

Intrathecal Baclofen Therapy: Ten Steps Toward Best Practice

Barbara Ridley, Patrice Korth Rawlins



Abstract: Practitioners from around the country who have extensive experience in intrathecal baclofen (ITB) therapy gathered in early 2004 to develop best-practice guidelines for ITB therapy. Discussion focused on the idea that ITB therapy is a program rather than a procedure. Key recommendations were made in areas including team coordination, patient selection and goals, patient education, patient screening, implant technique, long-term management, individualized dosing options, ongoing evaluation of patient response, appraisal of the integrity of the catheter and infusion system, and appropriate practice resources.

Intrathecal baclofen (ITB) therapy has been shown to benefit patients with severe spasticity related to spinal cord injury, multiple sclerosis (MS), cerebral palsy (CP), brain injury, and stroke (Albright et al., 2003; Meythaler, Guin-Renfroe, Brunner, & Hadley, 2001; Ordia, Fischer, Adamski, Chagnon, & Spatz, 2002). Possible outcomes vary greatly, based on the underlying neurological level of function, but may include improved ambulation or wheelchair seating, reduced spasticity-related pain, improved sleep, and easier positioning and caregiving (Azouvi et al., 1996; Gianino, York, Paice, & Shott, 1998; Stempien & Tsai, 2000). Documented complications occur in 10%–45% of patients; they may include catheter disconnections, kinks, or wound infections. Acute withdrawal syndrome is also possible but rare. (Campbell et al., 2002; Follet et al., 2003; Rawlins, 2004).

ITB therapy gained U.S. Food and Drug Administration (FDA) approval for managing severe spasticity of spinal origin in 1992 and for severe spasticity of cerebral origin in 1996. Adult and pediatric patients may receive ITB therapy in a variety of settings, including university medical centers, community hospitals, and private practices.

In March 2004, 14 practitioners with experience in ITB therapy met in Minneapolis to develop best-practice guidelines for providers. Participants included physicians from specialties such as neurosurgery, neurology,

and physical medicine, as well as four advanced practice nurses from around the country. This article presents the perspective of two of the nurses and summarizes what the authors believe to be the most important recommendations from the meeting, with particular emphasis on nursing implications (Fig 1). The goal of this article is to offer practical considerations for clinicians based on the discussions at the forum and the professional experiences of the authors. The forum took place a few months before the release of a new pump model, the SynchroMed II®; references to use of the new model reflect the opinions of the authors, not those of the forum as a whole.

Top 10 Recommendations

1. Intrathecal Baclofen Therapy Should Be Coordinated by a Team with a Designated Leader.

Successful management of patients who receive ITB therapy requires a committed team with designated medical leadership and an identified coordinator to ensure smooth transition between the different stages of the therapy and effective long-term follow-up. Physician leadership is usually provided by a neurologist or physiatrist who has a focus on function and quality-of-life outcomes and a commitment to maintaining a long-term relationship with these patients. The role of the team coordinator is best suited to an advanced practice nurse with critical analysis skills, such as a nurse practitioner or clinical nurse specialist, who can address ongoing patient and family educational needs and ensure that comprehensive follow-up progresses smoothly.

Rehabilitation therapists, particularly from physical therapy and occupational therapy, are essential team members who can help monitor the patient's response to treatment and changing functional status over time. The team must make arrangements for continuous emergency coverage related to pumps and must develop mechanisms for effective communication with clinical partners in other areas, including the primary care physician, emergency department staff, and providers from school programs, day centers, or group homes.

As with any program, experience and volume increase the competence of the clinicians and therefore reduce the rate of complications and improve outcomes. This is a particularly important consideration with respect to the implanting surgeon's surgical experience. However, a successful ITB therapy program involves more than an experienced surgeon. The surgeon should be actively involved with the team for system-related problem

Questions or comments about this article may be directed to Barbara Ridley, RN FNP, at 510/204-5259 or ridleyb@sutterhealth.org. She is a nurse practitioner in rehabilitation at Alta Bates Summit Medical Center, Berkeley, CA.

Patrice Korth Rawlins, MN ARNP, is a clinical nurse specialist at the Neuroscience Implant Program, Wichita, KS.

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1. Intrathecal baclofen therapy should be coordinated by a team with a designated leader.
2. Patients must be carefully selected.
3. Goals must be clearly identified and documented.
4. Patient education must be a focus.
5. A screening test is necessary.
6. An implant technique that minimizes complications and enhances outcomes should be used.
7. Individualized dosing patterns that enhance patient satisfaction and outcomes should be used.
8. Ongoing evaluation should be provided by consistent providers to facilitate best outcomes.
9. Ongoing evaluation of the catheter and pump system is necessary.
10. Program success requires appropriate practice management resources.

Fig 1. *Top 10 recommendations for an intrathecal baclofen therapy program*

solving and be willing to participate in quarterly or biannual team meetings to review outcomes.

The team coordinator should ensure that mechanisms are in place to provide adequate training for all staff through competency testing and annual review, as necessary. It is particularly valuable to review data on complications with all team members, including the implanting surgeon, as part of ongoing quality improvement activities.

2. Patients Must be Carefully Selected.

To qualify as a candidate for ITB therapy, a patient must have hypertonicity related to spasticity of cerebral or spinal origin that causes significant impairment and is unresponsive to more conservative treatment (e.g., oral medications, local injection therapy, physical modalities). The patient, family members, caretakers, and healthcare providers must agree that spasticity is a significant problem negatively affecting function and that treatment is indicated.

The only contraindication for Lioresal® ITB therapy for a patient with significant spasticity is an allergy to baclofen, which rarely occurs. Adverse effects such as drowsiness, lethargy, nausea, or mental clouding with oral baclofen are common side effects not to be confused with an allergic reaction and are good criteria for ITB because the intrathecal delivery minimizes these side effects (Laborde, Weibel, Meythaler, & Narayan, 1999). Several relative considerations for ITB therapy have been identified, however, and appropriate patient selection involves a comprehensive assessment of more than just the physical aspects of spasticity.

Relative considerations for ITB therapy include untreated hydrocephalus, which could impede intrathecal drug absorption and increase the risk of cerebrospinal fluid leaks around the catheter (Albright, Ferson, & Carlos, 2005; Gilmartin et al., 2000); general medical instability; poorly controlled seizures; and severe depression, which

may be exacerbated by ITB (Ivanhoe, Tilton, & Francisco, 2001). Other concerns include a history of poor compliance in keeping medical appointments, inadequate family or other social support, and financial barriers such as inadequate insurance coverage or inability to take time off work to attend appointments, especially if long travel distances are involved. Patients should be carefully evaluated to determine whether or how much they need their spasticity to maintain trunk balance, walk, or transfer. Physical assessment should also include evaluation for an adequate body mass and abdominal girth to support the pump.

The patient and family need to understand the time required for each stage of therapy; the need, in most cases, for physical or occupational therapy to maximize the benefits; the long-term commitment; and the costs involved in returning to the center for dose adjustments and pump refills. A social worker's involvement is often beneficial to address issues related to insurance coverage and transportation. Some centers develop a contract for the patient, a family member, or caregiver to sign.

Unrealistic expectations must also be addressed at the patient-selection stage to avoid pitfalls later on. Providers must be clear with a patient with MS, for example, that ITB therapy is a treatment for the symptom of spasticity, not for the underlying disease. A young, ambulatory patient who has had a traumatic brain injury must understand that the baclofen pump may substantially improve his gait but is unlikely to return him to his pre-injury level of physical agility or mental function.

Referring a patient who is considering ITB therapy to another patient who has the pump is often helpful for peer support. Care must be taken, however, to not unwittingly promote unrealistic expectations by having a nonambulatory spinal cord-injured patient, for example, talk with a stroke survivor who can now walk without a cane. Large centers can usually find a good peer match, in terms of diagnosis and functional level, from within their own caseloads. Medtronic—the manufacturer of the SynchroMed® pump—has an ambassador program that can be of great value for smaller facilities or those just establishing their program.

Patient and family education must start in the screening phase and continue throughout the program (Table 1). Brochures, videotapes, and DVDs are available. A sample pump should be demonstrated to the patient during the selection stage to avoid any future surprises. Even the SynchroMed II pump, with its slimmer profile, is quite large, at 7 cm in diameter. Most patients, even young children or very small adults, tolerate the presence of the pump without problems once it is implanted, but concerns related to the pump's appearance and sensation should be addressed in the screening. Patients may be reassured by seeing or talking with another patient about this issue or by holding a demonstration pump in their waistband during an office visit.

Table 1. Key Elements of Patient and Family ITB-Therapy Education

Phase of Therapy	Topic
Patient Selection	Mechanisms of ITB therapy, intrathecal versus oral baclofen Establishment of individualized goals Overview of pump system, stages of therapy, placement, need for rehabilitation therapy, refills Long-term commitment, transportation Insurance coverage, preauthorization Preparation for screening test
Screening Test	Overview of procedure, what to expect Possibility of hypotonia Informed consent Individualized screening-test goals Evaluation of response to test versus continuous ITB therapy Review of ITB therapy stages, goals, commitment
Surgical Procedure	Pump model, reservoir capacity, drug concentration, and initial dose Postoperative wound care Pump identification card Emergency information card (signs and symptoms of overdose, withdrawal) Titration of ITB therapy, tapering of oral medications Refill schedule, pump alarms Initiation of rehabilitation therapy Factors that affect pump function
Ongoing Medical Management	Dosing options, monitoring response Factors that increase or decrease spasticity Signs and symptoms of overdosage, withdrawal Who to call Potential drug interactions Travel issues Battery replacement

3. Goals Must Be Clearly Identified and Documented.

The goals of therapy must be clearly identified in advance and individualized for each patient. Goals may range from improving gait to facilitating positioning in a wheelchair, controlling spasticity without drowsiness, controlling mental clouding from oral medications, improving oral motor control, or allowing caregivers to perform hygiene or bladder-management tasks (Azouvi et al., 1996; Bjornson et al., 2003; Meythaler, et al., 2001). Possible goals are summarized in Table 2. Discussion of the goals of ITB should include consideration of the need for physical therapy to help build muscle strength and facilitate new motor learning if the patient is using his or her spasticity for some functional benefit, such as transfers, trunk balance, or ambulation.

Goals need to be realistic, have clearly identified time frames, and be developed with input from the

patient, family, caregivers, and team members such as physical, occupational, or speech therapists in the institution, community, or school setting. It can be valuable to have the patient or a family member sign a modified consent form that includes the agreed-upon goals or, if feasible, to document the agreement of goals on videotape.

Goals may need to be modified as the patient progresses through the stages of ITB therapy. As response to the treatment is evaluated, outcomes and revised goals should be documented. The use of a validated tool to measure goal attainment is highly desirable, but because goals vary greatly, depending on underlying disability and level of function, identifying one tool to adequately address all patient situations is challenging (Pierson, 1997). The Functional Independence Measure (FIM™), the Short Form 36® (SF-36), the Gross Motor Function Classification System (GMFCS), and the Pediatric Evaluation of Disability Inventory (PEDI) are suggested, but all have

limitations. Rehabilitation disciplines such as physical, occupational, and speech therapy can also offer specific outcome tools. One measure that may be appropriate in a wide variety of situations is the Canadian Occupational Performance Measure® (COPM), which allows patients to rate their own performance and satisfaction with goal achievement in three domains: self-care, productivity, and leisure (Carswell et al., 2004).

4. Patient Education Must Be a Focus.

Success with ITB depends heavily on detailed patient and family education through every stage of the treatment, from patient selection through long-term management (Table 1). The patient, family members, and other caregivers must be active partners in the therapy to enhance their satisfaction, maximize their response, and prevent unnecessary after-hour calls. Many centers use a checklist to ensure that the key elements are addressed.

Table 2. Goals of ITB Therapy

Predictable	Unpredictable
Reduce tone in extremities	Improve quality of gait
Reduce spasms in extremities or trunk	Reduce spasticity-related pain with ambulation
Control clonus in extremities	Increase independence in transfers
Reduce spasticity-related pain	Increase upper extremity control and function
Improve sleep	Improve bladder and bowel function
Reduce side effects of oral antispasmodic medications	Reduce incidence of skin breakdown
Improve quality of life	Improve oral motor control and vocal cord dysfunction
Ease caregiving tasks, performance of hygiene, dressing, bathing	
Ease positioning in wheelchair	

Education is an important part of the patient-selection process. It includes the need to clarify goals and expectations, explain the stages of ITB therapy and the commitment involved, and answer all questions about the procedure. This process can last for weeks or even months in some cases, as patients try to make a decision about this elective, invasive procedure.

Patient and family education to prepare for the screening test requires review of many of the issues addressed in the patient-selection stage, with particular emphasis on what to expect in the screening procedure itself. Medtronic has videotapes and DVDs that describe the procedure and the goals. They are available in both adult and pediatric versions, and some are now available in Spanish. Additional patient teaching materials are available on the clinician Web site at www.medtronicconnect.com. These are valuable tools but need to be supplemented with individualized attention to the specific needs of each patient. The screening test is more successful if the patient and family are well prepared with realistic expectations.

Before the implantation surgery, education needs to address the plan for initiating ITB therapy and gradually tapering off of oral antispasmodic agents, in addition to the usual preoperative instructions. After surgery, the patient and family should receive written information about the device model, serial number, and catheter type and length. Patients should be encouraged to start an ITB file at home, where they will keep all relevant documentation. They will receive a wallet-sized emergency information card, which they should be instructed to carry at all times. This card, provided by Medtronic, contains important information for providers who may be unfamiliar with ITB therapy but may be called upon to treat patients with symptoms of overdose, drug withdrawal, or another emergent medical problem.

During ongoing management of patients with ITB therapy, education will continue to play a key role. Issues that need to be regularly addressed and reviewed include

monitoring of response to treatment, potential complications with dose changes, and interactions with alcohol and other prescription medications. The advanced practice nurse should periodically review issues related to ITB drug withdrawal and overdose. Initiating, discontinuing, or changing doses of medications, such as seizure medications or selective serotonin reuptake inhibitors, may alter the response to ITB therapy, and patients

must understand the need to keep all providers informed of any medication change. Patients, family members, and caregivers must also understand how to recognize and minimize irritants that may contribute to increased spasticity, such as urinary tract infection, constipation, skin breakdown, or poor positioning, to avoid unnecessary or inappropriate requests for ITB rate increases. In some cases, the patient's local primary care provider may need guidance on how to triage for and treat causes of increased tone, instead of simply treating the symptom of increased spasticity.

Patients and families need information about how their device interacts with other technology in the environment. They can be assured that the pump will not be affected by microwave ovens, televisions, or computers. The pump may, however, set off metal detectors at security checkpoints, for example; this will not affect the infusion of medication, but patients should carry their ITB-therapy identification card to avoid difficulties. Patients can also be advised to carry a MedicAlert® bracelet.

MRI can be safely performed on a patient with an implanted infusion pump. The pump will stop infusion for the duration of the MRI procedure and will automatically resume normal functioning afterward. Precautions must be taken by the MRI technician. A 24-hour technical support department at Medtronic (800/707-0933) provides assistance to MRI facilities. Medtronic also provides written technical information that can be faxed to radiology departments. Patients should be informed of this resource so they can share the information with providers.

5. A Screening Test Is Necessary.

Patients selected as appropriate candidates for ITB require a screening test to confirm that they will benefit from the therapy. The screening test involves a bolus intrathecal injection of baclofen administered by lumbar puncture. The patient's response is monitored for an 8-hour period following the procedure. A few circumstances (e.g., the

patient has a fused spine) may indicate implantation without a screening test. Performing the screening test, however, can provide useful information about future dose, response patterns, and potential functional outcomes, which can help those providing ongoing management after the pump is placed and can provide justification for third-party payers. A screening test is the standard of care.

The screening test may be performed in an inpatient or outpatient setting. Emergency treatment should be readily available in the event of serious adverse reactions, particularly severe respiratory depression. Conscious sedation may be necessary for young children or others with severe movement disorders.

The screening test is more likely to proceed smoothly if an advanced practice nurse has responsibility for overall coordination and patient and family education throughout the process. Clear communication is particularly important if one provider selects the patient and another performs the screening test. The goals for each patient should be clearly communicated. Before the screening test, the patient is tapered from anticoagulation medications, if necessary, and baseline spasticity is assessed. There is no need to taper oral antispasmodic medications before the screening test. Other issues that need to be considered include transportation; prior authorization, if required; and informed consent by a proxy if the patient is unable to consent. A checklist is helpful.

The standard dose of intrathecal baclofen for the screening test is a 50-mcg bolus. We emphasize that this is a one-size-fits-all dose to assess the patient's general response. It is important to explain that, after the pump is implanted, the dose will be adjusted over several months until the most effective level is determined. The provider may vary the screening test dose in certain clinical situations to improve the patient's subjective experience. It may be difficult to convince a patient who becomes extremely hypotonic that this response is dose dependent. Ambulatory patients with MS are particularly likely to become too hypotonic with the standard 50-mcg dose and may benefit from a lower dose of 25 mcg and monitoring for peak effect to occur earlier than with other patients. Nonambulatory patients with significant hypertonia or those with a combination of spasticity and severe dystonia may require a 75-mcg or 100-mcg dose to produce effect.

Although some providers are doing the baclofen screening test with a continuous infusion, this is an off-label use that is not recommended. Screening with continuous infusion does not in itself allow one to more accurately predict eventual functional outcomes because of the likely presence of underlying weakness and the need for physical therapy services and new motor learning to maximize the response.

The lumbar puncture is performed in the routine manner; experts recommend that opening pressure be obtained to rule out any undetected hydrocephalus.

Following the injection, the patient should lie flat for 2 hours to reduce the risk of a spinal headache but may then be up as tolerated and on the usual diet. Postprocedure monitoring should include vital signs (especially blood pressure, pulse, and respiration) every 15 minutes for 2–4 hours, with continuous pulse oximetry. A neurologically trained physical therapist should be available to evaluate changes in spasticity throughout the day.

The medication typically begins to take effect within 2 hours, peaks at about 4 hours, and then gradually wears off until the patient returns to baseline after approximately 8 hours. The effect on the patient's spasticity is usually measured every 2 hours using the Ashworth scale; a 1- to 2-point drop in key muscle groups indicates a positive response. However, depending on the patient's presenting complaints, functional level, and goals for ITB therapy identified in the selection process, it may also be appropriate to include other variables in the assessment (e.g., pain level, sitting tolerance, transfer ability, timed gait) and to use these changes as a measure of a positive response in addition to the Ashworth scores.

A preprinted set of standing orders and a designated documentation tool simplify the process and ensure that all elements are addressed. Documentation should include the baseline assessment of tone, spasms, reflexes, and pain. The goals for the patient, the time and size of bolus dose, and the time to peak onset and return to baseline should also be documented. Videotaping the response to record the before-and-after effect can provide an invaluable tool for later evaluation and is recommended. At 4–6 hours after injection, the physician or advanced practice nurse should review the response with the patient and family, including a discussion of the patient's experience.

If the screening test is done as an outpatient procedure, and if the patient remains very hypotonic after 8 hours with a delayed return to baseline, it may be necessary to consider hospital admission if some tone is required for the patient to perform activities of daily living or transfers. Most patients can go home after 8 hours without problems and with instructions to resume oral antispasmodic medications as usual later that evening. Advise patients to avoid strenuous activities for a few days, to drink plenty of fluids, and to stay lying flat if they experience a spinal headache.

6. An Implant Technique that Minimizes Complications and Enhances Outcomes Should Be Used.

The attendees of the best practice forum in 2004 agreed the intrathecal baclofen delivery system is reliable. They noted that improvements in the ITB system, such as catheter connectors and durability, have reduced the complication rate over time, primarily by reducing catheter kinking and leaking. However, the implanting physician's experience is the most important factor in preventing immediate postoperative complications and

problems with long-term system integrity. One of the most common surgical complications is infection. The infection rate for the infusion pump and catheter implant should not be higher than the infection rate for shunt procedures. Specific infection prevention standards and implant methods for best outcome have been published (Albright, Turner, & Pattisapu, 2006; Follett et al., 2004).

Nursing care also contributes to implant success. Discussion of pump size with the patient, family, and surgical team provides valuable information. The newest pump models are available with 20-ml or 40-ml reservoir volumes. Anticipated dosing needs, patient size, and patient habits should be considered when choosing the pump model and reservoir volume. A nurse's experience with ITB therapy contributes to successfully predicting dosing requirements, which provides guidance in pump selection. If a high dose is anticipated or the patient lives far from the clinic, the use of the 40-ml reservoir should be encouraged. Pump size is important in pediatric patients to reduce the risk of skin breakdown from pump erosion.

Currently planned or potential apparatus (e.g., wheelchair seatbelts, lateral supports, suprapubic catheters, shunts, feeding tubes) should be considered in deciding on the best placement for the pump and catheter. For instance, if a left upper abdominal quadrant feeding tube placement is expected in the future, implant of the infusion pump on the right side and tunneling of the catheter away from potential surgical sites should be encouraged.

The nurse coordinator should initiate team discussion about the spinal level of the catheter tip to improve therapeutic outcome. Presence of upper extremity spasticity indicates the need for higher placement. High-thoracic or low-cervical catheter tip placement is beneficial for upper extremity spasticity relief and poses no known added risk.

Although the pump is routinely replaced at the end of the battery life, the catheter is replaced only if there are signs of decreased cerebrospinal fluid flow or catheter deterioration or if the catheter-tip location is too low. A review of therapy effectiveness with the patient and with those providing long-term management is important to anticipate the need for catheter replacement. If the intrathecal catheter is replaced with one at a higher level, decreasing the dose to avoid complications of high-dose effect should be considered.

If any portion of a catheter has been replaced due to questionable integrity or flow, the initial postoperative intrathecal dose should be decreased in accordance with intraoperative findings. A dislodged or broken catheter or a defect large enough to allow cerebrospinal fluid flow through the defect implies that little, if any, baclofen was infusing to the catheter tip. The programmed infusion should be decreased to the initial implant dose of 50 mcg–100 mcg per day in simple infusion mode. Conservative adjustments and close patient observation determine the appropriate dose and should mimic the initial titration-dosing phase.

Current implant technique includes documentation of catheter-tip level by intraoperative fluoroscopy or postoperative X ray. Relevant information should be communicated to the providers of long-term therapy management. Catheter model, total catheter length, and catheter volume are crucial information to prevent high- or low-dosing complications at later stages; this is

Proper implant technique during initial system placement and routine end-of-battery pump replacement minimizes complications and enhances outcomes.

especially true for bridge bolus calculation and system assessment during dye studies. Documentation of catheter attachment accessories, as well as connection and anchoring technique, assist in evaluating system complications. The SynchroMed II pump software simplifies the process by allowing implant data and notes to be recorded and stored directly in the pump's memory.

Proper implant technique during initial system placement and routine end-of-battery pump replacement minimizes complications and enhances outcomes. The nurse coordinator contributes to implant success and decreased complications by discussing with the health-care team crucial information related to pump size and reservoir volume, location of implant, specifics of implanted equipment, and dosing adjustments. The nurse coordinator is the communication link between the family, community, and hospital team.

7. Individualized Dosing Patterns that Enhance Patient Satisfaction and Outcomes Should Be Used.

After implant, a period of more frequent visits is common during the titration phase. The *titration phase* is generally defined as the time it takes to achieve a steady dose for 4–6 weeks. These visits include slow, closely monitored dose adjustments, evaluation of positive and negative therapy effects, tapering of oral medications, and initiation of rehabilitation services. The titration phase may last weeks or months, depending on a number of factors. One influence is the patient's diagnosis. Those with static conditions such as anoxic brain injury may quickly reach adequate dosing, whereas those with progressive disorders such as MS require more time—perhaps 6–9 months. Another factor is the patient's sensitivity to dosage changes. Ambulatory patients are more sensitive to rate increases and may tolerate only a 3%–6% increase in the total daily dose. Patients receiving ITB for care and comfort may easily tolerate increases of 10% of their daily dose (Rawlins, 2004).

A patient's response during the screening test is generally a fair indicator of the response to rate changes during the titration phase. A rapid or long-lasting screening dose effect indicates the need for conservative dose

increases. Other factors include the number and dose of correlated oral medications that will be tapered and clinic accessibility. Appropriate dosing during the titration phase prevents loss of function and provides relief from severe spasticity.

Long-term maintenance visits for rate adjustment and refills should take place every 1–6 months. More frequent rate adjustments are common for young patients experiencing growth spurts, patients with progressive diseases or spasticity influenced by environmental changes such as weather, and those having orthopedic surgical procedures. Refill frequency is a factor of dose, pump model, drug stability, reservoir volume, and drug concentration. Lioresal Intrathecal is approved for as long as 6 months in the SynchroMed II system.

During the titration phase, the simple continuous-infusion delivery mode is most commonly employed. However, once a steady dose or definite pattern of tone throughout the day is identified, various infusion modes can be easily programmed. This flexibility is one of the major advantages of ITB therapy. New programming options have replaced complex continuous and periodic bolus with flex-infusion modes, with additional options for altering dosing by day of week. Flexible dosing for workweek and weekend schedules, days with therapy, home health care, or other activities promises to provide even more individualization.

A number of programming options are available to individualize ITB dosing for patients with changing needs (Kolaski, 2005). The use of various dosing patterns is usually based on the practitioner's level of experience and the particular practice population. For instance, patients with spinal cord injury usually achieve goals with a steady daily dose. Patients with MS may require a higher dose at night to prevent spasms and a lower dose during the day to facilitate transfers. Unless periodic-bolus programming is employed, more than 3–4 daily rate changes are rarely useful. Periodic bolus programming is beneficial for those with low catheter-tip placement who need more benefit in the upper extremities and is an option for those with severe hypertonia. Periodic boluses are usually programmed to infuse every 2–4 hours. In some instances, a once-daily bolus provides the relief needed to achieve the full effect of physical therapy or ease spasticity for bathing and dressing. Generally, the bolus is programmed to infuse 1–3 hours before its effect is desired. Technical support for these programming options is available through the manufacturer's dedicated phone line.

A wide range of total daily doses (50 mcg–1,500 mcg per day) is used to meet the variety of patients' needs. The daily dose varies with diagnosis, function, and severity of symptoms. Ambulatory patients require lower doses on average than immobile or bedridden patients. Patients with MS usually require lower doses than those with spinal cord injury or traumatic or anoxic

brain injuries. Patients with CP and stroke tend to have midrange doses.

One last issue is the use of commercially available Lioresal versus pharmacy-compounded solution. Refill kits with Lioresal solution are commercially available in 500-mcg and 2,000-mcg concentrations. Some clinicians contract with private pharmacies to compound up to a 4,000 mcg/ml solution or to mix solutions with other drugs. Many institutional guidelines prohibit the use of compounded drugs. However, if this option is used, discussion with the patient should include potential risks, including variability in drug strength and the effect on the pump manufacturer's warranty. The forum made no formal recommendation on this practice. The FDA offers a report on compounded drugs (FDA, 2003).

Individualizing ITB dosage takes time and requires input from other health-team members, the patient, the family, and caregivers. Because of regular patient contact, the ITB-therapy nurse coordinator has a unique opportunity to develop rapport with patients and families. This allows teaching the importance of patient and family attention to subtle physical changes and the effect of environment and emotions on spasticity to identify patterns of response. Use of dedicated patient notebooks or journals to track such changes is encouraged because it facilitates dose adjustments and specific programming to enhance individual satisfaction and positive effects of therapy.

8. Ongoing Evaluation Should Be Provided by Consistent Providers to Facilitate Best Outcomes.

Consistency of healthcare providers is ideal in nearly every healthcare situation but is especially crucial to care of those with chronic conditions. It allows early identification of changes in a patient's condition and appropriate changes in therapy management. For patients receiving ITB therapy, outcomes and identification of potential complicating factors may be influenced by patterns recognized over time. Determination of subtle changes is dependent on accurate documentation and corroboration among team members. The team must include the primary care provider and community contacts such as school therapists or home health providers. The nurse coordinator is frequently in an ideal position to collect and disseminate relevant data among team members.

The forum participants described ITB therapy as a program, not simply a procedure. Comprehensive ITB centers provide a full-service program not possible in small practices with only a few patients. Treatment in high-volume programs not only discourages patients from doctor shopping after implant or going from one private provider to another for refills but also enhances competency of the team through increased experience. However, this option may not be available to all patients who need the therapy. When patients or healthcare providers relocate, or pediatric patients graduate to adult healthcare providers, steps must be taken to communicate key information, such as catheter length, baseline

Table 3. Ongoing Evaluation: Factors That May Increase or Be Affected by Spasticity in Patients with ITB

System or Category	Factor
Neurological	Disease progression Shunt malfunction Seizures
Musculoskeletal	Positioning Seating system changes Orthotics
Cardiovascular	Edema Deep vein thrombosis Swallowing Bowel function
Genitourinary	Bladder infection, function Sexual function Menses
Integumentary	Skin breakdown
Pharmacologic	Prescription medications (especially antiepileptic drugs, antidepressants, sedatives, interferons) Over-the-counter medications Herbal remedies
Interventional	Physical therapy Yoga Hydrotherapy Hippotherapy Acupressure Massage
Environmental	Weather Stress

function, and goals, to ensure continuity of care.

During clinic visits, the core team that manages pump refills and dose adjustments documents procedure-related facts. Caregivers and community-based providers can also provide data on standardized forms to help fine-tune the baclofen dose. Information from caregivers also contributes to goal attainment and gives clues for needed adjustments in current equipment or addition of assistive devices. For instance, a wheelchair-dependent student may experience a slow, subtle decrease in trunk tone as the ITB dose is titrated. Simple adjustments in the seating system, such as adding lateral supports, may compensate for the new posture. This may be preferred to decreasing the ITB dose, especially if reduced extremity spasticity achieves goals such as ease of care and improved comfort. Such needs are difficult to determine during a clinic visit. They become apparent when the extended team is encouraged to provide discriminating input.

The documented effect of past ITB dose changes, dose-dependent side effects, and bolus infusions are the best guide to future dose changes and contribute to early identification of decreased benefit of ITB. For example, a 10% increase in daytime dose may prevent

an ambulatory MS patient from safely transferring for the first 3 days after the dose adjustment but afterward provide best function. The next time an increase is needed, two smaller increases may be more appropriate to ensure continued independent function. On the other hand, a patient with spinal cord injury may experience relief of spasms within 1 hour of a 10% bolus of the daily dose on a previous occasion, but experience no relief when this dose is repeated; in this case, further investigation of system function is in order. Knowing these details contributes to safety, quality, function, and patient satisfaction.

The nurse coordinator may be the healthcare provider patients receiving ITB therapy visit most regularly. Therefore, ITB therapy nurses address not only direct effects and side effects of ITB but also related issues such as changes in health, emotions, weather, and treatments that influence spasticity. It is important to document not only tone, spasticity, and strength but also changes in prescription or over-the-counter medications or alternative and herbal therapies. Traditional rehabilitative therapies as well as hippotherapy, hydrotherapy, and yoga may influence patient function and should be documented. System changes that warrant evaluation for their effect on spasticity are listed in Table 3. Ongoing assessment by consistent providers identifies these conditions and guides dose adjustments and referral to other team members for treatment as indicated. This holistic approach facilitates ITB therapy effectiveness with the lowest possible dose and contributes to best outcomes and patient satisfaction.

9. Ongoing Evaluation of the Catheter and Pump System Is Necessary.

Care by consistent healthcare providers and knowledge of a patient's ITB therapy not only improves outcomes but also provides the best mechanism to continually monitor system function. Experienced providers maintain an index of suspicion of system malfunction and develop a methodical process to identify and rule out causes of loss of benefit. Each center's resources dictate its specific plan of action. During evaluation for system disruption, the surgeon is an active participant, and radiologists are frequently introduced into the extended team. The role of the nurse coordinator, surgeon, primary care providers, and emergency room department for each setting must be discussed, outlined, and documented. The first line of contact varies by center; patients must know signs of acute withdrawal syndrome and overdose as well as the appropriate person to call. Written guidelines for the patient and various points of patient contact for emergent care are invaluable. Use of written protocols and standing orders ensure retention of institutional knowledge and consistency as team members change.

Catheter and infusion-system failure or overdosing is rare. However, because either can be life threatening, early recognition is crucial to minimize risk. Both severe

overdose and sudden withdrawal can be identified, and treatment is described in a number of sources (Coffey et al., 2002; Gianino, York, & Paice, 1996; Medtronic, 2002, 2005). Although not available at the time of the forum, the SynchroMed II clinical reference guide (Medtronic, 2004) and product monograph (Medtronic, 2005) review current treatment guidelines. In brief, overdosing symptoms are usually related to human error in catheter volume or dosage programming. Review of the latest pump programming or manipulation of the implanted system will identify the cause. For example, failure to aspirate the catheter contents before infusing contrast through the catheter port is dangerous as it results in approximately 0.2 ml of baclofen rapidly infusing into the cerebrospinal fluid and is likely to cause rapid, severe overdosing. Respiratory depression can result. On the other hand, sudden onset of severe withdrawal symptoms of spasms, spasticity, irritability, and pruritus is likely to be caused by either a missed refill date or pump system failure. After an empty pump reservoir has been ruled out, this situation requires immediate attention to identify the specific system malfunction and appropriate surgical repair.

Identification of the reason for gradual loss of therapeutic effect is more challenging. Causes include disease progression, a new or recurring condition, or a change in prescribed or over-the-counter treatment. Patient evaluation identifies disease progression or a comorbidity causing irritation such as urinary tract infection or skin breakdown. Appropriate treatment of concurrent illness as well as a temporary rate increase should resolve the spasticity. Addition or discontinuation of other agents may contribute to either high-dose effect or increased spasticity through drug interactions. One example is the interferon injection used by some patients with MS, which may increase spasticity. Identifying this pattern and treating it with oral baclofen is usually sufficient.

Evaluation of ITB dosing should be considered if no change in health status or treatments is identified. Review of response to past rate adjustments, specific patterns and activity surrounding the return of symptoms, and history of goal achievement may indicate that a revision in total daily dose or dosing pattern is needed. Rate increases are not unusual for patients with progressive diseases or during growth spurts in adolescents. The possibility of drug tolerance exists (Nielson, Hansen, Sunde, & Christensen, 2002).

An action for loss of benefit may include administration of an oral dose of baclofen at home as part of phone-triage care. This may be particularly useful for patients who live far from the center, in conjunction with the local primary care provider's evaluation of changes in general health status. Once the patient arrives at the center, the effect of a programmed bolus dose on signs and symptoms provides useful information and can be done while awaiting initial X rays. If these actions provide relief, further dose titration may be all that is needed. Intensity

and time to positive effect of the bolus can provide useful information to determine a treatment plan. A short-lived effect or no effect at all from the bolus dose is indicative of catheter or pump system failure. A bolus infusion may relieve symptoms even if there is a microtear, positional leak, or mass at the catheter tip. Catheter tip masses and arachnoiditis are known to occur with intrathecal pain management; they have not been reported with intrathecal baclofen but can be considered.

System-related loss of benefit is usually catheter related and requires careful radiological evaluation of the pump, catheter, and spinal canal. Methods to evaluate the implanted system are reviewed in a number of sources (Dickerman & Schneider, 2002; Hicks, Kaiff, Barzenor, Rahmat, & Kelly, 1989; Le Breton et al., 2001; Medtronic, 2002, 2004; O'Connell et al., 2004; Rosensen, Ali, Fordham, & Penn, 1990) and are beyond the scope of this article. Specific steps or order of tests depends on resources and varies among centers. If an X ray is not readily available, catheter port aspiration may be the first tool to rule out catheter dislodgement or fracture. A small leak or microtear is difficult to determine and verification may not be possible, even with nuclear medicine studies. Signs of inconsistent drug delivery or fluctuation in tone may be caused by subdural catheter tip placement, arachnoiditis, or a positional catheter leak. Positive response to a screening trial with no notable benefit from continuous infusion after weeks of therapy also warrants investigation of system function. If no specific radiological results are found, clinical judgment may lead to replacement of a potentially failed catheter based on symptoms alone.

One other potential complication contributing to loss of benefit may be a cerebrospinal fluid leak within the first weeks of surgery. This can be differentiated from a seroma by a history of headache (especially on arising) fluctuant collection of fluid at the pump or back incision, and lack of ITB therapy benefit. Fluid aspirated from the pump pocket will contain beta-2 transferrin, unique to cerebrospinal fluid, and confirm a leak rather than a seroma. Seromas are rare and tend to appear when a pump is replaced. The prevailing theory is that the amount of scar tissue and the extent of pocket revision are factors in the development of a seroma. For those with extensive scar tissue or significant pocket revision, seromas may be prevented by use of an abdominal binder after pump replacement and decreased activity level dependent on the patient's condition.

During routine refill and dose adjustment visits, ongoing evaluation of ITB therapy and the implanted system includes documentation of refill volume, actual reservoir volume compared to expected volume, rate changes, and dose effect. Prevention of serious adverse events is dependent on education of the patient, family, and team members. Such education can lead to early recognition of complications and initiation of appropriate skilled treatment.

10. Program Success Requires Appropriate Practice Management Resources.

In addition to a coordinated and collaborative clinical team, practice resources contribute to an efficient and profitable ITB therapy management program that provides quality care. These include leadership, adequate facilities, and support staff.

Designated team leaders are champions who maintain positive reputations with administrators and the clinician referral base. They represent the team and acquire required resources. Ideally, team members such as surgeons, therapists, and radiologists are geographically and administratively close to increase efficiency of the clinicians and convenience for patients and to allow for best reimbursement, which adds to program success.

Long-term management of ITB therapy usually occurs in a physician's office or outpatient clinic. An appropriate facility includes space for patient office visits, access to procedures, and equipment to troubleshoot potential complications. Patients requiring ITB therapy have various functional levels. They arrive at the clinic for pump refills and programming adjustments either ambulating or with assistive devices such as seating systems. A handicapped-accessible clinic setting with large hallways and doorways is mandatory. Exam rooms should accommodate not only the clinical team and patient but also the 2-3 caregivers who may accompany the patient.

Support staff enhance the efficiency of the clinical team. A reimbursement contact assists in appropriate billing, diligently tracks best procedural and visit codes, and explores reimbursement strategies. A mechanism to purchase specific supplies such as catheter access kits and refill kits should be identified.

Although patients should be encouraged to be accountable for scheduling refill appointments, support staff can oversee refill schedules to avoid low dosages or withdrawal. Information regarding the risks of refill delays must be communicated not only to the patient but also to those responsible for scheduling the patient's return visits. Scheduling refill visits several days before the anticipated low-volume-reservoir alarm date should be considered, especially if weather or distance may be a problem. When rate adjustments occur between routine refills, the appropriateness of prescheduled refill appointments should be verified; the dosage change will alter refill timing. Many centers develop a patient database to ease scheduling. Patients requiring frequent visits appreciate extended clinic hours, especially patients who attend school or work a regular workday. These accommodations diminish burden and encourage compliance.

Support staff or clinicians responsible for refill scheduling can enhance time management by allowing approximately 30 minutes for routine refills and allowing morning work-in time to evaluate patients with potential complications.

Summary

ITB therapy can be of tremendous benefit for patients with severe spasticity that is unresponsive to more conservative treatment options. However, it is not simply a procedure but a comprehensive program provided by a multidisciplinary team of healthcare practitioners. Nurses, particularly advanced practice nurses, are ideal to coordinate long-term management of patients receiving this therapy. Patient satisfaction and overall outcomes are enhanced when each stage of the therapy is managed with an emphasis on clear communication of the goals of treatment and a strong focus on patient and family education. The treating team must include rehabilitation therapy disciplines to maximize the patient's response to ITB therapy. Ongoing management should include individualized attention to dosing options and comprehensive evaluation by a consistent team of providers. Adequate mechanisms must be in place to provide for appraisal and troubleshooting of the pump and catheter system as needed, addressing of any pump-related emergency care, and problem solving as the patient's condition or situation changes.

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