

Evaluation of Patients for Implantable Pain Modalities: Medical and Behavioral Assessment

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Abstract:

Background: Advances in neurobiology serve as the basis for current and evolving implantable pain modalities, consisting of neurostimulation and neuraxial drug administration systems. Appropriate treatment of pain begins with an accurate diagnosis based on thorough physical and behavioral evaluations.

Measures: The medical evaluation includes a review of the patient's medical history, diagnostic studies, physical examination, complete diagnostic workup, and screening trial of the proposed implantable therapy. The behavioral evaluation includes a review of the patient's history and medical records, clinical interview, mental status examination, psychological testing, and determination of suitability for implantation.

Conclusions: Patients with chronic pain are subject to neurophysiological, emotional, and behavioral influences that govern their perception of pain and of pain relief. Therefore, treatment of chronic pain is multidisciplinary, drawing on cognitive and behavioral psychological therapies, functional rehabilitation, orthopedic and neurologic surgery, medications, nerve blockade, neuroaugmentative procedures, and sometimes neurodestructive procedures. Appropriate selection of patients helps ensure that implantable therapies are used for those who are most likely to benefit.

Key Words: Behavioral evaluation—Implantation—Neuraxial drug administration—Patient selection—Spinal cord stimulation.

Advances in neurobiology serve as the basis for current and evolving implantable pain modalities, consisting of neurostimulation and neuraxial drug administration systems. Neurostimulation applies electrical stimulation to the neural structures to modulate endogenous pain pathways. Epidural electrodes deliver low-voltage electrical stimulation to the spinal cord in spinal cord stimulation.¹ Peripheral nerve stimulation is specifically directed at occipital nerves for occipital headaches, sacral nerves for pelvic pain, and other peripheral nerves for specific indications. The discovery of opioid receptors^{2,3} provides a rational basis for intraspinal pharmacotherapy. By delivering drugs directly to opioid receptors,

intraspinal infusions limit systemic exposure, decrease the opioid dosage required for pain relief, and generally reduce side effects. The benefits of short-term spinal analgesia, primarily for patients with intractable cancer pain, have led to investigation of longer-term opioid infusions by implantable pumps for the management of both cancer and noncancer pain.

Appropriate treatment of pain begins with an accurate diagnosis based on thorough physical and behavioral evaluations. Patients with chronic pain are subject to neurophysiological, emotional, and behavioral influences that govern their perception of pain and of pain relief. Therefore, treatment of chronic pain is multidisciplinary, drawing on cognitive and behavioral psychological therapies, functional rehabilitation, orthopedic and neurologic surgery, medications, nerve blockade, neuroaugmentative procedures, and sometimes neurodestructive procedures.

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The literature is virtually unanimous in emphasizing the importance of appropriate patient selection if implantable pain therapy is to be successful. This article reviews the components of the medical and behavioral evaluations that serve as the basis for recommending or opposing implantable pain therapy for a particular patient.

IMPLANTABLE PAIN SYSTEMS

Implantable pain modalities encompass a variety of systems, including nerve stimulators and implantable drug delivery devices. The mechanism of action of neurostimulation remains elusive, even though the modality has been in clinical use for more than 30 years. According to the gate-control theory proposed by Melzack and Wall,⁴ stimulation may produce modulation of the transmission rate of action potentials from peripheral nociceptors to the central nervous system at the level of the spinal cord. The process is clearly more complex, with neurochemical changes occurring as a consequence of neurostimulation.

Electrodes for spinal cord stimulators are inserted through an epidural needle, usually with use of local anesthesia. The electrodes are then attached to a passive receiving device or a battery-powered stimulator. Patients generally control the strength and duration of stimulation once the optimal stimulating parameters have been identified. Peripheral nerve stimulation can also be delivered through cuff electrodes placed around a peripheral nerve at the area of injury.

Spinal cord stimulation has been used for many patients with failed back surgery syndrome as an alternative to reoperation.⁵ It has also been used to treat reflex sympathetic dystrophy (complex regional pain syndrome [CRPS]) and postamputation pain, postherpetic neuralgia, postcordotomy, spinal cord injury dysesthesias, and pain associated with multiple sclerosis.⁶ More recently, Kemler and colleagues conducted a randomized trial and found that in carefully selected patients with chronic reflex sympathetic dystrophy (CRPS), spinal cord stimulation reduced pain and improved health-related quality of life.⁷ Two decades of experience with spinal cord stimulation for patients with neuropathic pain indicate continued pain relief in 70% of patients using multichannel systems and 30% using single-channel systems.⁸ Peripheral nerve stimulation has proven effective in treating neuropathic pain caused by nerve injury. Good results were achieved in 82.5% of such cases, although the number of potential candidates for this application is relatively small.¹

Drugs can be delivered through implanted catheters with a subcutaneous injection site, totally implanted catheters with an implanted reservoir and manual pump,

and totally implanted catheters with an implanted infusion pump.⁹ The choice of system depends on the indication for intraspinal therapy, the need for bolus versus continuous infusion, the patient's general medical condition, available support services, ambulatory status, life expectancy, and cost. In general, a fully implanted pump is economical if life expectancy is greater than 3 months.¹⁰

DuPen and associates developed the first "permanent" catheter for intraspinal drug delivery in the 1980s. They adapted Broviac catheter technology to create an exteriorized, permanent, three-piece silicone epidural catheter. Two types of implantable drug delivery systems are currently marketed in the United States.^{11,12} The first commercially available implanted pump delivered medication at a fixed rate and consisted of two chambers separated by a flexible bellows, plus a side port for bolus injections (Infusaid Pump; Shiley, Infusaid, Norwood, MA, USA). A new pump without a side port has since superseded the original model (Arrow International, Reading, PA, USA).

The second implantable pump is a programmable electronic pump powered by batteries that last up to 7 years, depending on flow rate (SynchroMed; Medtronic, Minneapolis, MN). The pump contains a 10- or 18-mL collapsible reservoir and peristaltic pump that pushes medication through a bacteriostatic filter and catheter. The programmable feature allows flexible dosing options over time and permits precise dose titration. Both commercially available implantable pumps require refilling under sterile conditions at least every several months, depending on flow rate.¹³ As a rule, programmable pumps are implanted when dosage titration and regulation is anticipated, and fixed-rate pumps when dosage is expected to be stable. The flexibility of programmable pumps makes them a superior choice with regard to most important factors, excluding expense.

MEDICAL EVALUATION

Virtually all pain treatment algorithms rely on a stepwise approach that begins with therapies that are less invasive, are likely to have few side effects, and can be reversed (Fig. 1). Therapies may be prescribed alone or in combination. Patients typically start evaluation in a primary care setting and progress to a specialist's care by referral when pain becomes intractable. Thus, most candidates for implantable pain therapy have a long medical history. Reviewing this history is a crucial first step in the medical evaluation. Initial patient questionnaires often cover pain history, current medication and other therapies, disability status, and a visual analog scale (VAS) for rating their current pain. A review of records

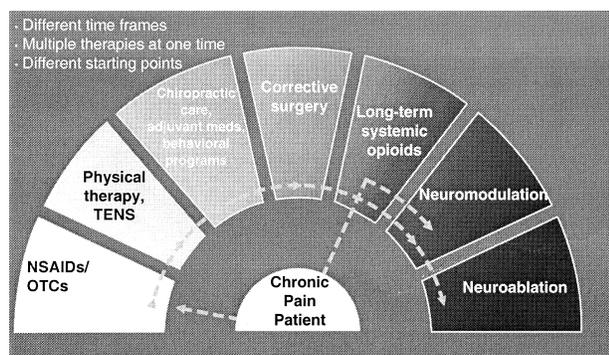


FIG. 1. Pain management continuum: a flexible approach.

from the referring physician can corroborate the patient's impression and provide objective evidence from earlier diagnostic studies. Objective evidence of a medical condition and of inadequate pain relief should be present before a trial of implantable pain therapy begins.

Physical examination

The physical examination, including complete neurological assessment, documents the patient's current symptoms. Any underlying reversible causes of pain should be addressed before implantable pain therapy is considered. In addition, less invasive therapies on the pain management continuum should have been given an adequate trial. This includes the use of orally administered opioids.

Diagnostic workup

If necessary, a complete diagnostic workup can be performed. Reversible causes must be ruled out and radiological techniques such as magnetic resonance imaging with contrast or computerized tomography with myelography may be helpful in identifying treatable causes of pain. The results of this workup may also help deter-

mine which treatment modality has the greatest likelihood of success.

Choice of implantable modality and position in treatment algorithm

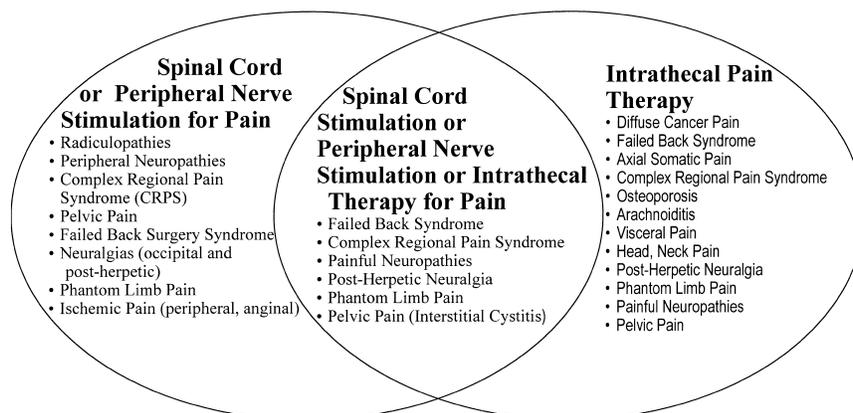
When a decision is made to proceed to a trial of an implantable modality, a modality must be chosen. For extremely focal problems, peripheral nerve stimulation may be appropriate. For a pain problem encompassing several contiguous dermatomes, spinal cord stimulation may be selected. For more diffuse problems or ones with varying distributions of pain, implantable drug-administration systems may be selected. Figure 2 illustrates the overlap of choices based on the etiology and distribution of the pain. In general, if neurostimulation can be used for a given pain syndrome, it is preferred and is attempted initially. When neurostimulation is effective it requires less ongoing maintenance and expense than drug-administration systems. Syndromes with mixed strong nociceptive and neuropathic pain may require neuraxial medication administration.

Traditionally, neuromodulation is reserved as a late modality in the pain treatment continuum. However, neuroaugmentive treatment such as spinal cord stimulation can enhance multidisciplinary care by facilitating participation in activities such as physical therapy, which is essential for rehabilitation.¹⁴ Spinal cord stimulation can be used as a temporary treatment that obviates the need for repeated neural blockade and can be used earlier in the treatment algorithm. The stimulation can be on a temporary basis as one component of treatment, without implantation of a pulse generator or receiver.

Screening trials

Screening trials of implantable therapies offer both the physician and the patient an opportunity to evaluate the

FIG. 2. Indications for advanced pain therapies.



therapy before committing to it. The patient's overall condition, the physician's preference and experience, the available facilities and resources, the practice environment, and payer coverage influence the choice of protocol. Two questions are fundamental: (1) Is the patient's pain responsive to the therapy? and (2) Can the patient tolerate the planned modality? The physician and patient should agree in advance on the goals of the trial and on the measures used to assess the outcome. For example, if returning to work is a goal of long-term therapy, a rehabilitation specialist should evaluate the patient during the screening trial. In general, candidates should not proceed to implantation unless their pain can be reduced by at least 50%.¹⁵

Because the cooperation of the patient is fundamental to the success of implantable therapies, the medical evaluation process should also include a discussion of the patient's and family's expectations regarding therapy. Patients should know in advance that complete pain relief is unlikely, that regular follow-up appointments are necessary, and that many patients experience postimplantation complications. This knowledge must be balanced against the functional benefits afforded by substantial pain relief.

Once a patient has been determined to be a candidate for an implanted modality, a screening trial is essential to determine if the modality is both efficacious and sufficiently free of side effects. Trials for neuraxial drug administration and neurostimulation each have special characteristics and concerns and are discussed separately.

Neuraxial medication trial

Indications and contraindications for intraspinal opioid therapy appear in Table 1. Understanding of pathophysiology relates to nociceptive pain versus neuropathic

TABLE 1. *Indications and contraindications for intraspinal drug delivery*^{11,12}

Indications
Chronic pain with known pathophysiology
Sensitivity of pain to medication being used
Failure of more conservative therapy
Favorable psychosocial evaluation
Favorable response to screening trial
Contraindications
Systemic infection
Coagulopathy
Allergy to medication being used
Inappropriate drug habituation (untreated)
Failure to obtain pain relief in a screening trial
Unusual observed behavior during screening trial
Poor personal hygiene
Poor patient compliance

Superscript numbers refer to reference list.

pain. Intraspinal drug delivery has been used primarily in patients with nociceptive pain that has proven to be opioid-responsive. Experience in intraspinal treatment of neuropathic pain is more limited, although several studies indicate that neuropathic pain may respond to intraspinal delivery of escalating doses of opioids or to non-opioid medications. Finally, a screening trial allows both the physician and the patient to assess intraspinal drug delivery before committing to pump implantation.

Numerous screening protocols exist. Trials can incorporate epidural or intrathecal administration, bolus injection, a series of injections, or continuous infusion and can be conducted on an inpatient or outpatient basis. Pure opioid or a mixture containing opioid can be administered. Duration of trials varies from 24 hours to more than a week. No protocol can be considered superior or definitive on the basis of current research findings. However, approximating the conditions of long-term therapy during the trial seems to offer the best chance for assessing efficacy and tolerance. Table 2 compares the advantages of each trial technique. The patient's overall condition, the physician's preference and experience, the available facilities and resources, the practice environment, and payer coverage influence the choice of protocol. Medicare reimbursement, for example, requires a preliminary trial of intraspinal opioid drug administration with a temporary intrathecal/epidural catheter. The question of epidural versus intrathecal administration continues to be debated, although no study has directly compared the two routes of administration. Although the epidural route is more convenient, an epidural dose must be roughly 10 times an intrathecal dose to provide equivalent analgesia. Proponents of intrathecal administration argue that the larger epidural dose may induce more severe side effects, deterring some patients from agreeing to intrathecal therapy that might be both beneficial and tolerable. For patients with syndromes that compromise distribution of medication in the epidural space, such as failed back surgery syndrome, an intrathecal trial optimizes the chances for uniform drug delivery and clearly simulates actual effect more accurately.

Neurostimulation trial

There are several ways to perform a neurostimulation trial. Carefully explaining the trial beforehand to the patient is essential. One way to perform a trial is to percutaneously place a lead and fix it to the skin. The alternative is to implant a lead and tunnel a temporary extension out of the skin. Table 3 summarizes the advantages and disadvantages of each trial technique. A purely percutaneous trial involves less surgical time initially and clearly produces less postoperative pain. Another advantage is that the lead can be removed without

TABLE 2. Comparison of neuraxial trial techniques*

Epidural trial	Intrathecal trial
Decreased risk of intrathecal infection	Most accurately simulates permanent catheter
Lower incidence PDPH	Lower dosage required
No risk of CSF drainage through catheter from disconnect	Smaller needle produces less severe PDPH
More common for outpatient administration	Even distribution of medication in FBSS
Bolus trial	Continuous infusion trial
Ease of administration	Most accurately simulates permanent implant
Does not require pump for trial	Can be titrated
Decreased trial expense if additional bolus is not necessary	Required by some carriers
	Does not produce peaks and troughs of medications
	Facilitates longer trial
	Fewer side effects by avoiding peaks
	Can incorporate placebo without need for second procedure
Pure opioid trial	Opioid with adjuvant medication trial
Predicts the effect of pure opioid	May more realistically predict long-term administration
No need to discern which medication had salutary or untoward effects	
Inpatient trial	Outpatient trial
Better monitoring may enhance safety	More accurately simulates normal activities
Easier to observe patient	Facilitates longer trial
Sterile technique more likely	More opportunity for titration
	Less expensive per day
Pure percutaneous catheter trial	Tunneled catheter trial
Less procedure-related pain during the trial	Decreases chance of CNS infection
Simpler to perform	Facilitates longer trial
Less invasive	Decreases chance of catheter dislodgement
Twenty-four hour trial	Longer trial
Less expensive	Can more accurately simulate normal activities
	More accurately predicts long-term result
	Decreases placebo response
Use of current systemic medications during trial	Withdraw systemic medications during trial
Eliminates possible systemic abstinence syndrome (abstinence symptoms can confound results)	Can observe the effect and side effects of neuraxial medication without additive effect of systemic medications

*Prager, J. Neuraxial medication delivery: the development and maturity of a concept. *Spine* (in press).

PDPH, postdural puncture headache; CSF, cerebrospinal fluid; FBSS, failed back surgery syndrome; CNS, central nervous system.

an incision. Because part of the lead is external, this lead must be discarded after the trial. An advantage of an implanted-device trial is that the trial lead is the permanent lead, which is a cost-savings. In addition, when the lead is permanently implanted initially, its position during the trial is the permanent one. There is no need to find the position that optimally stimulates the patient. A longer trial is facilitated when the lead is implanted, and clearly this provides more information. Current practice mandates a trial longer than several hours. Trials limited to stimulation during surgery are no longer acceptable. The goal of the trial is to simulate permanent implantation with as normal activities of daily living as possible.

TABLE 3. Neurostimulation trials: pure percutaneous versus implanted

Pure	Implanted
Less OR time initially	Only one lead used
Incision-less removal	No need to find the position at second stage (may save OR time)
Less postoperative pain to complicate the trial	Facilitates longer trial

OR, operating room.

With this information, the patient and physician have the best opportunity to evaluate the possibility of success.

Two questions are fundamental to trials of both modalities: (1) Is the patient's pain responsive to the neuromodulation technique? and (2) Can the patient tolerate it? The physician and patient should agree in advance on the goals of the trial and on the measures used to assess the outcome. For example, if returning to work is a goal of treatment with an implanted modality, a rehabilitation specialist should evaluate the patient during the screening trial. In general, candidates should not proceed to implantation unless their pain can be reduced by at least 50%. Intensive evaluation during the course of the trial is essential. In addition, we find it particularly useful for an unbiased third party (in this case, the psychologist) to discuss the trial with the patient afterward to determine how the trial met the patient's expectations. Behavioral evaluation during and after the trial optimizes the chance of success.

BEHAVIORAL EVALUATION

Pain is a subjective experience that is highly influenced by emotional factors.¹⁶ To have chronic pain is to

have an emotional reaction to the pain. The onset of a chronic pain condition is often accompanied by significant psychic stress that requires adaptation. A substantial body of literature has established the occurrence of mental disorder in chronic pain populations.^{17,18}

Patients with chronic pain are more likely to have a history of childhood trauma^{19–22} and traumatic stress.^{23–27} In addition, a growing literature suggests a specific neurobiological pathway for pain in some patients that is related to post-traumatic stress disorder.²⁸ Frequently, chronic pain coexists with depression,^{29–31} anxiety,^{32,33} and somatoform disorder.^{34–36} Recent studies suggest that patients with childhood psychological trauma will have a poorer outcome after surgical procedures than patients without such a history.³⁷

The involvement of clinical psychologists and other mental health professionals at the interface of pain and psychology is an accepted practice.^{38,39} Thus, there is an evolving standard of care for the treatment of chronic pain that accounts for the psychological along with the physical.⁴⁰ This area has been refined with the tradition of presurgical psychological screening for chronic pain syndromes. The screening method is now being applied to patients with chronic pain who are candidates for invasive procedures.

This premise is especially relevant with regard to the use of implantable devices such as spinal cord stimulators and intraspinal drug delivery systems.⁴¹ As pain specialists have become increasingly sophisticated in the use of neuromodulation interventions for intractable pain, assessment of psychological factors has evolved as a standard relevant to a given patient's presentation of pain and to medical decisions regarding implantable devices.^{42–45} The theory and technique of psychological assessment have also been applied to patients with chronic pain who are candidates for implantable devices.⁴⁶

Pre-interview considerations

Prior to consultation with a patient who is a candidate for implantation, the referring physician can improve compliance and reduce the patient's perception that their complaints of pain are not taken seriously by discussing the reason for the referral with the patient. Often, a patient with chronic pain has had no prior contact with the mental health care system. Therefore, meeting with a psychologist may be construed by patients as an indication that the referring physician believes they are "crazy." Preparation by the referring physician reduces anxiety and anger toward the psychologist and improves compliance with the referral.

Review of records

Prior to evaluation of the patient, the psychologist should review the relevant medical records. Awareness of the medical diagnosis and proposed course of treatment places the pain problem in context. If prior mental health evaluation and treatment records are available, they should also be reviewed.

Telephone contact

A patient referred for preimplantation psychological screening will benefit from a brief telephone call by the psychologist prior to the appointment. During the call, the psychologist should explain the reason for the evaluation, describe the procedure, clarify the patient's past experience with mental health care, discuss financial arrangements, and be available to answer any questions. A reassuring interaction before the appointment date increases the chances for success during the actual encounter.

Ethical issues

The relationship between a pain patient and the psychologist falls outside the common therapist-patient contract. With preimplantation psychological screening, both the referring physician and the patient are clients of the psychologist. The patient is not seeking mental health treatment services but is instead being directed to them by the physician. Therefore, the psychologist must clarify the ethical issues involved before the interview begins. The psychologist and patient should discuss informed consent regarding this triadic relationship and the need for communicating the findings of the psychological screening to the referring physician. Any restrictions of this communication desired by the patient should be discussed before the behavioral screening begins.

The clinical interview

It is helpful to begin the interview with a discussion of the patient's subjective experience of pain. You can begin by saying, "Tell me what your pain feels like to you." The resulting narrative is usually accompanied by pain behaviors. In addition, associative material relevant to the pain complaint (e.g., perceptions of victimization by the employer for a work injury, losses that accompany the pain disability, expectations for cure) provides valuable insight about how the experience of pain is organized in the patient's psyche.

The history of the pain illness and the treatments obtained are considered next. A brief review of the circumstances of the patient's life situation at the onset of the illness or injury is helpful in contextualizing the experience and identifying reinforcing factors. Issues such as timely medical treatment, response to both conservative and aggressive interventions, past involvement with

implantable devices, and ancillary treatments (alternative and behavioral) are important areas to explore. The way in which the past treatments have been received may predict the way in which the proposed implantation will be received.

The patient's emotional condition should also be comprehensively reviewed. After an open-ended question about the patient's perception of his/her emotional state, it is necessary to ask about depression, anxiety, anger, guilt, and thought disorder, as well as sleep, appetite, sexual functioning, and cognitive ability.

An understanding of the patient's current situation is considered next. Essential areas of inquiry include what the patient does with his/her time, how activities of daily living are approached, and how the patient interacts with others. Also relevant are external stressors and use of alcohol or drugs. The current situation will shed light on the patient's motivation for return to functionality—an issue that influences the success of the implantation. The patient should be asked how the implantation would affect future plans for return to function, if any.

Remaining areas to consider include the patient's comprehensive history and childhood and developmental history. The comprehensive history includes psychiatric symptoms and treatment, chemical dependency, family history of mental illness, education, marital history, vocational history, and legal, religious, and military service history. Discussion of the patient's childhood should include family structure; incidence of unusual circumstances, abuse, or trauma; family relationships; and history of medical illnesses.

Mental status examination

The mental status examination follows recording of the patient's history. General standards for mental status review apply. With regard to pain issues, attention should be given to the quality-of-pain narrative and presence of pain behaviors.

Issues related to implantation

An essential aspect of the preimplantation evaluation is consideration of issues directly related to implantation. The patient should be asked about his or her understanding of the implantable device and its mechanism of action and use. In addition, the psychologist inquires about the patient's understanding of the surgical procedure and follow-up, expectations for pain relief (100% versus a more reasonable level of 50% to 60%, depending upon the primary medical disorder), and strategies for coping with postimplantation pain. Asking patient to discuss their relationship with the implanting physician is another fruitful area of questioning.

Interview of significant others

Significant others often accompany patients for pre-implantation psychological screening. If the patient agrees, it is helpful to include these individuals at the conclusion of the clinical interview. Those with whom the patient has close contact are able to provide additional information about the patient's functioning and may shed light on issues not in the patient's awareness. Moreover, outcomes of implantation are improved when the patient's supporters understand the procedure, understand what to expect, and can identify the psychologist as a future resource.

Psychological testing

Psychological testing adds an objective database to the psychological evaluation. The patient can complete a screening assessment measure (e.g., the Beck Depression Inventory II and the Beck Anxiety Inventory) before the clinical interview. Abnormal items can then be reviewed with the patient during the first encounter. More comprehensive and objective psychodiagnostic assessment of psychological symptomatology and personality provides a basis for optimal understanding of a patient's suitability for implantation. Measures such as the Minnesota Multiphasic Personality Inventory II (MMPI-2), the Millon Clinical Multiaxial Inventory III (MCMI-III) and the Symptom Check List 90-R (SCL-90-R) augment the history and mental status examination. There are also specific pain screening measures (McGill). Many other assessment measures are available and can be used according to the individual psychologist's preference.

If standardized psychological testing is administered, it is helpful to have the patient return for a follow-up visit. Explaining the critical items and communicating the results and conclusions of the testing often lead to a greater understanding of the patient's mental state and dispel any misperceptions about the testing.

Psychological decision-making

When all data have been obtained, the psychologist must decide the patient's suitability for implantation. Factors in the decision include the presence of psychological symptoms or chemical dependency, the patient's history of and approach to pain treatments in the past, relationship with the referring physician, presence of character pathology, malingering or augmentation of symptoms, excessive regression or loss of function, litigation, understanding of the procedure, and plans for coping with pain and returning to functionality.

Categorization of suitability

At the conclusion of the evaluation, a patient is placed in one of four suitability categories.

1. No contraindication. The patient has a minimal level of psychological symptoms, and if symptoms are present they are being coped with adequately. The patient understands the technical issues related to implantation and has reasonable expectations. The patient's prior level of functioning was stable, the patient has attempted to maintain functionality, and, if disabled, the patient shows motivation to improve. Chemical dependency and character pathology are not present. There are no indications for mental health treatment. Patients in this category should be seen again after the implantation to assess their mental state and possible treatment needs.
2. Contraindicated due to behavioral issues. The patient is psychologically symptomatic (i.e., has depression, anxiety, cognitive impairment, chemical dependency, or character pathology). The patient does not understand the mechanism of action of the implantable device or the issues involved in committing to implantation. The patient is unrealistic about the efficacy of the device. However, the patient does have the potential for change and is willing to undergo mental health treatment (psychopharmacological evaluation, behavioral treatment [biofeedback or relaxation training], brief psychotherapy, or any combination of these). In this situation, the patient can be referred for the appropriate treatment and re-evaluated in 3 months.
3. Contraindication due to behavioral issues; implantation trial acceptable. The previously mentioned negative issues exist, but the patient is stable enough mentally for an implantation trial. A likely scenario would be a severe and progressive pain syndrome for which implantation is seen as essential, such as a worsening complex regional pain syndrome or dystonic pain due to paraplegia. The psychologist believes the patient would benefit from the medical treatment and would have a good prognosis with mental health treatment. The referring physician is advised to observe the patient's behavior at the time of the trial, given the findings of the psychological evaluation. The patient will be seen after the trial by the psychologist, and the experience of the trial and the physician's observations will be carefully reviewed. If permanent implantation is advised, mental health treatment or rehabilitation (or both) becomes a condition of proceeding.
4. Patient unsuitable. In this situation, the patient's presentation precludes implantation. It is the psychologist's judgment that to move forward with implantation poses a risk to the patient, given the psychological condition. Implantation would be

unlikely to provide a beneficial outcome and would pose a management problem for the referring physician. Implantation is usually contraindicated for patients with severe and longstanding psychological disorders and intractable psychiatric symptoms, severe character pathology, unremitting somatization with high use of health care services (yet without any improvement), relapsing chemical dependency, suspicion of malingering or factitious elements, profound regression and disability, serious and unmitigated external stress, and unresolved, difficult litigation.

CONCLUSION

The use of implantable devices for management of chronic pain requires a multidisciplinary team effort. Preimplantation medical assessment includes a review of the patient's medical history and diagnostic studies, physical examination, a complete diagnostic workup if necessary, and a screening trial of the proposed implantable device. Given the psychological issues that exist with chronic pain, behavioral evaluation of patients considered for implantation is essential to increase efficacy and improve outcome. Although the physician is the ultimate decision-maker, data obtained from a psychological evaluation are crucial. Essential elements of success, beyond the technical skill of the implanter, are the communication among all members of the implantation team and the ongoing behavioral evaluation both within the formal psychological evaluation and outside it. A critical factor for the successful outcome of an implantation program is the ability to appropriately evaluate and select patients for implantation.

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