Spinal Cord Stimulation: Indications and Selection

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Introduction

The selection of proper candidates for implantable spinal cord stimulation is a critical factor for producing acceptable outcomes for patients suffering from severe pain. A device in the proper location with the appropriate programming will not be helpful if the patient is a poor candidate for the therapy or if the disease process does not respond to the application of spinal cord stimulation. This chapter examines important factors for selecting patients who may need a device for the treatment of pain. The selection process can be narrowed into two specific areas – patient-specific characteristics and disease-specific characteristics – and each will be covered in detail in this chapter.
Patient-Specific Characteristics

Analysis of patient outcomes has shown that some predictability of success can be made in advance of trialing the patient for a stimulation system. These criteria are helpful in determining who may benefit from these advanced techniques and include:

1. The patient should have no untreated drug addiction problems. This refers to the psychological problem of addiction and does not refer to a patient who is taking properly prescribed opioids under the care of a vigilant physician. If substance abuse and addiction are concerns, the patient should be seen by a health care provider with expertise in these areas and treated. After successful treatment, the patient may be reconsidered for the device.

2. The patient should be psychologically stable for the planned technique. Many patients who are afflicted with chronic pain also suffer from depression and anxiety. Outcome studies have shown that the presence of these problems does not adversely affect outcomes if they are treated and stable. Psychological interventions such as cognitive behavioral therapy may be helpful both before and after the placement of a spinal cord stimulation device although no definitive outcome studies exist. Once the patient has been successfully treated for the problem, the procedure can be performed. Screening for depression or anxiety can be difficult. Work by Doleys showed that the Minnesota Multiphasic Personality Inventory (MMPI) is not predictive of an adverse outcome even if the patient’s scores indicated high levels of depression and anxiety. In this analysis, the patients with the worst scores on this inventory had excellent outcomes and showed a major improvement in repeat testing. Because of the complexity of this issue if the implanting doctor is concerned about the issue they should consult a psychologist or psychiatrist well versed in the relationship between pain and depression and familiar with spinal cord stimulation. While depression and anxiety may be controversial, the issue of the suicidal or homicidal patient is not an area of debate and should be considered inappropriate candidates for these devices. The other area of concern is that of personality disorders. While several personality disorders can lead to functional disabilities, the diagnosis of borderline personality disorder should be seen as a relative contraindication to moving forward with an implant. Antisocial personality disorder is another worrisome problem and should also be viewed with caution.

3. The patient should have appropriate cognitive ability to understand the procedure, the risks, and expectations of the therapy. The patient must also understand the use of the equipment and the technical responsibilities of having the device implanted. Cognitive functioning can be diminished because of neurological disease, medical illnesses, or from a baseline level of intelligence that does not allow for implanting. A psychologist or neurologist may be helpful in determining competence when the implanting doctor has doubts.

4. The patient should have no untreated bleeding disorders. Prior to implanting the device the patient should be questioned concerning diseases that affect clotting, liver function, and platelet activity. A preoperative workup would include a complete blood count including a platelet count. A bleeding analysis should be considered if a history of bleeding exists. INR appears to be the most helpful study. PT/PTT and bleeding times are not predictive of bleeding risks in these patients. Platelet function studies are a new test area that may lend information for patients on drugs that affect platelet function. Patients should be able to come off of drugs that effect bleeding for the appropriate length of time prior to invading the epidural space. The guidelines of the American Society of Regional Anesthesia on bleeding and medication should be considered when doing a patient evaluation. A new issue is the use of drugs that affect clotting such as clopidogrel, and similar drugs, which put the patient at risk of bleeding and epidural hematoma. Prior to moving forward with an implant, the physician prescribing of these medications should be involved in the decision making process to determine the safety of taking the patient off the medications prior to implant. The patient should be off clopidogrel and similar drugs for several days prior to the placement of spinal leads, and should remain off the drugs until the lead is removed in cases of stimulation trialing. In permanent implants, the
drugs may be restarted a few days after the leads are surgically secured. The number of
days required off of these drugs is controversial with most experts agreeing that the proper
time is between seven and fourteen days. New classes of drugs are being developed that
are much more potent than the currently available products and may result in new risks
for patients undergoing invasive procedures. The implanting physician should ask the
prescribing physician to recommend a time course in which the blood clotting should be
back to a normal baseline, but in many cases this may be difficult to determine.

5. The patient should be free of infection at the site of implant. Systemic infections should
be treated and under good control prior to moving forward. If any evidence of potential
bacteremia exists, the benefit of the stimulation system should be carefully weighed prior
to moving forward. In the case of local infections such as cellulitis the case should be
delayed until proper evaluation and treatment can be arranged. This danger should
be considered when the patient has had a recent procedure in the area of needle inser-
tion. This is not an uncommon concern when considering spinal cord stimulation is part
of an algorithmic process for the treatment of intractable disorders.

Table 2.1 shows the common issues involved with patient selection.

## Disease-Specific Characteristics

The second factor involved in the selection process is choosing the patient with the proper
disease state and indication. Several factors have been shown to be helpful in choosing
who we should select for this type of treatment and who may be a poor candidate. The
indications for spinal cord stimulation that are best supported by published studies include
burning, or shooting pain in the extremity after spinal surgery, complex regional pain syn-
drome, types I and II, peripheral nerve injury, painful neuropathies, refractory angina with
no correctable lesions, ischemic pain, and pain related to peripheral vascular disease. Some
disease processes may respond but are not as well supported in the literature. These include
axial pain in the lumbar spine with or without a history of spinal surgery, intercostal
neuralgia, spinal cord injury, and phantom pain or neuropathic pain after trauma, and
chest wall pain. In some patients, despite proper lead placement and proper stimulation coverage, no improvement is seen. Patients at high risk of failure include those with spinal cord injury, thalamic stroke pain, or pain of any origin within the brain, pain in the rectum and anus, complete nerve root avulsion and aching nociceptive pain of the limb. These generalizations are based on peer reviewed studies showing that SCS is more effective for radicular pain following spinal surgery of the cervical or lumbar spine. Emerging technology has allowed more effective treatment of axial disorders particularly with new dual and tripolar lead arrays and new computer models for driving current to deeper areas of the cord. Conclusions regarding ischemic pain are based on considerable data suggesting positive results on both flow and pain reduction in patients with diminished blood flow. Existing data are also strongly supportive of the use of spinal cord stimulation for the treatment of angina pectoris. Many of these publications are based on European cardiology evidence that show improved function, reduced pain and reduced need for nitrates. Complex regional pain syndrome has been shown to respond well to SCS when considering pain reduction and improved function. Recent outcome analysis has also shown improvements in costs of care and overall utilization of the health care system. Table 2.2 summarizes the disease states considered for spinal cord stimulation and the probability for success with each area of pain.

### Table 2.2. Disease based selection for stimulation.

<table>
<thead>
<tr>
<th>High probability of successful pain reduction</th>
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<tr>
<td>Chronic radicular pain (cervical and lumbar)</td>
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<td>Complex regional pain syndrome (CRPS), types I and II</td>
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<tr>
<td>Painful peripheral neuropathies and mononeuropathies</td>
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<td>Angina pectoris refractory to conventional drug therapy and not amenable to surgical bypass</td>
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<tr>
<td>Painful ischemic peripheral vascular disease not amenable to conventional drug therapy or surgical bypass</td>
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<th>Low probability of successful pain reduction</th>
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<td>Neuropathic pain following spinal cord injury</td>
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<td>Central pain (e.g., poststroke pain)</td>
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<td>Nerve root avulsion (e.g., brachial plexus avulsion)</td>
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<th>Unknown probability of pain reduction (case reports of successful treatment)</th>
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<tbody>
<tr>
<td>Postherpetic neuralgia</td>
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<td>Axial low back pain (improving with new lead arrays and programming)</td>
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<td>Phantom limb pain</td>
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Suggested Reading

Atlas of Implantable Therapies for Pain Management
Deer, T.R.
2011, XVII, 201 p., Hardcover