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Point/Counterpoint

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Does Every Patient Require an Intrathecal Baclofen Trial Before Pump Placement?

CASE SCENARIO

You are asked see a 45-year-old man with spastic paraparesis in your outpatient spasticity clinic. He has an established diagnosis of primary progressive multiple sclerosis (MS) that began some 15 years ago. He is alert and cognitively intact, with his primary challenge in symptom control during the past 4-5 years being hypertonia and weakness, ultimately resulting in his admission to a local long-term care facility about 2 years ago. He requires minimal assistance for upper and maximal assistance for lower extremity activities of daily living. He requires total assistance for transfers but once out of bed is reasonably mobile at household distances with a manual wheelchair, albeit slow and quite taxing. During most nights, he awakes 3-4 times from uncomfortable leg spasms. The spasms also occur intermittently during the day. His medical history is significant for pulmonary embolism 4 years ago (currently on warfarin), well-controlled hypertension, placement of a super pubic bladder catheter 6 months ago, and 2 incidences of stage 2 sacral decubiti during the past 18 months—both now well-healed.

As part of the work-up for MS, he received a lumbar puncture after which he experienced a significant spinal headache. His past treatments for spasticity have included oral baclofen, which was discontinued at a dose of 40 mg/day because of sedation, and injection of moderately high-dose botulinum toxin into the key leg muscle will little noticeable improvement. He currently is taking 24 mg/d of tizanadine and 6 mg/d of diazepam, which he tolerates well but still does not adequately control his symptoms.

On inspection, he demonstrates a typical "wind-swept" appearance of his legs, with flexion at the bilateral hips and knees and equinovarus at both ankles. Although the patient demonstrates little ability to actively move his lower extremity muscles, surprisingly his legs can be somewhat straightened passively with effort. All lower extremity muscles consistently demonstrated Modified Ashworth scores of 3 on examination. You are unsure whether passive end range of motion limitation at the hips, knees, and ankles is caused by contracture or spasticity.

Ultimately, you feel the patient would benefit from placement of an intrathecal baclofen (ITB) pump. It so happens that one of your practice partners, who also provides spasticity management, overhears you presenting the case to your office scheduler to set a date and time for the standard ITB trial, before pump placement. Your partner asks gently, "Why don't you just move directly to pump placement in this case? What purpose is the trial serving?" How would you answer your partner's inquiry? Supporting a trial as usual is Gerald S. Bilsky, MD, and supporting the option of foregoing the trial is Michael Saulino, MD, PhD.

Gerald S. Bilsky, MD, Responds

This case, like many in clinical medicine, presents a challenging patient care issue with multiple facets. The patient described has had a long course with a debilitating disease. He has experienced multiple complications and is dealing with functional deficits. Many physicians would agree that spasticity can be extremely problematic and often warrants treatment. The management of spasticity frequently is multimodal and can consist of both physical and pharmacologic interventions. ITB is being considered for this patient. We know it provides excellent management of spasticity, and patients usually can be weaned off oral antispasmodics [1].

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Systemic side effects seen with oral medications generally are not experienced when ITB is used. Furthermore, there are studies demonstrating ITB is also cost-effective in that intrathecal management may be less expensive overall than all the combined physical and pharmacologic therapies. Over time, the cost of ITB (for good management) often is less than that for other combined interventions (with suboptimal management) [2]. One could make a cogent argument that ITB is not only worthy of consideration for this patient but could have been contemplated a few years previously. After all, ITB is not a treatment of last resort.

Although the decision to consider ITB is an excellent one, the decision to implant a pump should not be taken lightly. The risk/benefit ratio must be considered, like with any management paradigm. The initial question to address is: will this treatment truly be effective? There are no guarantees, but a prudent clinician should be nearly certain that an intervention will be beneficial and risks minimized. Thus, an ITB screening test should be performed. Why? Let us explore this further.

First, the clinician must determine whether ITB is even an option. How does the treating physician know the medication will work? We have a means to independently determine this, thus the value of the screening test. Many practitioners familiar with ITB assume it will work, and in fact, historically this is an excellent therapy. In my 25+ years of being involved with ITB, I have become convinced of its efficacy. In fact, I find it is often life-changing for my patients that I feel are appropriate candidates. Not every patient, however, has a successful screening test. No study with a significant sample size shows a 100% conversion rate from screening test to subsequent implantation. Several studies show approximately 86% conversion rates from screening test to actual implantation [3]. Ineffective pharmacologic results, adverse reactions, and unattained desired functional goals account for this phenomenon. Thus, because it is not 100%, it is incumbent on the physician to be as certain as possible that this intervention is right for this patient.

We also must avoid doing harm. Several complications of ITB have been noted in many studies [4,5]. One of the major harms one might encounter would be a severe reaction to the medication, such as anaphylaxis or a respiratory complication. Although rare, there were some reports in the original ITB research. A screening test would provide the opportunity to ascertain whether such a reaction might occur. If so, it can be addressed immediately and not after a surgical procedure was completed and a device implanted. One may argue that oral baclofen was tried with no reaction other than sedation. This patient, however, has not had sedation with diazepam, which is another γ-aminobutyric acid–mediated medication. Thus, the potential exists that some type of idiosyncratic reaction is accounting for the excessive sedation the patient experienced with a low-dose regimen.

This patient has clear hypertonicity with diffuse lower extremity Modified Ashworth scores of 3; however, there is uncertainty as to whether some range of motion limitations are "due to contracture or tone." This leads to another major issue that needs definition. Specifically, what are this patient's goals? Although goals are not delineated, major limitations for him include needing maximum assistance for lower extremity dressing and total assistance for transfers. Will ITB facilitate improvement in these areas? It very well may; however, if there are fixed contractures, then success may be less likely. Albright et al [6] showed that hip range of motion may not improve like knee range of motion in a pediatric study. A screening test can easily help address this diagnostic concern. He is somewhat mobile once up in his wheelchair, so helping to define whether the aforementioned functional tasks are remediable with ITB should be determined before committing to implanting a pump. This is a way to help determine the answer.

In addition, some patients use tone to assist with transfers and other functional tasks. In other patients who do not have complete spinal cord injuries, the need to experience tone reduction should not be minimized. Although intrathecal dosing can be titrated, many patients need to "feel" the decreased hypertonicity. And, occasionally, some patients decline implantation as a result of not liking being "too loose" [7]. Adversely effecting lower extremity function in these circumstances is unacceptable.

This is another point in favor of performing a screening test. Furthermore, a decision about the initial intrathecal starting dose is often based on the screening test results.

This surgical procedure, and the ongoing therapy maintenance, carries risks. Although low in incidence, they are not necessarily insignificant. The common surgical risks include bleeding, seroma, local infection, meningitis, cerebrospinal fluid leak, and headache. Therapy risks include potential withdrawal and overdose. Patients may have alterations in bowel and bladder function. Our patient has had a pulmonary embolus and is on chronic anticoagulation. Surgical intervention will require being off therapy for a period of time. This may be anywhere from 3 to 10 days, depending upon the surgeon. The patient will clearly be at risk during this therapeutic hiatus, and it is absolutely necessary to gain maximum information before adding this risk to the other-recognized surgical risks already inherent with the procedure. Anything less is a disservice in this case.

Another aspect to consider is compliance. ITB requires a commitment from both the health care team as well as the patient. Patients need to follow through with