Multiple sclerosis is a common neurodegenerative disorder that affects more than 400,000 people in the US per year. One of the most common complicating factors in patient function as well as a primary cause of morbidity is the development of spasticity. Some degree of spasticity will develop in more than 70% of patients throughout the course of their disease. In many cases the spasticity progresses until the patient’s function is significantly impaired. In cases in which patients reach the point where they require full care, spasticity and contracture may limit their ability to obtain care outside of a professional setting. In addition, in many patients painful spontaneous or sensory-evoked muscle spasms develop, which are often unpredictable and are a significant cause of discomfort and disability. When patients can’t be adequately treated medically, either due to ineffectiveness of oral drug therapy or to side effects limiting the ability to titrate medications, ITB therapy is a potential treatment option. In many cases, patients are enthusiastic about pursuing this treatment option. Nevertheless, patient satisfaction and the long-term efficacy of therapy are less clear.

We have evaluated 35 consecutively treated patients who were prospectively identified as potential candidates for ITB therapy. We have reviewed these patients with regard to their response to their screening dose, surgical technique, perioperative/pump complications, short- and long-term outcomes, and patient and caregiver satisfaction. Outcome and satisfaction were assessed in a multipoint questionnaire.

Clinical Material and Methods

We studied 35 consecutive adult patients who were identified as potential candidates for ITB at the Multiple Sclerosis Center of the Medical College of Georgia. This study was completely voluntary and was approved by the Institutional Review Board at the Medical College of Georgia.

Patient Population

Patients were considered candidates for ITB therapy when careful evaluation revealed no underlying cause for spasticity other than multiple sclerosis. In all cases, patients were either refractory to or intolerant of medical therapy after extensive trials with single or multiple drug regimens and increasing drug dosages.

Patients were extensively counseled regarding the option of ITB therapy. Care was taken to explain to the patient, family members, and caregivers the requirements of an ITB delivery system. In addition, the patient and caregivers had an opportunity to view an educational video about ITB and could see a demo pump and catheter. Emphasis was placed on the requirement to undergo periodic, scheduled pump refills as well as regular visits to evaluate and reprogram the device. Patients and/or their caregivers were required to articulate an understanding of their responsibilities once this device was implanted and to demonstrate an adequate level of comprehension. Patients with adequate support mechanisms who desired ITB therapy then received an initial baclofen test dose. In all

Abbreviations used in this paper: ADL = activities of daily living; ITB = intrathecal baclofen.
cases, patients received 50 \( \mu \)g baclofen/1 ml vehicle injected into the lumbar subarachnoid cistern by using a standard lumbar puncture technique. Patients were evaluated before and after injection by a specially trained therapist who used the Ashworth Scale and the Spasm Severity Score (see Zahavi, et al., for a description of these scales). Objective assessment of a successful trial required that there be no adverse response to the drug and an improvement of at least one point on the Ashworth Scale, or a reduction in spasm number or frequency. Subjective success was determined based on the patients’ impression of their response to the injection. Patients with both subjectively and objectively successful test doses were offered implantation of the pump and catheter.

Surgical Procedure

The standard technique for implanting the subcutaneous pump and subarachnoid catheter has been reviewed in detail previously. In general, the pump is placed in the right lower abdominal quadrant, given the possibility of the need for a feeding tube in the future. The left side could be used in patients with significant postural issues. The standard, mid- to upper lumbar entry point was selected for catheter access to the subarachnoid space. The level to which the subarachnoid catheter was advanced was determined by the distribution and degree of spasticity. Typically, patients with upper-extremity involvement underwent catheter placements at approximately T3–4, whereas patients with only lower-extremity involvement underwent placements at approximately T7. The catheter tip position was confirmed with the fluoroscope. Patients received a standard starting dose of 50 \( \mu \)g baclofen/day after a bolus infusion to clear the pump tubing and catheter of saline and cerebrospinal fluid.

Patient Follow-Up Care

Routine surgical follow-up evaluations included wound assessment and suture removal at 2 weeks. Pumps were reprogrammed for the first time after a minimum of 72 hours, and subsequent programming was then based on individual patient requirements. Programming was performed by the neurologist or physiatrist. Patients were also followed closely by both physical and occupational therapists.

Data Collection

Patients’ medical records were reviewed, focusing on operative reports, surgical technique, and complications. Patients were then contacted and asked to complete a questionnaire designed to assess their overall satisfaction with ITB therapy. This was accomplished using a multipoint data collection tool designed to assess the overall response in four categories: ADL, musculoskeletal, mobility, and functional improvement. Each category included subcategories for additional insight.

The ADLs were broken down into dressing, eating, bathing, toileting, and grooming. Patients were also asked to indicate their general level of function before ITB therapy. Musculoskeletal subcategories included spasms, overall comfort, and standing. Mobility subcategories included alteration in mobility and fine motor function/coordination. In this category patients were again asked to indicate their initial level of function before ITB therapy. The functional category included energy level, cognition, sleeping, and self esteem/body image. In cases in which patients were unable to respond, the primary caretaker was asked to assist in answering these questions. In addition, a special category for caretakers was included and focused on ease of care and decubitus ulcer incidence and recovery if applicable. In each subcategory, ratings were assigned on a scale of 1 to 9 (mild, moderate, and severe subgroups). Patients were asked to indicate a number on this scale for each subcategory, reflecting their condition before ITB therapy, within 6 months of pump implant, and at the time of the assessment.

Results

Response to Test Dose and Pump Implantation

Of the 35 patients undergoing an intrathecal test dose, 33 wished to proceed with a permanent implant. All patients had an objective response to the baclofen and in no case were adverse responses noted. The two patients who declined an implant had experienced what they defined as an overresponse and were concerned that they would be unable to walk because of hypotonia if the pump were implanted. There were no intraoperative or perioperative complications noted in the 33 patients who underwent implantation. In addition, no procedures were required in the long term to repair pump and/or catheter complications over the mean follow-up duration of 31.9 months. One patient requested removal of the pump because she believed it was not helping her, despite encouragement from her therapists that she was obtaining benefit from the ITB therapy.

Data Questionnaire: General Overview

Of the 33 patients from our institution who were eligible to complete the survey, 13 did not (seven were lost to follow up, three were unable to complete the survey, and three died). Of the 20 patients who completed the survey, 80% were female and 20% were male. The mean age was 51 years, and patients who underwent implantation had the pump for a mean of 31.9 months.

Medications. Eighteen (90%) of the patients who completed the questionnaire were being treated with oral baclofen before receiving ITB therapy. After placement of the ITB pump, 14 patients (77.7%) were able to discontinue oral baclofen, and the other four were able to decrease the dosages. Six patients were receiving muscle relaxant therapy (Zanaflex or Flexeril) before ITB treatment. Three of them were able to discontinue this therapy, and the other three were able to decrease their dosages.

Weight Changes. Ten patients noted weight gain after pump placement, with a mean gain of 19.3 lb. Five patients noted weight loss after pump placement, with a mean loss of 19 lb (two of those patients attributed their losses to diet and exercise changes after surgery).

Recommend Pump and Procedure. Of the patients who underwent pump placement, 70% said they would recommend the device for other patients, 15% said they would not, and 15% were undecided. All seven of the caregivers polled recommended the pump for other patients. Seventy

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percent of patients stated that they would undergo surgery again, 20% said they would not, and 10% were undecided. Six (86%) of the seven caregivers polled stated that they would encourage the patient to undergo surgery again, and one (14%) stated that she would not.

Response Categories

Changes in ADLs. The patients were asked about changes in their ADLs, including dressing, eating, grooming, toileting, and bathing, after the ITB pump placement. On average, no significant differences in ADLs were noted after pump placement.

Musculoskeletal. Patients were questioned about the number of spontaneous or triggered spasms they experienced before and after ITB pump placement. Before they received the pump, patients stated that, on average, they had suffered spasms approximately 44.5% of the day. After the pump was implanted, this was reduced to 21%. The patients’ comfort level rose from a 4.7 before to a 6.0 after the surgery (1, severe discomfort; 3, mild discomfort; 5, discomfort; 7, comfortable but conscious of spasticity; and 9, no discomfort). The ability to stand did not change significantly immediately after surgery (Score 5.6 before and 5.25 after), but when questioned on their ability to stand on their own at the latest follow-up visit, this score had been reduced to 4.45 (1, extremely difficult [requires assistance]; 5, no assistance but difficult; and 9, no difficulty). This could be explained by the progression of the disease itself.

Mobility. Alterations in mobility did not occur after the surgery. Fine motor function coordination worsened somewhat after placement of the pump (Score 4.25 after pump placement and 3.65 currently, according to the following scale: 1, worse; 5, unchanged; 9, significantly improved). Again, this could be explained by the progression of the disease.

Functional. Cognition did not change with pump placement. The energy level had improved somewhat, to a score of 5.5, immediately after surgery, but was unchanged (Score 5.0) compared with the score at the latest follow-up visit (1, worse; 5, unchanged; 9, significantly improved). Ability to sleep had improved to a score of 5.8 after surgery and a 6.0 on the day of the survey (1, extremely difficult; 3, somewhat difficult; 5, expected; 7, better than expected; and 9, no difficulty). Self-esteem/body image had worsened somewhat after pump placement, to a score of 4.4, and a 4.55 currently.

Caregiver Assessment

Ten caregivers were questioned regarding their ability to care for the patient after pump placement. Seven (70%) stated that the ability to take care of the patient had improved, two (20%) stated that care was unchanged, and one (10%) stated that the ability had worsened. The mean score in response to this question was a 5.8 (1, worse; 5, unchanged; 9, significantly improved). No patients suffered decubitus ulcers after pump placement.

Discussion

The overall results of the survey outlined here were very encouraging. Patients undergoing implantation of an ITB delivery system experienced no complications related to the implant procedure. The longevity and long-term efficacy of the pump system was outstanding, with no system-related revisions during a mean duration of 31.9 months of follow up. Of the 20 patients available for review, the majority of them were quite pleased with the overall level of relief provided by the ITB system. In cases in which deterioration was seen over time, such as with fine motor function or overall level of mobility, patients and caregivers were both quick to point out the role of progression of the disease as the major factor responsible for this decline. Self-esteem/body image also worsened somewhat after pump placement. This is surprising given the high level of patient satisfaction, and may also be attributable to disease progression. In these cases, patients and caregivers believed that they would be even worse off without ITB therapy.

The primary value associated with ITB therapy appears to relate to the ability of three quarters of patients to discontinue oral medication therapy. Almost all remaining patients were able to reduce their medication requirement dramatically. Although long-term cognitive side effects can become evident with oral baclofen therapy, based on this questionnaire, this significant elimination or reduction of drug therapy did not directly correlate with an improvement of cognitive function. Most patients also reported a change in weight. Patients who were more impaired were able to gain weight due to the reduction in their caloric demands related to their spasticity. Patients who were at a higher functional level prior to ITB therapy experienced an improvement in their level of activity. Several patients attributed their weight loss to this improvement.

The most remarkable functional response to ITB therapy across all patient groups was an improvement in spontaneous and/or sensorily triggered spasms. These changed from 44.5% before ITB therapy to 21% after therapy. No significant changes were identified in ADLs, mobility, and cognition, although subtle alterations within individual patients were noted. In these cases, the subtle changes were most likely not enough to move patients from one functional category (that is, mild, moderate, or severe impairment) to another, and therefore no significant change was reported.

Conclusions

Intrathecal baclofen therapy is an excellent alternative for patients whose disease is refractory to medical therapy. Most patients will respond to an intrathecal test dose and will then be candidates for a pump and catheter system implant. Implants are safe, with a low morbidity rate reported in this and other series. In addition, patient satisfaction is high, and most patients would recommend the device to others. Spasms are particularly benefited by ITB therapy. An effort to determine which functional subgroups will respond based on the patient’s level of function may help predict outcomes and better educate candidates before referral for ITB therapy. This type of subanalysis will require a larger study.

References

1. Beard S, Hunn A, Wight J: Treatments for spasticity and pain in...


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