CERVICAL CATHETER TIP PLACEMENT FOR INTRATHECAL BACLOFEN ADMINISTRATION

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OBJECTIVE: Intrathecal baclofen can reduce congenital and posttraumatic spasticity. Traditionally, the catheter tip for baclofen delivery is placed in a low thoracic position, which can result in a lumbar-to-cisternal cerebrospinal fluid baclofen concentration gradient. We investigated whether more rostral catheter placement was technically feasible, safe, and able to control upper extremity spasticity.

METHODS: The records of 48 patients with a baclofen pump were reviewed retrospectively to evaluate the safety and efficacy of cervically placed intrathecal catheters for baclofen administration. Twenty-three patients had a catheter located in a cervical position and 25 had a catheter in a thoracic position (control group). Complications, including baclofen overdose, mechanical failures, and infections, were noted. Pre- and postoperative Ashworth scores were determined by a physical therapist using a standardized protocol.

RESULTS: The mean duration of the follow-up period was 10 months. The groups were not significantly different in patient age, baclofen dose, or duration of follow-up, but differed somewhat in the causes of spasticity. For patients with a cervical catheter tip position, upper extremity Ashworth scores decreased significantly from 4.0 $\pm$ 0.8 (standard deviation) preoperatively to 3.0 $\pm$ 0.9 postoperatively ($P = 0.003$). In both groups, lower extremity spasticity was significantly reduced. Postoperatively, one patient with a cervical catheter developed aspiration pneumonia, possibly because of sedation. Other complications included hardware infections, mechanical malfunctions, and pseudomeningoceles.

CONCLUSION: In this series, placement of intrathecal baclofen catheters in the cervical region resulted in equal control of spasticity in the upper and lower extremities and did not increase complications related to the catheter position.

KEY WORDS: Catheter, Intrathecal baclofen, Spasticity

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Spasticity can result from a wide spectrum of conditions, including trauma, cerebral palsy, cerebrovascular accidents, and multiple sclerosis. Patients with spasticity have impaired walking and dexterity, and spasticity in profoundly disabled patients makes daily care by providers more difficult. Intrathecal baclofen is an established treatment for spasticity, and several studies have demonstrated that intrathecal baclofen improves spasticity for both spinal (6, 8, 17, 22, 23) and supraspinal (1, 2, 7, 12, 26) causes.

Traditionally, baclofen is administered via an implantable pump with the intrathecal catheter tip situated in a low thoracic position. In patients with spasticity involving both the upper and the lower extremities, however, a low catheter tip placement may not be ideal. Hydrophilic compounds, such as baclofen, do not cross the blood-brain barrier and, instead, form a concentration gradient along the cerebrospinal fluid spaces. Intrathecal baclofen administered in the lumbar spine has a lumbar-to-cisternal concentration ratio of 4.1:1 (15). Radionuclide testing demonstrates that this decline in drug level is gradual (16). Thus, the cervical spine is exposed to approximately 25% of the baclofen dose that the lumbar spine receives. If the goal of treatment is to reduce the spasticity in both the arms and the legs, then placing the intrathecal catheter in a more rostral position may lead to more equal baclofen dosing of the cervical and lumbar regions and a more even reduction in spasticity of the upper and lower limbs. In our experience, simply increasing the baclofen dose with a more caudal catheter placement is not ideal. First, a high baclofen dose with a thoracic catheter sometimes reduces the rigidity in the trunk too much, resulting in difficulty retaining upright

posture. Secondly, increasing the dose requires more frequent refills of the baclofen pump.

We performed a retrospective review of patients who have undergone placement of a programmable pump for baclofen administration with the intrathecal catheter tip positioned in the cervical spine. Patients with the catheter tip in a thoracic position served as a control group. The goal of this review was to evaluate the feasibility, safety, and efficacy of treating both upper and lower extremity spasticity with intrathecal baclofen administration at the level of the cervical spine.

METHODS

Subjects

With the approval of the University of Utah institutional review board, a retrospective chart review was performed on all patients who underwent placement of a programmable pump for intrathecal baclofen administration between June 2002 and March 2004. Two groups were defined by the position of the catheter tip. Patients in the study group had the catheter placed in a cervical position (C5–C7), whereas those in the control group had the catheter placed in a thoracic position (T2–T12). The patients who had the catheter placed in a cervical position had both upper and lower extremity spasticity, whereas the patients with a thoracic catheter had predominantly lower extremity spasticity. The purpose of the control group was to evaluate mechanical and surgical complications and to demonstrate that the Ashworth scores were consistent in our institution.

Pump Implantation

Surgeries were performed at the University of Utah Hospital by the senior author (JDM) after an efficacious trial of intrathecal baclofen was documented for each patient by a physical therapist. Each procedure was performed under general anesthesia, with the patient in a lateral decubitus position. In each case, a pocket to accommodate the programmable pump (Synchromed programmable pump; Medtronic Inc., Minneapolis, MN) was created against the anterior rectus fascia. The intrathecal catheter was placed with a Touhy needle using a paramedian approach. The catheter tip position was confirmed in all cases with intraoperative fluoroscopy (*Fig. 1*). In all cases, the intended position for the catheter was attained. The catheter was then passed subcutaneously to the pump and trimmed to an appropriate length. A single continuous catheter was used in all cases rather than a two-piece device. Patients received one dose of intravenous cefazolin preoperatively and three doses postoperatively for infection prophylaxis.

Outcome Measures and Statistical Analysis

Charts were reviewed to identify complications of implanting the programmable pump and intrathecal catheter, such as cerebrospinal fluid leak, infection, hematoma, or mechanical failure (e.g., catheter kinking, disconnections, or pump failure). Special attention was paid to complications suggestive of baclofen overdose, including weakness, somnolence, respiratory depression, or seizures (9, 11, 27).

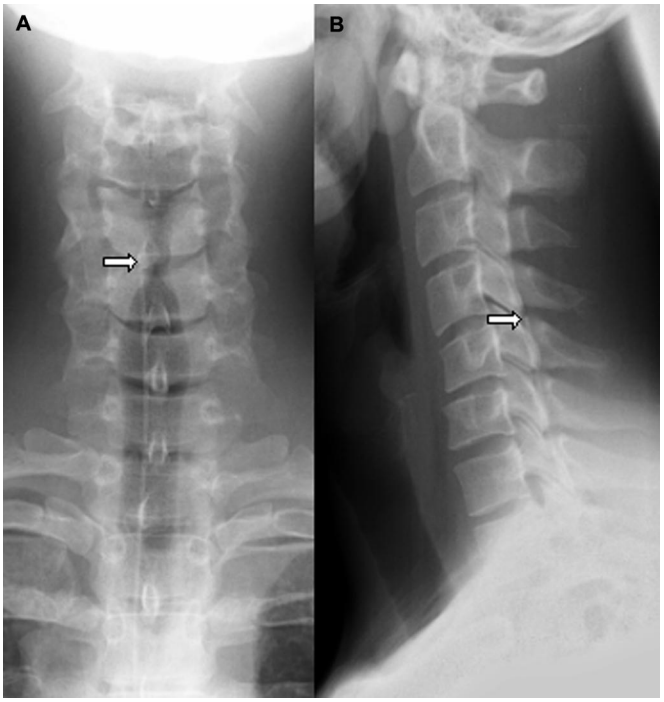

FIGURE 1. *Plain x-rays demonstrating an intrathecal catheter tip (*arrows*) for baclofen administration in a mid-cervical position.*

Spasticity of the upper and lower extremities was evaluated by a physical therapist pre- and postoperatively using the Ashworth scale (*Table 1*). The physical therapist was not blinded, but the evaluation was performed independent of the authors. If more than one Ashworth score was documented preoperatively, the last assessment before surgery was used. Likewise, the last Ashworth score documented postoperatively, along with the associated intrathecal baclofen dose, was recorded. All statistical analyses were calculated using the Mann-Whitney *U* test. Because of significant differences in the causes of spasticity between the two groups and the low preoperative upper extremity tone in the thoracic group, we

TABLE 1. Ashworth scale

Score	Examination
1	No increase in tone (normal)
2	Slight increase in tone when the joint is flexed or extended
3	Higher tone, requiring effort by the examiner for passive motion
4	Considerable tone, making passive motion difficult
5	Affected joint is rigid in flexion or extension

did not attempt to compare the Ashworth scores between groups.

RESULTS

Patient Demographics

We identified 48 patients (34 men and 14 women) who underwent de novo placement of a programmable baclofen pump. The catheter tip was in a cervical position in 23 patients, whereas 25 patients had a thoracic catheter position. The average patient age at the time of surgery for implantation of the pump and intrathecal catheter was 36 years (range, 14–69 yr). Only one patient was not an adult. The average time between injury resulting in spasticity and surgery was 89 months. An average follow-up duration of 10 months after surgery was found, at which time the baclofen dose (mean ± standard deviation) was 293 ± 272 μg/day. The cervical and thoracic catheter groups were not significantly different with regards to patient age, duration of spasticity, length of follow-up, or baclofen dose (*Table 2*). The most common indications for surgery were traumatic brain injury, cerebral palsy, spinal cord injury, multiple sclerosis, and stroke (*Table 3*). Both groups had several patients with traumatic brain injury, but the cervical catheter group had a large proportion of cerebral palsy and stroke patients, whereas the thoracic group was dominated by spinal cord injuries and multiple sclerosis.

TABLE 3. Causes of spasticity in 48 patients who underwent implantation of a baclofen pump

Etiology of spasticity	Cervical catheter	Thoracic catheter	Total
Traumatic brain injury	6	5	11
Cerebral palsy	5	2	7
Spinal cord injury	1	6	7
Multiple sclerosis	1	5	6
Stroke	6	0	6
Hereditary spastic paraparesis	0	3	3
Anoxic brain injury	1	1	2
Drug overdose	1	0	1
Neurofibromatosis type 1	1	0	1
Stiffman's syndrome	0	1	1
Subarachnoid hemorrhage	0	1	1
Tumor resection	1	0	1
Unknown etiology	0	1	1

TABLE 4. Complications of catheter tip placement in 48 patients with programmable pump for baclofen administration

Complication	Cervical catheter	Thoracic catheter	Total
Broken or retracted catheter	2	2	4
Malfunction of unidentified cause	3	1	4
Pump flipped over	1	1	2
Infection of pump	2	0	2
Pseudomeningocele	1	1	2
Aspiration pneumonia	1	0	1

Complications

The most common identified complication was a broken or retracted catheter, occurring in two patients in each group (*Table 4*). Four patients, three of whom were in the cervical group, also experienced a malfunction of the baclofen pump and catheter system of unidentified origin after surgical exploration. Other complications unrelated to catheter tip position included two pump infections in the cervical group, one pump flipping over in each group, and one pseudomeningocele in each group.

One patient in the cervical group developed aspiration pneumonia after placement of the programmable pump and intrathecal catheter. The patient was somnolent when she aspirated, and her depressed mental status was thought to be secondary to her baclofen therapy. At the time, the patient was still on oral baclofen as she was transitioning to her intrathecal baclofen treatment. The somnolence resolved after the oral baclofen dose was discontinued without a change in the intrathecal baclofen dose. Intravenous antibiotic therapy effectively treated the pneumonia.

TABLE 2. Demographics of the cervical and thoracic catheter groups

	Cervical catheter placement	Thoracic catheter placement	Total
No. of patients	23	25	48
No. of male patients	15	19	34
Mean age (range)	36 (21–69)	37 (14–62)	36 (14–69)
Mean duration of spasticity (mo)	84	94	89
Mean length of follow-up (mo)	10	10	10
Mean baclofen dose	306	279	293

Ashworth Scores

Ashworth scores (mean ± standard deviation) in the upper extremities declined significantly from 4.0 ± 0.8 to 3.0 ± 0.9 ($P = 0.003$) after intrathecal baclofen therapy with the catheter tip in a cervical position, but the decrease from 2.6 ± 1.5 to 2.1 ± 1.2 in the thoracic group was not significant (*Fig. 2*). In the lower extremities, Ashworth scores decreased significantly from 4.0 ± 0.9 to 3.1 ± 1.0 ($P = 0.01$) after therapy in the cer-

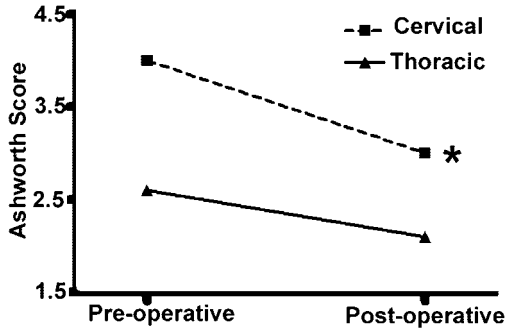

FIGURE 2. *Line graph showing that Ashworth scores for upper extremities improved significantly after surgical placement of a programmable pump for baclofen administration with an intrathecal catheter tip in the cervical position.* Asterisk, *P = 0.003. Patients with thoracic catheter placement had lower mean preoperative Ashworth scores, which likely limited their magnitude of improvement.*

vical group (*Fig. 3*). The thoracic group also had a significant reduction in Ashworth scores of the lower extremities from 3.5 ± 0.7 to 2.3 ± 1.2 ($P = 0.0006$).

DISCUSSION

Baclofen (4-amino-3 [p-chlorophenyl] butyric acid) is an agonist of γ-aminobutyric acid-B receptors and exerts its effects by reducing the release of presynaptic neurotransmitters in excitatory spinal pathways (10). A decrease in spasticity achieved through targeted delivery of the baclofen within the central nervous system may be accompanied by specific complications that correspond to the placement. γ-aminobutyric acid-B receptors in the dorsal horn substantia gelatinosa mediate the antispastic effects of baclofen, but these receptors also occur in several other central nervous system structures (15, 24). Therefore, baclofen overdose can result in various symptoms, including weakness, sedation, coma, respiratory depression, and seizures (9, 11, 27). Intrathecal baclofen overdose is generally caused by errors involved with pump programming or refilling (4, 17, 23, 25), with overdose incidences usually ranging from 0 to 5% (6, 9, 17, 21).

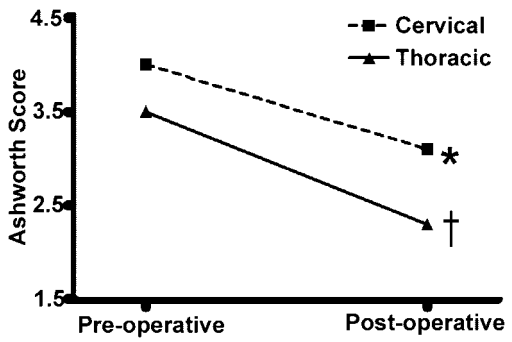

FIGURE 3. *Line graph showing that Ashworth scores improved significantly in lower extremities with the catheter tip in a cervical (*asterisk, *P = 0.01) or thoracic location (†, P = 0.0006).*

Placing a catheter tip in the upper spine for the administration of intrathecal baclofen could potentially lead to an increased incidence of central side effects of baclofen by increasing the supraspinal concentration of baclofen in the cerebrospinal fluid. In this series, one out of 23 (4%) patients developed a baclofen overdose, which was manifested by somnolence and aspiration pneumonia. This isolated case of baclofen overdose was likely caused by the simultaneous oral and intrathecal baclofen doses, especially considering the somnolence resolved when the oral baclofen was discontinued. Nevertheless, the incidence of intrathecal baclofen overdose with the catheter tip in a cervical position was comparable with the incidence of overdose in other studies when the catheter tip was in a more caudal position (9). Chappuis et al. (5) also evaluated the safety of rostral catheter tip placement (C1–T6) for intrathecal baclofen treatment and found that their rate of adverse effects was similar to or lower than previously published values.

Placing the catheter tip in a more rostral position did not lead to additional technical difficulties. Once the catheter was placed within the lumbar subarachnoid space with the aid of a Touhy needle, the catheter was advanced to the desired location without resistance in every case. The overall rate of mechanical failure in this study was 21% (n = 10), which is less than the rate of technical incidents recently reported (37%) in a series of 40 patients. A cervical catheter position could potentially lead to cervical spinal cord injury, but this was not observed in any patients in this series. A longer catheter could lead to a greater likelihood of kinking, breaking, or obstruction. In this series, the cervical and thoracic groups had an equal number of catheter-related malfunctions, although the follow-up period was only 1 year. The cervical catheter group did have two pump infections, whereas the control group had none, although it is difficult to attribute a pump infection to the cervical catheter placement alone.

The importance of catheter positioning for effective control of spasticity with intrathecal baclofen has been addressed by several authors (7, 13, 14). Meythaler et al. (20) demonstrated that a mid-thoracic (approximately T6) catheter tip position for intrathecal baclofen led to improved control of upper extremity spasticity compared with more caudal (T10) placement. Burns and Meythaler (3) and Meythaler et al. (18, 19) have also established that mid-thoracic (approximately T6) catheter tip placement provides a significant reduction in upper extremity spasticity caused by a variety of conditions, including traumatic brain injury, spinal injury, and stroke. In these studies, upper extremity spasticity was reduced between 0.6 and 1.4 (Ashworth scale), and lower extremity spasticity was decreased between 1.4 and 1.9. Thus, although a reduction of upper extremity spasticity was achieved with a thoracic catheter placement in these studies, the effect was not as pronounced as that achieved in the lower extremities. Grabb et al. (13) demonstrated that a mid-thoracic catheter placement treated upper and lower extremity spasticity equally, but their study included only children with cerebral palsy, and, there-

fore, the results are difficult to generalize to our study population.

With a cervical catheter tip position, we attained a reduction in upper and lower extremity spasticity of 1.0 and 0.9, respectively. Although this reduction in Ashworth scores is less than that reported by Meythaler et al. (18–20), a relatively equivalent response between the upper and lower extremities was achieved with a cervical catheter. It is unclear why Ashworth scores improved less in this study than in previous reports. Ashworth scores are observer-dependent, and differences between observers make comparisons between studies difficult. In this study, the thoracic catheter group had low preoperative upper extremity spasticity and also different causes of spasticity than the cervical group. Direct comparison of Ashworth scores between these groups to evaluate efficacy are, therefore, inappropriate. The similar magnitude of spasticity improvement in the lower extremities between the two groups, however, suggests that our modest improvement in tone among the cervical catheter patients may be a function of the subjective nature of the Ashworth score. Differences in baclofen dosing are not an issue because the average baclofen dose for our patients was 307 μg/day, compared with a range of 268 to 301 μg/day in the long-term (1-year follow-up) studies by Burns and Meythaler (3) and Meythaler et al. (18, 19). Another possible explanation for the less robust response to the intrathecal baclofen in this study is the long period between the injuries resulting in spasticity and the surgery for placement of the pump and intrathecal catheter. Our patients had an average of 89 months between injury and surgery, whereas the other studies by Burns and Meythaler (3) and Meythaler et al. (18–20) required that the time between injury and surgery be just 6 months or greater. In one study in which the data are available, the average injury duration was only 33 months (3). Variations in the origin of spasticity between studies may also lead to different results. For example, the patients with anoxic brain injury required a mean baclofen dose of 88 μg/day, compared with the multiple sclerosis patients who required a mean dose of 382 μg/day.

CONCLUSION

In this limited series, a rostral catheter tip position in the cervical spine was technically feasible and safe. The rate of mechanical complications specifically attributable to the cervical catheter location was comparable to that in patients with a thoracic catheter position. The rate of baclofen overdose with a cervical catheter position was comparable to other studies with a more caudal catheter tip placement. An equivalent reduction in spasticity for the upper and lower extremities was achieved using rostral catheter placement without sacrificing control of lower extremity spasticity. To determine the optimal treatment for combined upper and lower extremity spasticity, a prospective randomized study is needed to compare the efficacy of different intrathecal catheter tip positions in cohorts with similar etiologies of spasticity.

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COMMENTS

This retrospective study concludes on the basis of 23 patients that cervical placement of a catheter for intrathecal baclofen infusion is "technically feasible, safe and able to control upper extremity spasticity." Undoubtedly, most neurosurgeons who deal with intrathecal baclofen therapy hold these views. Unfortunately, the study does not prove these points. No technical problems occurred with placement of the cervical catheters in this group of patients, but they were followed for only 10 months and there are no x-rays to show that the catheter tip remained in the same position. A much longer follow-up with radiographic imaging is required to know the incidence of the catheter movement or dislodgement.

A similar problem is encountered with the claim for safety. More patients need to be followed for a much longer time. As everyone knows from recent problems with pacemakers, serious side effects can only be discovered after thousands of implanted patients have been followed for many years.

The one clear cervical catheter-based complication was aspiration pneumonia. We do not know if in this patient if the initial intrathecal baclofen dose caused the brainstem depression or if it was the oral dose that caused the problem. If one out of 23 patients has a problem, as in this study, does that mean there is a 5% incidence of aspiration pneumonia with cervical placement? Obviously not, hundreds of patients have to be studied to evaluate the true percentage. If this is a real problem, even below 5%, a warning should be issued stating that when using cervical catheter placement, oral medications must be reduced before intrathecal baclofen therapy is started. Errors in intrathecal baclofen dosage, which sometimes occur, might also be more dangerous with cervical catheters. Because no such errors were reported, it is impossible to evaluate the potential danger of bolus doses of baclofen.

Finally, does cervical placement treat upper extremities spasticity better? To answer this question would require a prospective study with similar patients implanted with a cervical or a low thoracic catheter. The authors cannot supply such information. They chose patients with upper extremity spasticity for cervical catheters. As they rightly point out, spasticity could not be compared between this and the "control" group.

Where does that leave us? Cervical placement of a catheter for upper extremity spasticity is reasonable. Extra care should be taken to watch these patients when starting treatment, and oral medications should be reduced, especially the first night after surgery. Most important, long-term complications of drug pumps need to be gathered and the type and number of complications should be available to physicians in a timely manner. The experience with implanted defibrillators is sobering. The proposals for cardiac implants could be a model for neurological implants. Devices do not stop needing improvement once released by the Food and Drug Administration. Only by constantly collecting information after release can safety problems be assessed and proper improvements be made.

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As experience with intrathecal baclofen therapy for spasticity and dystonia has increased, catheter tips have been positioned at progressively higher levels, primarily in an attempt to obtain better upper-extremity effects than are seen with lower catheters. In 2001, we reported that intrathecal baclofen therapy catheters positioned at T4 and higher were associated with significantly less dystonia than those positioned at T6 or below (1). Since then, we have used catheters positioned at C1–C4 to treat generalized dystonia in many children with no increase in adverse side effects. There has been some concern that higher catheters would be associated with more sedation or respiratory depression than are seen with lower catheters, but that has not been the case. When children with spastic quadriparesis are treated with cervical catheters, the resultant decrease in tone is sometimes considerably greater in the upper extremities than in the lower, and the catheter tip may need to be lowered a few levels to improve the lower extremity effects.

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McCall and MacDonald have reported on a retrospective study of 23 patients receiving continuous infusion of intrathecal baclofen with the intrathecal catheter placed at the cervical level compared with a group of patients in whom the catheter was placed at the thoracic level. Based on the preoperative Ashworth scores, it would seem that these patients with cervical level placement had spasticity that was of similar severity in the upper limbs compared with the lower limbs. The intrathecal baclofen infusion with the catheter in the lower cervical area achieved similar reductions in spasticity as measured by the Ashworth scores in the upper limbs and lower limbs. Assuming that the goal of the surgery was to reduce the spasticity equivalently, the placement in the lower cervical region seems to have achieved that goal. The impact on upper limb spasticity seems to be greater with cervical than thoracic catheter placement; although, as the authors have indicated, the two groups were not strictly comparable with respect to diagnosis and extent of upper limb involvement.

These findings, coupled with the results of Meythaler et al. (2), who showed that mid-thoracic placement of the catheter reduced upper limb spasticity but not quite as much as the reduction in lower limb spasticity, suggest a benefit to cervical placement in reducing upper limb spasticity. On the other hand, as the authors have indicated, similar equivalent reductions in Ashworth scores were achieved by Grabb et al. (1) with midthoracic catheter placement in children with quadriparetic cerebral palsy. Whether the reduction of upper limb spasticity reflects a different age group of the patients (pediatric versus adults), a different underlying diagnosis, or the extent of upper limb involvement is not known. However, in the light of their findings, one has to question how advantageous it might be to place the catheter in the cervical region to effect reduction in upper limb spasticity.

It is important to recognize that, in general, reduction of spasticity is not the end point of this procedure, but one is trying to achieve

some improvement in the quality of life of the patient, improve motor function, or decrease pain and painful spasms. It is possible to have equivalent spasticity in the upper and lower limbs, and it could be that the lower limb spasticity is what needs to be reduced the most in order to improve the patient's function. On the other hand, it is possible that reduction of spasticity in all limbs would be equally important. Each patient has to be judged individually with respect to his or her needs. Having said that, the findings of this study and others would suggest that one can use the position of the intrathecal catheter as a way to achieve the optimal reduction in spasticity.

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1. Grabb PA, Guin-Renfroe S, Meythaler JM: Midthoracic catheter tip placement for intrathecal baclofen administration in children with quadriparetic spasticity. **Neurosurgery** 45:833-836, 1999.
2. Meythaler JM, McCary A, Hadley MN: Prospective assessment of continuous intrathecal infusion of baclofen for spasticity caused by acquired brain injury: A preliminary report. **J Neurosurg** 87:415-419, 1997.

McCall and MacDonald describe their experience with high placement of intrathecal catheters for treatment of cerebral spasticity in a series of 23 patients. They analyze their results with respect to reduction in Ashworth scores in upper and lower extremities. They compare their results with a group of 25 patients whose catheters were placed in the usual thoracic position, and attempt to draw conclusions on the advantages or disadvantages of the catheter placement based on their retrospective review. They conclude that the efficacy of intrathecal baclofen therapy in spasticity is not dependent on the position of the catheter tip within the spinal canal. And although this is a rather small patient population to make definitive statements regarding safety, they report no increase in the number of complications related to the higher catheter placement. Although the conclusions of the authors are not surprising, this is useful information given the current level of enthusiasm for tailoring catheter tip placements in patients with various causes of spasticity (1).

Because this is a retrospective review and is not randomized in distribution of patients, the conclusions of such an analysis are, by definition, rather limited. The patient groups, for example, are not necessarily comparable because they include a variety of causes for spasticity, which may affect the distribution of complications and other outcome measures. Moreover, the follow-up period (10 mo) is rather short, which may affect the observed complication rate (2). Finally, the reported complications seem to be more numerous in the cervical group than thoracic group (10 versus 5 complications). Although, admittedly, some of the complications are likely independent of the placement of the catheter tip, it would be difficult to conclude from these data that the complication rates are equal. In fact, because both patient groups exhibited good efficacy at similar baclofen doses, this study seems to support a thoracic placement of the catheter. This placement seems to be as effective as the cervical placement, is technically simpler, and may well have a lower complication rate.

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