Intrathecal baclofen pump implantation

Background

Intrathecal baclofen (ITB) refers to the delivery of the drug baclofen into the body’s cerebral spinal fluid using a surgically implanted pump. It is a treatment used for spasticity that results from a disorder of, or injury to, the central nervous system. These disorders or injuries can prevent messages from the brain from moving back and forth across the spinal cord, and as a result, muscles stay tight or contracted. Severe spasticity may be due to cerebral palsy, multiple sclerosis, brain injury, stroke, or spinal cord injury.

Baclofen is a drug that mimics the chemical normally found in the spinal cord that prevents spasticity and movement disorders. In the injured or impaired nervous system, this chemical balance is often lost.

Attempts to re-establish the chemical balance with oral medications often are ineffective and associated with side effects. By delivering the baclofen directly into the spinal fluid via an implanted programmable pump, the efficacy is extremely high while side effects are low.

A screening test determines whether ITB therapy will work for a patient. In this test, a health care professional injects a small dose of the medication into the fluid around the patient’s spinal cord. If the muscles become loose, it means that ITB therapy will probably work effectively.

Once it has been determined by the baclofen trial that there is a successful reduction in muscle tone, the patient can then undergo pump implantation. The pump is surgically inserted in the abdomen while the patient is under general anesthesia. The procedure lasts about one hour. A catheter runs under the skin from the pump to the back and is inserted through a needle into the spinal fluid.

The pump is programmed by a computer to continuously release a specified dose of baclofen that is determined by the physician. The pump needs to be refilled every two to five months, depending on the pump size, concentration, and dose. Refills are done using a syringe and needle and take approximately 10 minutes to complete. The battery in the pump lasts four to five years, at which time the pump will need to be replaced.

Involved specialties

Neurosurgeons, orthopedic surgeons, anesthesiologists, neurologists, and psychiatrists.
The American Academy of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) define neurological surgery as a discipline of medicine and specialty of surgery, which provides the operative and nonoperative management (i.e., prevention, diagnosis, evaluation, treatment, critical care, and rehabilitation) of disorders of the central, peripheral, and autonomic nervous systems.

This definition includes supporting structures and vascular supply; the evaluation and treatment of pathological processes, which modify the function or activity of the nervous system, including the hypophysis; and the operative and nonoperative management of pain.

The AANS and the CNS cite the Accreditation Council for Graduate Medical Education (ACGME) program requirements as the requisites for residency education in neurological surgery.

ACGME requirements

1. The training program in neurological surgery must include a minimum of one year of training in an ACGME-accredited program in general surgery or at least one year of a program accredited for the acquisition of fundamental clinical skills, which must include at least six months of surgical disciplines other than neurological surgery. This training should be completed prior to the third year of neurological surgery training.

2. The neurological surgery training program is 60 months in duration, in addition to the year of acquisition of fundamental clinical skills, and must provide 36 months of clinical neurological surgery at the sponsoring institution or one of its approved participating institutions.

3. 21 months of the total 60 months should be devoted to any of several aspects of the training program, depending on the needs of the resident.

4. A block of training of three months minimum in an ACGME-accredited neurology training program must be arranged for all residents, unless they have previously had a minimum of one year of formal residency training in an accredited neurology training program. This training may be taken during the year of fundamental clinical skills.

5. There must be a 12-month period of time as chief resident on the clinical service of neurological surgery in the sponsoring institution or its approved participating program.

6. Residents must be introduced to the practice of neuro-
surgery in an outpatient setting where nonemergency patients are seen by the resident for evaluation before and after surgical procedures.

In regard to ITB pump implantation, an AANS spokesperson states that this is a procedure that a neurosurgeon would perform. It comes under the category of pain management.

According to the American Academy of Orthopaedic Surgeons (AAOS), orthopedic surgeons are specifically trained to diagnose and care for disorders affecting

- bones
- joints
- soft tissues of the upper and lower extremities, including the hand and foot
- spine, specifically including intervertebral disks
- bony pelvis

In addition, their education includes experience related to clinical areas, including the treatment of certain neurological disorders.

The American Society of Anesthesiologists (ASA) publishes Guidelines for Delineation of Clinical Privileges in Anesthesiology. In these guidelines, the ASA states that clinical privileges in anesthesia are granted to physicians who are qualified by training to render patients insensible to pain and to minimize stress during surgical, obstetrical, and certain medical procedures using general anesthesia, regional anesthesia, or sedation/analgesia to a level at which a patient's protective reflexes are likely to be obtunded. Performance of preanesthetic, intra-anesthetic, and postanesthetic evaluation and management are essential components of the practice of anesthesia.

Privileges in anesthesia should be awarded on a time-limited basis, not to exceed two years. The granting, reappraisal, and revision of clinical privileges should be in accordance with medical staff bylaws and institutional/facility rules and regulations, as applicable.

Educational criteria to be considered for delineation of clinical privileges in anesthesia:

- Graduation from a medical school accredited by the Liaison
Committee on Medical Education, from an osteopathic medical school or program accredited by the American Osteopathic Association (AOA), or from a foreign medical school that provides medical training acceptable to and verified by the Educational Commission on Foreign Medical Graduates

- Completion of an anesthesiology residency training program approved by the ACGME or by the AOA

- Permanent certification by the American Board of Anesthesiology (ABA) or current recertification within the time interval required by the ABA

- Current Physician’s Recognition Award of the American Medical Association or completion of 100 hours of continuing medical education (CME) over two years, of which 40 hours are in category 1 of the Accreditation Council for Continuing Medical Education

- Compliance with relevant state or institutional requirements for CME

- At least 50% of CME hours in the primary specialty of practice

- Certificate indicating completion of a course in advanced life support within 24 months preceding application for clinical privileges

Educational criteria to be considered for practice in a subspecialty of anesthesiology:

- Completion of a fellowship approved by the ACGME (critical care medicine, pain medicine, pediatric anesthesia) or by the AOA, or a fourth clinical year or fellowship of at least 12 months duration not accredited by the ACGME or by the AOA (e.g., obstetric or cardiac anesthesia)

- Current ABA certification in pain management (Certificate of Added Qualifications in Pain Management) or in critical care medicine (Certificate of Special Qualifications in Critical Care Medicine)

Licensure criteria:

- Current, active, unrestricted medical or osteopathic license
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in a United States state, district, or territory of practice

• Current, unrestricted Drug Enforcement Administration (DEA) registration or no history of revocation of DEA registration within the past five years

• No disciplinary action (final judgments) against any medical or osteopathic license or by any federal agency, including Medicare/Medicaid, in the last five years

Note: None of the above organizations (AANS, CNS, AAOS, ASA) publishes any credentialing or privileging criteria concerning ITB pump implantation.

A. Leland Albright, MD, a pediatric neurosurgeon and the director of the Spasticity and Movement Disorders Center at the Children’s Hospital of Pittsburgh in Pennsylvania, believes that only neurosurgeons and not orthopedic surgeons or anesthesiologists should be surgically installing ITB pumps, particularly in children and individuals with any movement disorders. He gives the following three reasons:

• Orthopedic surgeons and anesthesiologists are not as well-trained as neurologists and neurosurgeons in neurological disorders and could have problems with patient selection. For example, they might not recognize other movement disorders that mimic spasticity; e.g., familial spastic paraparesis, and could miss a common disorder like dystonia that is treated in a different manner than spasticity.

• They are not trained to manage hydrocephalous that is present in a number of children and adults who need pumps.

• They are not trained to diagnose and treat patients who develop spinal fluid leaks.

“These problems are more prevalent with children, especially those who have cerebral palsy, than they are with adults who have spasticity as a result of spinal cord injury or head injury,” says Albright. As a result, orthopedic surgeons or anesthesiologists may successfully implant pumps with 90% of their patients, but their lack of neurological training could give them problems with the other 10%.

Positions of other interested parties

Children’s Hospital of Pittsburgh
Pittsburgh, PA

A. Leland Albright, MD
“An orthopedic surgeon could acquire the additional training needed for special situations,” Albright says, “but it would be almost impossible for anesthesiologists because they have no training in surgical techniques.”

According to Albright, neurosurgeons are currently trained in pump implantation in their residency programs. For physicians who have not had this training, Medtronic, the pump manufacturer, sends out representatives who go over the procedure on videotape and are present in the operating room during the physicians’ initial procedures.

“If implanting physicians do two or more cases under this kind of close supervision,” says Albright, “then they should be competent to perform the procedure on their own.” For maintaining competence, he recommends at least one procedure every quarter or four implant procedures per year.

Medtronic, Inc.
Minneapolis, MN

According to a spokesperson for the Minneapolis, MN–based neurological division of Medtronic, Inc., the manufacturer of the programmable SynchroMed drug pump and marketer of ITB therapy, implanting physicians are mainly neurosurgeons. Orthopedic surgeons and anesthesiologists also perform implantations if they are already implanting pumps for the delivery of morphine to patients with chronic pain or cancer pain. “We consider that if they have the surgical skills for pain implants,” says the spokesperson, “they would have the skills for spasticity implants as well.”

Before Medtronic sells a pump to an implanting physician or to a hospital or clinic, a company clinical educational specialist or therapy consultant must train the physician on all aspects of how the pump works, its indications and contraindications, and the surgical procedure. The Medtronic specialist usually observes a physician’s initial implantation procedures, and the company highly recommends that the physician be proctored by an experienced pump implanting physician as well as attend Medtronic-sponsored training workshops.

Medtronic does not have a set number of implantations for competence or for maintaining competence, but instead leaves it up to the comfort level of the individual physician.

“A surgeon probably doesn’t need much help in mastering pump implantation procedures,” says the spokesperson,
“whereas an anesthesiologist who doesn’t have the same surgical skills may require more training.”

CRC draft criteria

Basic education: MD or DO

Minimum formal training: The successful applicant must have successfully completed an ACGME- or AOA-accredited neurosurgery, orthopedic surgery, or anesthesiology residency training program. If ITB pump implantation was not included in residency training, the applicant must demonstrate that he or she has completed formal instruction in ITB pump implantation that included preceptorship by an experienced ITB instructor or practitioner, patient selection criteria, and management of such special situations as hydrocephalus and spinal leakage.

Required previous experience: The applicant must be able to demonstrate that he or she has successfully performed at least six ITB pump implantations in the past 12 months.

Note: A letter that evaluates competency must come from the preceptor of the applicant’s initial ITB pump implantations or from the ITB therapy director at the institution where the applicant was last affiliated.

Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully performed at least six ITB implantations in the past 12 months.

In addition, continuing education related to ITB therapy should be required.

For more information

For more information regarding this procedure, contact:

American Academy of Orthopaedic Surgeons
6300 North River Road
Rosemont, Illinois 60018-4262
Telephone: 847/823-7186
Fax: 847/823-8125
Web site: www.aaos.org
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American Academy of Neurological Surgeons
22 South Washington Street
Park Ridge, IL 60068-4287
Telephone: 847/692-9500
Fax: 847/692-2589
Web site: www.aans.org

American Society of Anesthesiologists
520 North Northwest Highway
Park Ridge, IL 60068-2573
Telephone: 847/825-5586
Fax: 847/825-1692
Web site: www.asahq.org

Children’s Hospital of Pittsburgh
3750 Fifth Avenue
Pittsburgh, PA 15213
Telephone: 412/692-5094
Fax: 412/692-5921
Web site: http://neuronet.pitt.edu/groups/ctr-childped/spasmdc.html#Team

Congress of Neurological Surgeons
475 South Frontage Road, Suite 101
Burr Ridge, IL 60521-6282
Telephone: 888/267-5577
Fax: 630/989-6989
Web site: www.aans.org

Medtronic, Inc.
850 Third Avenue, NE
Minneapolis, MN 55421-1200
Telephone: 612/514-5000
Fax: 612/514-5078
Web site: www.medtronic.com/neuro/itb/
Privilege Request Form  
Intrathecal baclofen pump implantation

In order to be eligible to request clinical privileges for ITB pump implantation, an applicant must meet the following minimum threshold criteria:

• Education: MD or DO

• Minimum formal training: The successful applicant must have successfully completed an ACGME- or AOA-accredited neurosurgery, orthopedic surgery, or anesthesiology residency training program. If ITB pump implantation was not included in residency training, the applicant must demonstrate that she or he has completed formal instruction in ITB pump implantation that included preceptorship by an experienced ITB instructor or practitioner, patient selection criteria, and management of such special situations as hydrocephalous and spinal leakage.

• Required previous experience: The applicant must be able to demonstrate that he or she has successfully performed at least six ITB pump implantations in the past 12 months.

• References: A letter that evaluates competency must come from the preceptor of the applicant’s initial ITB pump implantations or from the ITB therapy director at the institution where the applicant was last affiliated.

• Reappointment: Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully performed at least six ITB implantations in the past 12 months.

In addition, continuing education related to ITB therapy should be required.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ________________________________

Typed or printed name: ________________________________

Date: ________________________________
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