed SCS trial and one patient who requested removal of the SCS system 6 months into the treatment, it seems that there may be a few shared characteristics defining this group. Most of these patients had a poor response to sympathetic nerve block, while most who later responded to SCS actually had a positive response to sympathetic block (see Results section and Table 1). Predictive value of the sympathetic nerve blocks has been suggested for success of SCS when used to treat other sympathetically mediated chronic pains [17]. Visceral sympathetic nerves that play a role in mediating visceral pain are considered a potential target for SCS [18,19]. Therefore, it is not surprising to observe such a response in our patients with long-standing visceral pain. Still, the size of group that failed SCS trial is too small to confirm that their negative response to sympathectomy should be considered as a negative predictive factor for successful SCS (Table 1).

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One of the reasons why we conducted this retrospective overview was to learn more about the technical aspects of SCS for visceral abdominal pains such as the best target for lead positioning or the type and number of leads leading to optimal results, etc. The anatomic placement of most of our leads was at the T5 or T6 level that is consistent with successful stimulation from previous case reports [10,11,20]. Our findings also suggest that the number of leads used for trialing was not related to the success of the trial (see Figure 3) and all of the leads were mainly placed near the anatomic midline of the spine.

We did not observe improved therapeutic effect when a transverse tripole lead configuration was used as opposed to conventional stimulation (Figure 4). This is consistent with some of the published clinical experience when transverse tripole leads were used for the treatment of lower back pain, and thus, it appears that tripole leads have no distinct advantages over standard SCS lead configurations [21]. Mathematical modeling by Holsheimer and Struijk's [22,23] on the assumption that stimulation of dorsal root fibers is the primary limiting factor in achieving greater dorsal column stimulation and that lateral guarding might allow more selective and deeper activation of the dorsal columns. Clinically, it is possible that sudden loss of the pain control during the SCS stimulation when transverse tripol configuration is used may be caused by impedance variability with the lateral micro-movement of the leads. Simply, it appears that with minimal lateral lead movement, such SCS configuration is lost in majority of the patients. In our study group only one patient maintained long-term transverse tripol configuration of stimulation and an effective pain control.

The majority of our patients received long-standing pain relief of their chronic visceral abdominal pain using continuous SCS. The mechanisms involved in such modulation of visceral abdominal pain by SCS are currently unclear. Animal studies suggested antidromic activation of primary efferent fibers within the dorsal columns to be important mechanism of neuromodulation [2]. Other mechanisms of pain relief suggested previously when SCS was used for treatment of various chronic pain syndromes include the spinal gating theory where stimulation of large afferents may produce a reduction in small diameter visceral fibers transmission [24] or suppression of the sympathetic outflow [25]. Our patients who responded to SCS trial had also substantial, but short-lasting response to sympathetic nerve blocks.

In conclusion, our results suggest long-term improvements in pain scores with decrease of the opioid use in the patients with chronic visceral abdominal pain of various causes. Given the dismal history of conventional treatment for chronic visceral pain, our results suggest that SCS may be a very useful therapeutic option. Even a relatively large case series such as the one we present is subject to considerable bias (notably selection bias and measurement bias) that could be ameliorated with a randomized approach. However, it will be relatively difficult to conduct randomized, sham studies of SCS for chronic visceral abdominal pain. SCS produces characteristic paresthesias in the receptive field subserved by the spinal segment being stimulated which can't be mimic transcutaneously, therefore such randomized trials could not be easily blinded.

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