Best-practice surgical techniques for intrathecal baclofen therapy

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In March 2004, a multidisciplinary conference, “ITB Therapy Best Practice Forum,” was held in Minneapolis, Minnesota. The goal of the conference was to develop recommendations for techniques to implant intrathecal baclofen (ITB) pump and catheter systems more effectively and with fewer complications.

The authors present the techniques for optimal pump and catheter implantation, including subfascial pump placement; insertion of the Tuohy needle in an oblique, paramedian trajectory; and positioning of the catheter tip at levels commensurate with the therapeutic indication: approximately T10–12 for spastic diplegia, C5–T2 for spastic tetraparesis, and C1–4 for generalized secondary dystonia. Techniques to minimize the incidence of cerebrospinal fluid leakage are described, including the identification of preoperative occult hydrocephalus and the use of a suture ligature around the Tuohy needle at its exit site from the fascia. Techniques to minimize surgery-related infection are also detailed; most involve the use of iodine solutions multiple times intraoperatively. Techniques to insert intrathecal catheters during spinal fusion are addressed, particularly the technique of inserting the catheter cephalad to the fusion site.

Panel members advocate the aforementioned techniques to improve the efficacy of and decrease the morbidity associated with ITB therapy.

KEY WORDS • spasticity • surgical technique • cerebral palsy • baclofen, intrathecal • pediatric neurosurgery

In the past decade, ITB has been increasingly used to treat spasticity and dystonia. Intrathecal baclofen pump and catheter systems are usually implanted by neurosurgeons but are occasionally inserted by orthopedists, anesthesiologists, and general surgeons. A wide variety of implantation techniques are used and a wide variety of outcomes result. Large differences in complication rates have been observed at the various centers in which the pumps are used. High complication rates dissuade some parents and patients from undergoing ITB pump implantation. Although pump insertion is considered by some to be similar to shunt placement (that is, merely the installation of hardware), there are different nuances to each operation that influence outcome.

The ITB Therapy Best Practice Forum was held in Minneapolis, Minnesota, in 2004 to discuss patient selection and screening, surgical technique, and ongoing medical management. Fourteen faculty members representing five medical specialties participated in the conference (Appendix). Implantation techniques were discussed, and recommendations were developed to help surgeons implant pumps effectively while minimizing surgical complications. The recommendations came from a consensus of the panel with the sole objective of improving patient care. The techniques are described in this paper. They apply particularly to pediatric patients, but several techniques are applicable for use in adults as well.

Best-Practice Techniques for ITB Therapy

Implanters/Implantation Centers

Although pumps are currently inserted by various medical specialists, the panel considers neurosurgeons the most appropriate specialists to insert pumps, for reasons that will be discussed. The panel believes that, ideally, the neurosurgeon implanting the pump should be involved in patient selection, rather than acting as a technician only, and that the neurosurgeon should also be involved in the evaluation and management of complications, particularly the management of CSF leaks and pump-related infections.

Because the panel found data correlating experience with outcome, we urge that implanting neurosurgeons undertake 10 or more such procedures annually to maintain facility with the operation. We recommend that there be three to four teaching centers/centers of excellence where neurosurgeons can obtain hands-on training in best-practice techniques. These centers would also offer courses covering best practices in patient selection, pump implantation, troubleshooting, programming, and complication management.
**Pump and Catheter Implantation Techniques**

The implantation operations are performed after induction of general anesthesia; the child is placed in the lateral decubitus position. Because most surgeons are right handed and because in many children needing pumps a left-sided upper-quadrant gastrostomy has been made, most pumps are inserted in the right side of the abdomen. The epidermis is opened using a slightly oblique 3-in incision approximately one finger’s–breadth below the right costal margin, with the lateral extent of the incision in line with the anterior superior iliac spine. The subcutaneous tissue and fascia are opened using needle-tip cautery. The edges of the skin may be lined with iodine-soaked cottonoid patties to minimize contamination from skin microorganisms.7 The fascia is opened between the external oblique muscle laterally and the rectus abdominus muscle medially, and the fascia is then dissected from the two muscles to create a subfascial pocket, using the cautery tip to separate the fascia from the underlying muscle (Fig. 1).2,15 Approximately 10% of the dissection is superior to the fascial opening, whereas the remaining 90% is caudal. The caudal dissection is aided by an army–navy retractor. The pocket must be generous enough to contain the pump without creating undue tension on the overlying tissues. Subfascial placement is particularly advisable in thin, small children, but the technique has some advantages even in obese patients, in whom it may reduce the risk of the pump becoming flipped if the retaining sutures break.

Because most patients who need ITB therapy also require frequent drug adjustments, programmable pumps are usually most appropriate. Recently available pumps are smaller yet contain larger volumes than previous-generation pumps. The panel has no specific recommendation regarding the optimal method for securing the pump to the tissues—that is, the use of pumps with suture eyelets or the use of a Dacron pouch.

Posteriorly, a vertical incision is made at L2–3 or L3–4, levels associated with less movement than the L4–5 level and, therefore, less wear-and-tear on the catheter. Subcutaneous tissues may be lined with iodine-soaked cottonoids, and a Tuohy needle can be inserted through the fascia approximately 5 mm lateral to the midline. The needle is directed obliquely to penetrate the thecal sac one to two levels cephalad to the insertion site (Fig. 2).11 Advancing the needle under fluoroscopic guidance facilitates penetration of the dura mater on the first pass. Multiple dural punctures allow CSF to flow into the subdural or epidural space, with the result that the thecal catheter might be erroneously assumed to be within the arachnoid because CSF can be aspirated through it. The catheter is advanced cephalad to a level that varies according to therapeutic indication: for ITB treatment for spastic diplegia, the catheter tip is positioned at T10–12; for spastic tetraplegia, at C5–T2; and for generalized dystonia, at C1–4. The catheter length must be sufficient to reach the desired level.

After the catheter is inserted and its position confirmed fluoroscopically, a purse-string suture is inserted around the Tuohy needle, and the needle and guidewire are then withdrawn. Spontaneous CSF flow must be observed and must continue while the purse-string suture is tightened around the site where the catheter exits the fascia. To minimize the risk of the catheter migrating outward, it should then be anchored to the fascia or muscle with a silastic butterfly flap and a nonabsorbable suture. After the catheter is tunneled anteriorly through a shunt passer, one should be able to aspirate CSF from the anterior end of the catheter before it is connected to the pump. When the catheter is snapped onto the sideport of the pump and that connection is secured with a suture, the suture should not be tied too tightly; we have seen several cases in which the suture cut through the tubing and caused an intermittent leak that was not visible on radiographic or dye-based studies. The pump should be oriented within the subfascial pocket so that the sideport is not beneath the incision.

Because no ideal catheter is available at present, the panel has no recommendation as to which intrathecal catheter to use. Some neurosurgeons prefer a long, single-piece catheter because it avoids the potential for a posterior disconnection; others prefer a two-piece system (a larger-diameter subcutaneous catheter from the pump to the back) because they assume that the larger catheter will be less prone to kinking or fracture than smaller catheters. If two-piece catheters are connected posteriorly with the metal straight connector and the connection is overlaid with the silastic strain-reducing sleeve (Fig. 3), the tip of the straight connector can

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**Fig. 1.** Intraoperative photographs.  
Left: The subfascial pocket is dissected between fascia and muscle of the external oblique and rectus abdominus muscles.  
Right: The pump is inserted into the subfascial pocket.
still perforate the thin intrathecal tubing. A newer straight connector (Fig. 3) may decrease the chance of such perforation, but there are insufficient data to confirm this.

Techniques to Minimize Infection

Skin bacterial colonization can be decreased before the operation by having the patient wash with an antibacterial soap the night before and the morning of surgery, or by taking Hibiclens showers for 3 days prior to surgery. Prophylactic antibiotic agents have been shown to decrease the risk of shunt-related infections and are recommended for operations involving the implantation of pumps, although data are not available to confirm their effectiveness. Intravenous cephazolin (25 mg/kg), oxacillin (50 mg/kg, max 2 gm), or vancomycin (10 mg/kg) should be administered before the skin incision is made. Skin at the operative site can be prepared in numerous ways. Neurosurgeons on our panel favor washing the site with a scrub brush and then applying two coats of Duraprep (3M Health Care, St. Paul, MN), a mixture of isopropyl alcohol (74%) and iodine (0.7%) that is bactericidal and continues to have an antibacterial effect postoperatively. The double-gloving practice is advisable and has been shown to be associated with a lower infection rate in studies involving shunt surgery and in orthopedic studies. We favor the application of an iodine-impregnated drape (Ioban; 3M Health Care), although there are no published data to document its effectiveness in neurosurgery.

After the skin incision, the skin edges can be lined with iodine-soaked cottonoid patties and stapled to the skin edges. The catheter access port must not be positioned beneath the incision. Positioning of the access port at the 5 o’clock position (on the right side) allows considerably easier insertion of sutures into the pump’s eyelets. After the pump and catheter have been placed, the wound can be irrigated with a pulse irrigator and iodine solution (100 ppm). The wounds are closed using subcutaneous absorbable sutures (for example, Vicryl; Ethicon Inc., Piscataway, NJ) and subcuticular sutures; then Dermabond (Ethicon) or Indermil (Syncture, Norwalk, CT) is applied along the incision to minimize the egress of subcutaneous fluid to the exterior and the ingress of bacteria from the exterior.

Techniques to Minimize CSF Leakage

Surgical techniques that minimize CSF leakage are essential to successful ITB therapy. Cerebrospinal fluid leaks usually develop within 2 weeks of pump/catheter insertion and may present as subcutaneous swelling posteriorly beneath the lumbar incision, anteriorly over and around the pump, or both. These leaks impair wound healing, and if CSF transgresses through the incision to the exterior, an infection usually develops.

If a screening trial is conducted to evaluate the response to ITB before the pump is implanted, the CSF opening pressure should be measured when the lumbar puncture is performed. If the opening pressure is higher than normal, computerized tomography or magnetic resonance images of the brain should be reviewed to see if ventriculomegaly is present, even if the child has no symptoms of hydrocephalus. If ventriculomegaly is present and the opening pressure is high, insertion of a ventriculoperitoneal shunt may be considered before implanting the pump to reduce the risk of a postoperative CSF leak.

The catheter insertion techniques described earlier in this article also reduce the incidence of CSF leakage because the catheter obliquely traverses several centimeters of para vertebral musculature before a single needle puncture is made to enter the subarachnoid space, and because the purse-string circumferential suture is inserted around the Tuohy needle before it is withdrawn.

Management of the Fused Spine

If patients present for pump/catheter implantation and have a history of spinal fusion, there are three techniques with which to insert the intrathecal catheter. In the most simple, but infrequent case, in which fusion is radiographically demonstrated not to obliterate the L5–S1 interspace, a Tuohy needle can be inserted under fluoroscopic guidance at L5–S1 and the catheter can be advanced cephalad through the needle, as if no fusion were present. A longer intrathecal
catheter may be required in this scenario to advance the catheter tip to the desired level.

The L5–S1 interspace is usually obliterated by the fusion mass, however, and the most commonly used technique of catheter insertion is to drill a tunnel through the fusion mass and between the fusion rods. If that technique is to be used, it is helpful first to obtain a computerized tomography scan of the region in which the catheter is to be inserted to plan the trajectory for the tunnel and catheter. Once the dura mater is visible at the bottom of the tunnel, it can be punctured using a No. 11 blade tip or the Tuohy needle, and the catheter can be advanced cephalad to the desired level. Because the dural exposure is so limited when using this technique, no purse-string suture can be applied around the catheter where it enters the dura. Cerebrospinal fluid leakage is relatively common unless the site where the catheter exits the dura is reinforced (using muscle, gelfoam, a blood patch, or a fibrin glue, for example). The optimal reinforcement method is unknown.

The third surgical option is insertion of the catheter above the fusion mass. In this technique, a 4 to 5–cm vertical incision is made in the midline at the superior extent of the fusion, and tissues are dissected away from the spinous process and laminae of two lower cervical vertebrae. A limited laminectomy is performed to expose approximately 12 × 8 mm of dura. A purse-string suture is inserted into the dura, which is then opened using a No. 11 blade tip, and the catheter is advanced to the desired level. After the guide wire is removed and CSF backflow is confirmed, the purse-string suture is tightened around the catheter. The subcutaneous catheter can be passed from the pump up to the cervical opening through a shunt passer. This technique has been used in 23 children who had previously undergone spinal fusions, and no CSF leakage has been observed (Fig. 5) (A.L.A., unpublished data). A similar technique has been recently reported.17

Pump and Catheter Replacement Issues

It is better to replace a pump under elective conditions than to wait until the battery dies and replace it in an emergency procedure. Pump batteries last 4 to 7 years, depending on the pump model. Although some pump batteries last more than 7 years, current pump programming technology cannot determine how much battery life remains, and re-
placements should be scheduled according to the usual battery life expectancy.

If a pump is located subcutaneously and protrudes prominently from the abdomen, it is appropriate to relocate the new pump in a subfascial pocket. If the pump was encased in a Dacron pouch, and that pouch produced thick fibrosis around the pump, the fibrous tissue should probably be removed if the new pump is being relocated below the fascia because the fibrous tissue is poorly vascularized, potentially increasing the risk of infection.

If a new intrathecal catheter is to be inserted, the management of the old catheter needs to be considered. If the old catheter is simply withdrawn, CSF usually migrates from the well-established catheter tract and generates a chronic CSF leak. Techniques to prevent such a leak include injecting a blood patch along the catheter tract, placing a purse-string suture around the catheter at the point where it exits from the lumbar spine, and (perhaps optimally) tying off the catheter but leaving it in place. In our experience, retained intrathecal catheters have not increased the risk of complications.

Management of Surgery-Induced Complications

Despite the use of meticulous techniques, complications such as catheter breakage, CSF leakage, and infection occur occasionally. Management of these complications requires vigilance and willingness to respond rapidly and decisively to minimize long-term deleterious effects.

The management of CSF leaks varies depending on the location and on whether the fluid drains through the incision. Cerebrospinal fluid leaking externally through the incision represents a surgical emergency, with its management depending on the timing of the leak. If the leak occurs within hours or a few days of pump implantation, the wound can be oversewn and an occlusive tissue adhesive (for example, Dermabond) applied to the wound edges. If the leak occurs thereafter, the possibility of a wound infection should be considered.

Subcutaneous CSF accumulations can be treated with bed rest, aspiration (testing to see if the fluid is CSF by measuring β₂-transferrin level), and pressure dressings. If the leak persists, radiography should be conducted to determine whether the catheter is disconnected. If no disconnection is identified, a dye study should be performed, with the dye injected via the sideport of the pump to localize the source of the leak.

Pump and catheter–related infections, in contrast to superficial wound infections, are diagnosed by finding positive cultures in the fluid around the pump. Cultures of both peripump fluid and intrathecal CSF should be examined; the latter can be obtained by aspiration of the pump side port or by lumbar puncture. If fluid samples around the pump and from the CSF are both infected, the most effective treatment usually involves explantation of the entire system (pump, catheter, and connectors) and a 2-week course of intravenous antibiotic therapy. If only the peripump fluid is infected, a 3-day course of intravenous antibiotic therapy should be initiated, the fluid sample retested for a positive culture. The hardware should be removed only if the second culture is also positive. Antibiotic agents have been administered via the pump as an adjunct, but the likelihood of curing staphylococcal infections that involve both intrathecal CSF and the fluid around the pump is small. In general, intrapump antibiotic agents contribute little to the effectiveness of intravenous antibiotic therapy. Intrapump antibiotic medication is not indicated for infections of the fluid surrounding the pump if the CSF is sterile.

If the pump and catheter are removed, baclofen withdrawal must be anticipated; this should be treated prophylactically by providing large doses of oral baclofen (for example, 20 mg every 4–6 hours). If oral baclofen alone is insufficient, oral clonazepam is helpful (1–3 mg every 8
hours). If the dose of ITB is high before pump removal (for example, > 900 μg/day), oral medications may be insufficient. In such cases, a lumbar drain may be inserted when the ITB catheter is removed. The drain can be connected to an external microinfusion pump to deliver tapering ITB doses until the oral medications are sufficiently therapeutic.

Many children needing ITB therapy are severely malnourished and this causes wound healing to be poor. Pumps in these children may erode through the skin, either along the incision or along the rim of the pump. We have not been able to avoid pump-related infections with surgical revision of the eroded wounds; thus, we recommend removal of the entire system if the pump is visible through the skin.

Lastly, neurosurgeons need to be aware of relatively well-defined catheter-related complication syndromes. Patients with catheters positioned partially in the subdural space and partially in the intrarachnoid space may present with intermittent overdosage because baclofen that collects in the subdural space overflows into the intrarachnoid space. Catheters with a microleak, sometimes apparent on dye-based studies but never on plain radiographic studies, may be associated with postural symptoms; ITB produces better effects when the patient is in certain positions than others.9 We have treated several patients who presented with intermittent ITB effectiveness and normal findings on radiographic dye-based studies, and in whom catheter cracks were found intraoperatively that were visible only when the catheters were in a certain position.

Discussion

The recommendations discussed in this paper were developed by a multidisciplinary panel that included three neurosurgeons, two of whom (A.L.A. and M.T.) had each implanted more than 750 pumps. All recommendations were vetted by the entire 14-member panel; the sole objective of the recommendations was to improve patient care.

The panel advocated that neurosurgeons implant ITB systems in pediatric cases involving spasticity and movement disorders. That recommendation is contentious and some would say self-serving. The rationale for this opinion is based on the following factors: 1) neurosurgeons are trained in the diagnosis of movement disorders to be treated with ITB (such as spasticity and dystonia) and are thus knowledgeable about the desired catheter position; 2) they are trained in diagnosing and treating hydrocephalus, which is often present and occult in children needing ITB therapy and is a source of potential morbidity if untreated; 3) they are experienced in inserting intrathecal catheters; and 4) they are experienced in diagnosing and treating CSF leaks.

The panel acknowledged that at times neurosurgeons are neither available nor interested in treating children with ITB, and in such cases, it is more important for the child to receive ITB therapy than for the operation to be conducted by a neurosurgeon.

Pump implantation techniques have changed considerably since 1988, primarily those involving subfascial placements. One of us (A.L.A.) first heard of the subfascial technique from an orthopedist in England in 1994. Before adapting this technique, incisions under tension often healed poorly and pumps often eroded through thin tissues. The subfascial placement diminishes tension on the incision, decreases external pump bulging, and may be associated with a lower complication rate.2,15 One potential risk of subfascial pump placement is the inadvertent and unrecognized opening of the peritoneum: we have heard of pumps dropping into the peritoneal cavity. Subfascial placement also decreases the chance of pump flipping, which is a particular concern in obese patients. As long as the pump implant depth remains 2.5 cm or less, subfascial placement does not increase the difficulty of refilling the pump with medication, as the fascia is only 0.5 mm thick—too thin to hamper feeling the refill portal. Indeed, refilling even be easier because subfascial pumps are less mobile.

The technique of paramedian, oblique insertions of the Tuohy needle and intrathecal catheter has been advocated by Follett, et al.,11 and has two advantages compared with the traditional perpendicular needle trajectory to the thecal sac. First, because the oblique trajectory is more parallel to the thecal sac, it facilitates the insertion of the intrathecal catheter. Second, it may help reduce CSF leaks by having the catheter traverse several centimeters of paravertebral muscle, which impedes the egress of CSF along the catheter.

The incidence of CSF leakage in children undergoing ITB therapy is considerably higher than that in adults. In two pediatric series, the leakage rate was 6 to 15%, a substantially higher incidence than the 1% rate reported in adults.8 Some CSF leaks in children with cerebral palsy are associated with occult hydrocephalus. In a recent study the authors evaluated lumbar opening pressures in 24 children with cerebral palsy and ventriculomegaly but in whom there were no signs or symptoms of hydrocephalus.5 Ventriculomegaly was mild or moderate in 23 of 24 patients. Opening pressures were higher than normal in 23 of the 24 children (median pressure 27.8 cm). When lumbar opening pressures are considerably higher than normal (for example, ≥ 25 cm), it is probably reasonable to undertake either intracranial pressure monitoring for 24 hours to confirm the pressure, or to treat the hydrocephalus by placing a ventriculoperitoneal shunt before the pump and catheter are inserted, partly to decrease the risk of post–pump placement CSF leaks, and partly because of the potential risks of chronically increased intracranial pressure.

In most cases, intrathecal catheters inserted to treat spastic tetraparesis or generalized dystonia should be positioned more superiorly than those typically described. When Penn and colleagues18 developed ITB therapy to treat lower-extremity spasticity in patients with spinal cord injury and multiple sclerosis, they placed the catheter tip at the lumbar enlargement, T10–12. Since then, some surgeons have assumed that the T10–12 location is optimal for catheter tip placement in any patient requiring ITB therapy. Kroin and associates16 demonstrated that if baclofen is infused in the lumbar region, the resulting concentration is fourfold higher than that at the cervicomedullary junction. The site of action of intrathecal baclofen for spasticity is in the superficial layers of the spinal cord. Thus, if a patient suffers upper- and lower-extremity spasticity, placement of the catheter more cephalad along the spine will result in a greater baclofen concentration at the cervical enlargement, providing better relief of upper-extremity spasticity.13 It has been postulated that in the treatment of dystonia the site of baclofen action is over the cerebral convexities.8 Because of this, intrathecal catheters are now routinely positioned at the C1–4 levels, and their efficacy has greatly improved compared
Techniques for implanting ITB pumps

with those previously implanted in the midthoracic region, and without any increased incidence of drowsiness or other side effects.5

Several of the techniques recommended to decrease the risk of infection—such as using Duraprep, an Ioban-imregnated drape, lining skin edges with iodine-soaked cottonoids, and pulse irrigation with iodine solution—involves the use of iodine. The effectiveness of iodine solutions in killing staphylococci was demonstrated by Choi, et al.,7 who noted that Betadine, a commonly used preparation solution, contains less than 1 ppm free iodine. They evaluated the in vitro killing of staphylococcal species by iodine solutions (5–1000 ppm) and found a 100% bactericidal effect with concentrations of iodine greater than or equal to 20 ppm.

Conclusions

During the past 15 years, techniques of baclofen pump and catheter insertion have evolved, as have the techniques for decreasing the risk of CSF leaks and infection. The techniques recommended herein were refined from experience with hundreds of patients treated with ITB and are offered in hopes of improving the efficacy of ITB and decreasing the risk of complication.

Disclosure

The ITB Best Practice Forum was funded by Medtronic, Inc. Dr. Albright is a consultant, grant recipient, and stockholder in Medtronic, Inc. Dr. Turner is a consultant for Medtronic, Inc.

Appendix

Participants in the ITB Therapy Best Practice Forum

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