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Life Care Planning for the Client with Severe Spasticity: Intrathecal Baclofen Therapy

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Abstract. *This article reviews the implications of life care planning for clients with severe spasticity. Intervention options are discussed, focusing on an algorithm for use of an intrathecal Baclofen (ITB) pump for individuals who have not responded to other forms of treatment. Client criteria for ITB therapy as well as the screening trial, surgical implantation, post-operative care, and chronic ITB therapy is reviewed. A table outlining areas for consideration in the life care plan is included as well as photographs of an implantable pump device.*

Introduction

Life care planning for an individual who has sustained a brain injury (BI), spinal cord injury (SCI), stroke (CVA), multiple sclerosis (MS), cerebral palsy (CP), or congenital neurologic disease is a complex process (Barker & Saulino, 2004). As part of the evaluation of a client's present and future medical needs, the life care planner should review all relevant medical records including laboratory, radiologic and electrodiagnostic studies, conduct a comprehensive client assessment, communicate with appropriate health care providers, and conduct necessary research (Barker, 1999; Barker, 2002). In addition to the many significant symptoms experienced by clients with neurologic dysfunction, spasticity commonly is identified as a major disabling condition that contributes to other problems affecting the client's quality of life (QOL).

Definition of Spasticity

According to the authors, spasticity is a velocity-dependent increase in resistance to passive range of motion and is a hallmark of diseases that affect the upper motor neuron (UMN). It can also include involuntary muscle contractions of antagonist muscle groups. The client may complain of tight, stiff muscles that impair movement or function which may or may not be associated with pain. Examples include a clenched fist, bent elbow, an arm held tightly against the chest, extended knee, or adducted thigh. Spasticity can result in either flexor or extensor synergies with both types occasionally being seen in some patients. In addition to difficulty with movements, individuals with severe spasticity may also be at risk for sleep disturbances, reduced strength, impaired dexterity, balance dysfunction, skin breakdown, or contracture development. Additional energy requirements may also be associated with severe spasticity.

Spasticity affects not only the client, but also family members or caregivers who provide the client's routine treatment. Severe spasticity can make client care more difficult and increase the caregiver's responsibilities, potentially including problems lifting, positioning, feeding, bathing, grooming, dressing, and performing exercises for the individual. Severe spasticity may make it very difficult to position the client comfortably, perform range of motion (ROM) exercises, or transfer the client. Limitations in wheelchair tolerance and mobility can also be observed as a result of spasticity.

Client Evaluation

It is important for the medical team to determine if the client is at high risk for spasticity or at risk for developing severe spasticity during their expected lifetime. Follow-up for a client assessed to be at risk for spasticity may require a consultation with the client's physiatrist, neurologist, or primary health care provider. Spasticity in itself is not a completely deleterious clinical entity. In the authors' experience, potential positive effects of spasticity include assistance with mobility, maintenance of posture, improvement of vascular circulation, preservation of muscle mass and bone mineral density, reduction of thromboembolic risk and assistance in reflexive bowel and bladder function. Health care providers for clients with spasticity must evaluate and consider both the positive and negative aspects of the client's spasticity before embarking on a treatment plan. Additionally, the clinicians may not desire complete reduction of spasticity, but rather a titration of the hypertonia to maximize the risk/benefit ratio. Thus, any anti-spasticity regimen must be customized to the client's individual needs (Meythaler, 2003; Hinderer & Dixon, 2001).

Spasticity Interventions

Potential interventions for spasticity management include non-pharmacological and pharmacologic treatments. The two mainstays of non-pharmacologic spasticity management are the removal of noxious stimuli that can drive hypertonicity, and the application of physical modalities to the client's affected areas. Pharmacologic treatments include both oral and non-oral administration of medication. Common oral medications include:

- Baclofen
- Diazepam
- Clonidine
- Dantrolene sodium
- Gabapentin
- Tizanidine

The two major choices for non-oral interventions regarding spasticity management include chemodenervation techniques and alternative routes of administration of the above medications (Gracies, Elovic, McGuire, & Simpson, 1997; Gracies, Nance, Elovic, McGuire, & Simpson, 1997). Chemodenervation is the technique of injecting a chemical into a neural structure for the purpose of decreasing the excitability within that target. In the authors' view, this is an excellent technique for areas of focal hypertonicity. It is pertinent to note that multiple interventions for spasticity management can be utilized simultaneously (see Figure 1). A review of client side effects of oral medications may reveal problems with sedation,

confusion, hypotension, nausea, dizziness or hepatotoxicity. Undesirable side effects, documented client complaints of dissatisfaction with the use of oral medications, or escalating dosages with no apparent improvement in function are indicators that the client is a potential candidate for intrathecal baclofen (ITB) therapy.

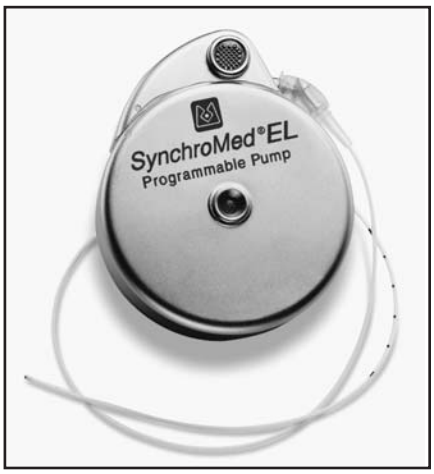

Figure 3. SynchroMed EL Programmable Pump

ITB Therapy

ITB therapy utilizes a programmable pump (see Figure 3) to deliver a liquid form of the antispasticity medication Baclofen from the pump reservoir to the cerebrospinal fluid (CSF, the liquid that surrounds the brain and spinal cord). Baclofen administered in this fashion is more effective than oral Baclofen because a higher concentration of medication is achieved within the nervous system via the intrathecal delivery system. ITB therapy was approved by the Food and Drug Administration (FDA) for the management of severe spasticity of spinal origin in 1992 and severe spasticity of cerebral origin in 1996 (Abel & Smith, 1994).

Client Criteria for ITB Therapy

According to the authors and based on their experience, the criteria for ITB therapy includes:

1. Clients
    a. whose spasticity is poorly controlled with conservative measures, or
    b. who are poorly tolerant of previous therapies, or
    c. who require the precise control afforded by the intrathecal delivery system.

2. Clients must be considered clinically stable with most individuals being at least one year into the disease process that is causing the spasticity.

3. The client must demonstrate adequate understanding of the risks and benefits of this intervention.

4. The client must have a support system in place that will ensure compliance with required follow-up for pump refills and dosing adjustments throughout their lifetime.

Discussion regarding the algorithm for ITB therapy (see Figure 2) is below.

Algorithm for ITB therapy

After appropriate consultation to determine whether the client meets the criteria for ITB therapy, the life care planner may receive a recommendation to include ITB therapy in the life care plan (LCP). All components of ITB therapy must be included in the LCP. It is important

to recognize that ITB therapy is typically considered a chronic therapy with the client receiving medication for the duration of the his/her lifetime.

Screening Trial

Once the client has been deemed an appropriate candidate for ITB therapy, they will proceed to a screening trial. In this procedure, a test dose of Baclofen is administered to the CSF via a lumbar puncture (LP). A pre-procedure assessment of the client's strength, tone, range of motion, posture, and mobility is executed by a trained physical therapist. These same parameters will be evaluated during the course of the trial.

The trial can be performed as a prolonged outpatient procedure or as a short inpatient stay either in an acute care or rehabilitation hospital. The LP may utilize an indwelling catheter and physicians have the option of using fluoroscopic localization for the LP. These options will account for the variability of the costs associated with the screening procedure.

According to the authors, a bolus injection of intrathecal Baclofen will demonstrate a significant decrease in spasticity in up to 85% of selected patients. See Table 1, Ashworth Scale, for one assessment tool that can be used during the screening to determine its effectiveness (Bohannon & Smith, 1987). If successful, the decrement in hypertonicity occurs a few hours after the test dose is given. During the screening, the client is closely monitored for any adverse reactions from either the LP or ITB itself. These untold effects include hypotonia, somnolence, nausea, vomiting, headache, dizziness, meningitis, seizures, herniation, further neurologic damage, and death. Intravenous access should be maintained during the trial so that fluids and/or medication antidotes can be delivered in the event of adverse event. Clients who demonstrate a positive response to the test dose can then be referred for surgical implantation, assuming all other criteria described earlier in this article is met (Stempein & Tsai, 2002).

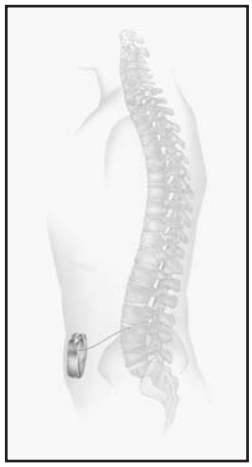

Figure 4. Side View of Spine Showing Catheter Connected to Pump

Surgical Implantation of ITB Delivery System

If the client meets the criteria, including a successful screening trial, they can proceed to pump implantation. While considered a relatively minor neurosurgical procedure, the individual will need to complete all pre-procedure testing, understanding that the risks of the procedure are similar to the risks of the screening trial. Pump and catheter implantation is typically performed under general anesthesia though local or regional anesthesia is possible. The pump is generally implanted subcutaneously in the right or left lower quadrant and the catheter is intrathecally inserted between vertebrae, usually in the third or fourth lumbar region (L3 or L4). The catheter is then tunneled subcutaneously and connected to the pump (see Figure 4). The tip is typically placed at the thoracic tenth or eleventh level (T10-T11) although more rostral placement may be attempted to address upper extremity hypertonicity (Burns & Meythaler, 2001) (see Figure 5).

Liquid preservative-free Baclofen is then placed in the pump and released intrathecally. Because the initial dosage of intrathecal Baclofen is usually insufficient to achieve the desired degree of hypertonicity control, the client should continue all oral antispasticity treatments

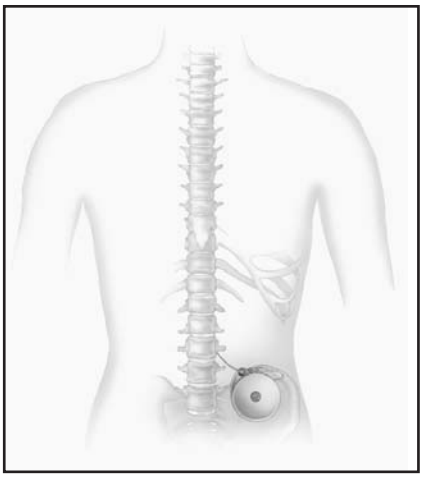

Figure 5. Front View

until a weaning schedule is prescribed by the physician.

The length of stay in an acute care hospital for pump implantation is usually between 2 and 4 days. Discharge instruction should include incision care, medication regimens, activity restrictions, emergency contact information (i.e., Medic Alert® bracelet with pump information), and follow-up physician appointments. Some physicians may limit the client's mobility for a few weeks following surgery to allow for proper healing and potentially reduce the risk of catheter damage.

The pump begins delivery of intrathecal Baclofen during the implantation procedure with the initial daily dosage similar to the screening dose (e.g., 50 micrograms of intrathecal Baclofen per day). As stated above, the client should continue with pre-operative oral anti-spasticity medications until otherwise advised by the physician. Clients should be given an identification card with the pump model number, reservoir size, drug name, and follow-up physician contact.

Immediate Post-operative Care

Immediately following implantation, the client's intrathecal Baclofen dosing will be titrated to achieve the desired therapeutic effect (See Figure 6). Dosing adjustments can occur as frequently as every 24 hours during this initial phase. Various dosing regimens include simple continuous (the same amount of Baclofen is delivered around the clock), complex continuous (variable amounts of Baclofen are delivered around the clock), and periodic bolus (regularly scheduled boluses of Baclofen). During the titration phase of intrathecal Baclofen therapy, the client may be weaned from their oral anti-spasticity medications. Weaning and adjustments of the intrathecal Baclofen dosing should be done by experienced clinicians since over- or under-dosing of this medication can have serious side effects (Delhaas & Brouwers, 1991; Elovic & Kirshblum, 2003; Green & Nelson, 1999). This phase of therapy usually lasts six to nine months following the implantation surgery.

Figure 6. N'vision Electronic Pump Programmer, Model 8840 (front view)

If intrathecal Baclofen is anticipated to affect the client's functional status, the authors suggest that a rehabilitation program post-implantation may be appropriate. The setting, scope, and complexity of the program will vary depending upon the client's individual needs. Potential disciplines include physiatry/neurorehabilitationist, physical therapy, occupational therapy, and rehabilitation nursing. The authors have found that issues potentially requiring attention include:

- incisional care
- medical management (spinal headache, pain assessment, medication adjustment, dosing changes)
- mobility
- assistive device use
- wheelchair modification
- self care ability
- bowel/bladder function
- caregiver training.

Chronic ITB Therapy

Following the titration phase of intrathecal Baclofen therapy, the client enters the chronic maintenance phase of therapy. Aspects of this segment of treatment include the following:

- Scheduled refilling of the pump reservoir with medication
- Troubleshooting any pump malfunction
- Replacing the pump for battery replenishment

Figure 7. N'vision Electronic Pump Programmer, Model 8840 (back view)

Reservoir refills are a sterile procedure that occur every few weeks to few months for the duration of intrathecal Baclofen treatment (see Figure 7). Although refills are routinely done in the physician's office, in some instances, qualified advanced practice nurses or nurse practitioners who have been specially trained and certified in ITB may be able to refill the pump in the client's home under sterile conditions. However, the authors caution that this service is not available in the majority of cases and must be carefully screened before considering. Potential malfunctions during this phase of therapy include over or under-dosing of ITB, catheter dysfunction (kinks, holes, occlusions, etc.), or mechanical difficulties with the pump. Potential signs of Baclofen overdose include:

- Drowsiness
- Muscle weakness
- Dizziness
- Respiratory depression
- Hypotension
- Altered level of consciousness

Treatment of Baclofen overdose may require prompt physician evaluation. Potential interventions include cardiopulmonary support, hydration, antidote administration (physostigmine or flunzenil) or pump reprogramming. Conversely, Baclofen withdrawal may

occur quickly after interruption of drug delivery and may be mild or severe depending on the client and the dose. Drug withdrawal can be life threatening and requires immediate intervention. Treatment includes supplementation with oral Baclofen or IV valium, pump refill/reprogramming, catheter revision, or battery replacement (Levin & Sperling, 1995). Battery replenishment/replacement, typically a same day surgical procedure, is undertaken approximately every 5 years (average) and can vary depending on the client's usage and amount of medication dose.

The life care planner should include all the associated costs for ITB therapy in the life care plan (Barker & Saulino, 2004). For easy reference, see Table 2, which outlines the following areas:

- Physician evaluation
- Screening trial, including test dose
- Hospital and/or rehabilitation admission
- Surgical consultation and implantation of the infusion system
- Titration phase
- Maintenance and pump refill return visits, approximately every 2-3 months to life expectancy (can be up to 10-12 times per year)
- Troubleshooting of pump malfunction
- Battery replacements approximately every 5 years (average)
- Medic Alert® application and identification
- Case management services

Case Report

A 22 year-old male client was evaluated by the physiatrist for spasticity following an automobile crash that resulted in severe BI. After his acute hospitalization and acute rehabilitation, he was discharged home with community home health services: physical, occupational, speech/language therapies, and home health aides for personal care and supervision. He was non-ambulatory and used a manual wheelchair due to spastic left hemiparesis. The client was very frustrated that he was unable to bear weight on his left leg and ambulate due to the spasticity. He had some relief with oral medication but was intolerant due to medication side effects. Botulinum toxin (Botox) injections gave only a few months of relief. The life care planner reviewed the medical records and discussed with the physician the client's potential relief from spasticity using ITB therapy. Ultimately, he was evaluated and considered a good candidate for ITB therapy. The decision was made to include ITB therapy and associated costs in the LCP as a probable need for the client based on the physician's recommendation and the client's desire.

Projecting Costs

The algorithmic nature of intrathecal Baclofen facilitates its insertion into a life care plan and the reader is again referred to Table 2 which describes the components of ITB therapy. Potential costs that the life care planner should research and include related to ITB are physician charges, facility costs, medication costs, diagnostic testing, and rehabilitation needs. The authors wish to note that cost information related to each of the items for the life care plan intentionally are not included in Table 2 due to a wide variance in cost which is dependent on

geographic location, physician and facility charges, and other variables that necessitate specific research into each client's location and with each provider to determine accurate costs.

Conclusion/Summary

When working with individuals with catastrophic neurologic impairments, spasticity management can be a critical component to the life care plan. Consequences of neurological disease that result in spasticity should be identified in the life care plan and treatments for spasticity, including ITB therapy, should be considered and investigated for inclusion in the LCP. One of the purposes of the LCP is to list probable medical interventions that will benefit the client and help to avoid potential complications as well as allow the individual to achieve the highest level of function for the best possible quality of life (Staal, Arends, & Ho, 2003).

Table 2. Components of Intrathecal Baclofen Therapy

Component		Frequency	Duration	Associated costs*
Initial Physician Evaluation		Typically once, though multiple visits may be appropriate in complex clients	Up to one hour	Specific physician charges
Screening Trial		Generally up to three times	Short inpatient (<2 days) or extended outpatient procedure	Specific physician charges; facility charges; and medication costs
Surgical Consultation		Typically once	Up to one hour	Specific physician charges
Implantation		One time only	Short acute care stay (typically <4 days)	Specific pre-operative testing; physician charges; facility charges; and medication costs
Titration Phase		One time only	Six to nine months after implantation	Specific rehabilitation cost; physician charges; and medication costs
Chronic Maintenance Phase	Reservoir refill	Typically 4-10 times per year	Up to one hour each	Specific physician charges and medication costs
	Pump malfunction	Variable	Variable	Specific diagnostic studies; physician charges; facility charges; medication costs
	Battery Replenishment/ Replacement	Every 5 years (average)	Short, same day procedure	Specific pre-operative testing; physician charges; facility charges; and medication costs

Used with permission from Barker & Saulino, 2004.

* Cost information related to each of these items for the life care plan are not included due to a wide variance which is dependent on geographic location, physician and facility charges, and other variables. It is necessary that the life care planner conduct specific research into each client's location and with each provider to determine accurate costs.

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Table 1. The Ashworth Scale

0. No increase in tone
1. Slight increase in muscle tone, giving a "catch" when affected part(s) moved in flexion or extension
2. More marked increase in tone but affected part(s) moves and is easily flexed
3. Considerable increase in tone; difficult with passive movement
4. Affected part(s) is rigid in flexion or extension

Figure 1. Multiple interventions for spasticty management can be utilized simultaneously as shoen. (Used with permission from Barker, E. & Saulino, M., 2004).

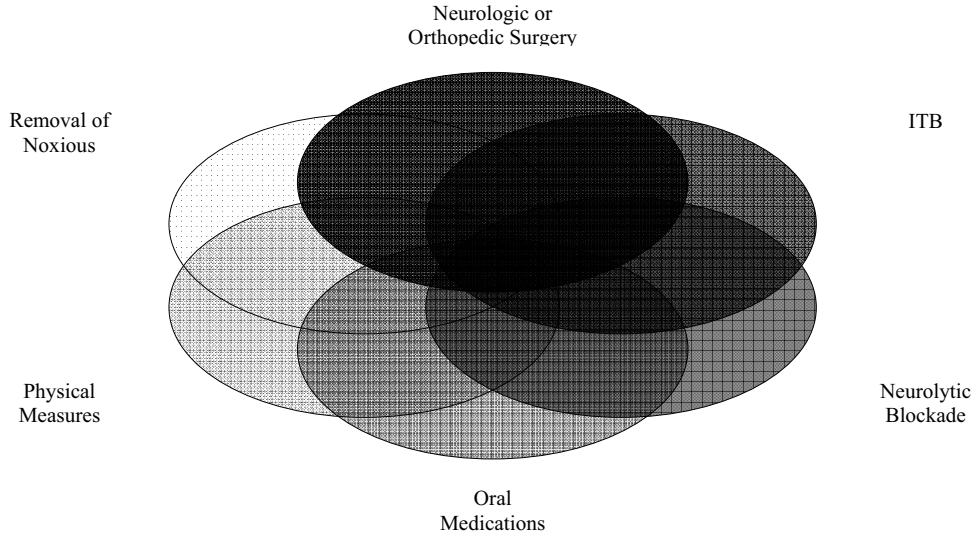

Figure 2. Algorithm for ITB therapy (Used with permission from Barker, E. & Saulino, M., 2004).

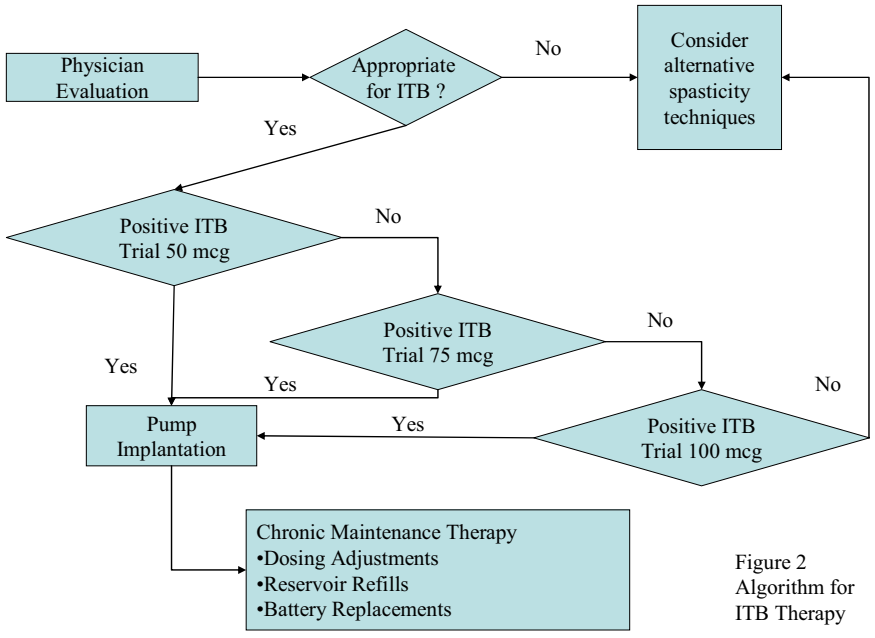

Figure 2
Algorithm for
ITB Therapy

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Clinician's Perspective

Spasticity is a common condition in the population of clients that rehabilitation professionals serve. When managing spasticity, a stepwise approach from the least invasive to the most invasive interventions is recommended. This approach was discussed in the *Journal of Life Care Planning*, 2(4), pp. 191-194. Fortunately, non-invasive "low tech" approaches such as reducing the stimulus for spasticity, range of motion (ROM) exercises, physical modalities, whirlpool, weight bearing, stretching, orthotics, positioning, and oral medications manage spasticity well for many, if not most, clients. Spasticity that is resistant to these tools may require motor point blocks, and/or Botox injections if the ill-effects of spasticity are focal.

Intrathecal Baclofen (ITB), like all medical interventions, has indications and contraindications, benefits and ill-effects. The risk/benefit ratio of ITB must be carefully considered when looking at spasticity management. Accidental overdose with ITB has resulted in respiratory arrest, coma, and seizures. Sudden withdrawal from ITB can cause seizures, hallucinations, or a life threatening condition called malignant hyperthermia. ITB pumps or lines can become infected and a hematoma can develop at the site of implantation. ITB should only be considered in clients with severe spasticity, who are compliant with medical care, and are assured adequate follow-up for long-term management and care of the ITB program.

Conclusion: ITB is a very important resource from which some clients with severe spasticity will benefit. The life care plan must insure high quality follow-up care for clients who use ITB.

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