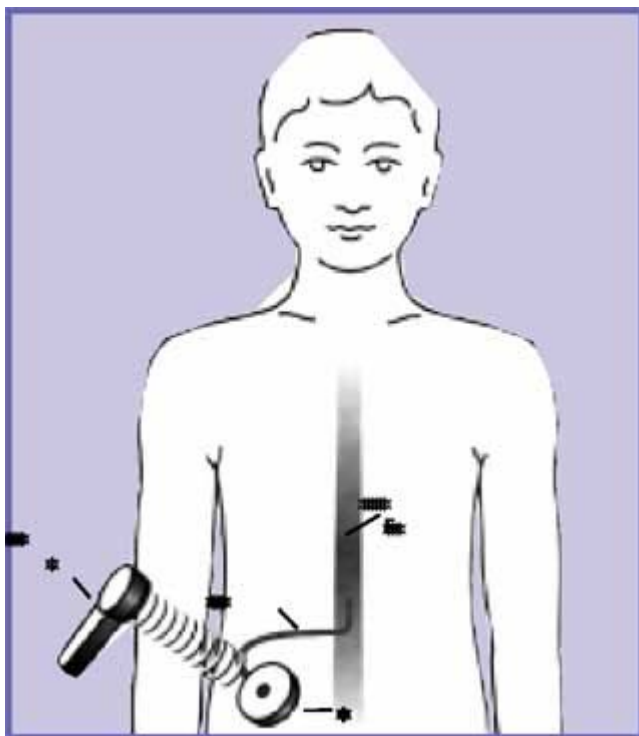


## Intrathecal baclofen significantly reduces spasticity and improves functioning

by Linda Krach, M.D.

Oral baclofen has long been used as a medication to help reduce spasticity. Its effectiveness, however, is limited. In individuals with severe spasticity, high doses of baclofen are often needed before any reduction in spasticity can be observed. This can result in unwanted side effects including sedation, slower muscle response and/or dizziness.

Over the last six to seven years, however, the intrathecal baclofen pump has drastically changed baclofen use in children and adolescents with cerebral origin spasticity. Unlike its oral counterpart, intrathecal baclofen is administered directly into the intrathecal space surrounding the spinal cord via a hockey-puck-sized pump that is surgically implanted under the skin of the abdomen. It takes only a minute dose of the medication to achieve a significant reduction in spasticity. And side effects are greatly reduced.



**Fig. 1** The ITB pump is programmed externally with a hand-held wand (transducer) to deliver precise amounts of a special formulation of the drug baclofen directly into the spinal fluid.

*(Used with permission from Medtronic.)*

Following clinical trials in the early 1990s (including at Gillette Children's), the FDA approved the use of the intrathecal baclofen pump in 1996 for children with spasticity of cerebral origin. The pump, manufactured by Medtronic, Inc., is computer programmed to dispense a prescribed amount of baclofen through continuous infusion. There are two sizes of pump — an adult size that holds 18 mL and a pediatric size that holds 10 mL. In general, the pumps need to be refilled and reprogrammed in the clinic setting every one to three months, depending on the patient's dosage (see figure 1).

The literature from around the country indicates that ITB clearly reduces spasticity and improves functional ability — often significantly — for patients with cerebral palsy. This has also been the experience at Gillette Children’s (where more pumps were implanted in 1998 than at any other center nationwide).

## Study results positive

In a multi-center study that included Gillette, 44 patients who were eligible for an ITB pump were selected at random. Of these, two classifications of subjects showed significant improvement in their functional ability at six and/or 12 months after the pump implantation (see table 1). The Gross Motor Function Measure was used to assess each patient’s functional abilities both pre- and post-implantation. At the conclusion of the study, the patients or caregivers were asked to complete a questionnaire to elicit information about qualitative changes they may have noted. Respondents frequently reported increased ease of positioning, improved sleep and decreased pain.

## Patient selection for ITB

Potential candidates for ITB include a range of patients, from those who ambulate to those who are totally dependent for daily living activities. The goals of ITB therapy include improving the patient’s functional ability and independence, preventing contractures, reducing spasticity-related pain, and/or making caretaking easier for a care provider.

**Table 1** Functional changes following ITB treatment for cerebral palsy patients\*

	Functional improvement 6 months after onset of treatment	Functional improvement 12 months after onset of treatment
Patients who ambulated with assistive devices	improvements in lying/rolling, sitting and crawling trended toward statistical significance	improvement in rolling/lying and sitting became statistically significant and crawling trended toward significance
Patients who were totally dependent in daily activities	improvements in lying/rolling trended toward statistical significance	improvements in lying/rolling became statistically significant

\*Individuals with spastic cerebral palsy, ages 4 and older, who demonstrated severe spasticity of the lower extremities were considered for this study.

**Table 2** Ashworth Scale (1964)

1	No increase in tone
2	Slight increase in tone, giving a “catch” when affected part(s) are moved in flexion or extension
3	More marked increase in tone but affected part(s) are easily flexed
4	Considerable increase in tone; passive movement is difficult
5	Affected part(s) rigid in flexion or extension

ITB may be effective in individuals who have:

- significant spasticity (Ashworth score of 3 in lower extremities — see table 2)
- significant generalized dystonia
- mixed tone
- rigidity
- a movement disorder
- mixed tone and previous selective dorsal rhizotomy surgery
- VP or LP shunts

A child must be big enough in size to physically support the implanted pump (usually age 4 or older) with a weight/ height ratio of the 5th percentile.

ITB therapy is usually contraindicated in patients with athetosis (continuous writhing motions), and chorea (irregular spasmodic movements).

Careful consideration should be taken with children who have weak neck and trunk muscles as these may be further weakened by ITB. In some of these children, however, the benefits of ITB may outweigh the drawbacks. For example, this may be true in a child who is floppy in the neck and trunk but significantly rigid in the extremities. A pump can help prevent contractures and improve ease of care, which may be of more importance than preventing additional weakness. Head and trunk support, and a tilt-in-space wheelchair can help compensate for any increased trunk and neck weakness.

## Pre-implantation trials

Prior to deciding to implant an ITB pump, a bolus dose of the medication is administered directly into the spinal fluid and the patient's muscle tone is monitored over a period of several hours. Onset of action is usually 30 to 60 minutes after administration. Peak effect occurs in about four to six hours. (In patients with significant scoliosis, the test dose may need to be performed under fluoroscopic guidance.) For movement disorders or significant dystonia, a trial infusion may need to be performed (most of these individuals do not respond to a bolus dose of ITB).

If the test dose proves beneficial, and there are no problems with side effects, the individual may be considered for ITB therapy. Once a pump is implanted, the continuous infusion effect becomes apparent after about eight hours, and takes 24 to 48 hours to take full effect. Therefore, any changes in dosage should be made no less than 24 hours apart.

## Complications

ITB is not without its potential complications. In fact, experience shows (both at Gillette and other ITB centers) that the rate of infection following baclofen pump implantation approaches 10 percent. There are several precautions that can be taken to reduce the risk of infection, including antibiotic washes of the operative area the day before and day of surgery, intraoperative antibiotics and a brief course of IV antibiotics following surgery.

If an infection is suspected after the pump is implanted, a culture of the spinal fluid and the fluid around the pump is done. With significant infection, it is often necessary to remove the pump and treat with IV antibiotics. It is generally possible to reimplant a pump about three months after completion of a course of antibiotics.

CSF leaks also occur in a small percentage of ITB patients. The needle used to create the opening in the dura during the surgical procedure is larger than the catheter inserted through the needle, leaving an opening for potential leaks. This situation can be treated with bed-rest, and if necessary, a blood patch.

There can also be problems with the catheter breaking, twisting or disconnecting, or with the pump itself flipping over if the sutures holding the pump in place break. In these cases, surgery is usually necessary to correct the problem.