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Tined Lead Implantation: Results of the First 37 Implants in Maastricht

A. C. van Voskuilen, E. H. J. Weil, Ph. E. V. A. van
Kerrebroeck

Department of Urology, University Hospital, Maastricht,
The Netherlands

Introduction

Since its introduction in the early 1990s sacral neuromodulation is applied in patients with refractory urge incontinence, urgency-frequency, and nonobstructive urinary retention (1-4). Usually potential candidates are tested with a temporary lead before the implantation of a permanent neuromodulation system is considered. Clinical experience with the test procedure for neuromodulation showed that the temporary lead is prone to migration during the test phase. Due to this fact and because of the probability of infections in temporary leads that are *in situ* for a long time, the duration of the test phase is limited to a maximum of about 1 week. Moreover, some patients have different results with the temporary lead and the permanent implant.

In 2003 Spinelli et al. introduced a new minimally invasive method for the implantation of a permanent lead (5,6), allowing a prolonged duration of the test phase. Moreover, the lead can easily be removed if the test results are insufficient. In this article we describe our first experiences with the new lead according to this minimally invasive procedure.

Methods

Thirty-seven patients with urgency-frequency (UF), urge incontinence (UI), or urinary retention (UR), who were refractory to conservative therapy, underwent a staged test procedure using the new lead. In a minimally invasive procedure a "tined" lead (Model 3889, Medtronic) was placed in the left or right S3 foramen. The lead is furnished with silicone barbs (tines) that allow fixation in the tissue above the sacrum. The lead was placed under local anesthesia. This allowed for lead placement using both patients' sensory and motor responses as a guide. The depth of the lead was controlled by lateral fluoroscopy. Using an extension cable the lead was tunneled to a small ipsilateral gluteal incision and connected at a contralateral exit point to an external stimulator (Model 3625, Medtronic). This procedure was carried out on an outpatient basis and took about 45 min. The average duration of subchronic testing was 8.9 days (SD = 6.4 days). During this test period, patients were asked to keep voiding diaries to record the behavior of their urinary symptoms. These data were compared to baseline voiding diaries. Patients with more than 50% improvement got an implantable pulse generator (IPG). The IPG was connected to the same lead as the one used during test stimulation. The implantation of the IPG was also carried out in an outpatient procedure under local anesthesia and took about 20 min. After the internalization patients were followed up at regular intervals.

Results

Three patients with UF, 23 with UI, and 11 patients with UR were implanted with a tined lead. In the UI and UF group, 22 out of 26 patients (84.6%) were eligible for a permanent implant, while in the UR group eight patients

performed implantation in 17 patients with IC. Compared to baseline, 94% of the patients had a significant reduction in the number of daily voids and nocturia episodes and significant improvements of the IC symptom index and IC problem index at 14 months follow-up ($p < 0.01$). No studies in children have been published so far.

SNS is a promising new treatment modality for FI, refractory IC, and chronic pelvic pain in a well-selected patient population. However, further investigation is needed to improve patient selection and to confirm its long-term efficacy and safety especially in children.

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Pathophysiology, Measurement, and Treatment of Spasticity in Children

K. Desloovere

Laboratory for Clinical Motion Analysis (CERM)
Pellenberg, Department of Rehabilitation Sciences,
Catholic University, Leuven, Belgium

Definition

Spasticity is a highly complex phenomenon, which has not been defined in precise and quantifiable terms. Viewpoints vary considerably among experts. Spasticity has been defined in physiological terms by Lance as: "A motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes ('muscle tone') with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex as one component of the upper motor neuron syndrome" (1).

In individual patients, spasticity can arise from a multitude of lesions (2). Spasticity affects certain muscle groups more than others. The disability produced by spasticity varies considerably among patients. The velocity-dependent character of spasticity emphasizes the dynamic nature of spasticity. The degree of hypertonia is directly related to the velocity of the muscle stretch (3).

Spasticity is seldom an isolated problem. It is frequently associated with other primary problems (muscle weakness, loss of selective control and coordination, balance problems), and with secondary problems (muscle contractures and bony deformities) that develop slowly due to the impact of increased tone, growth, and pathological motor patterns.

Mechanisms of Spasticity: What Is Disordered?

Roughly, muscle tone is controlled by the reflex arc in the spinal cord, which is itself controlled by supraspinal signals from the brain. From the brain, inhibitory and excitatory signals descend to the spinal cord. On the other hand, sensory signals from a muscle give feedback to spinal motor neurons of the same muscle. Integration of excitatory and inhibitory inputs to the alpha motor neuron and spinal interneurons normally results in an appropriate level of resting muscle tone and activity (4,5).

Muscle tone is controlled by brainstem nuclei, especially the reticular and vestibular nuclei. A lesion decreases spinal cord modulation of the reflex motor pathways. Studies of spasticity have been focused primarily on the group IA muscle spindle afferents, which have direct

synaptic contacts with alpha motor neurons. However, there are also arguments in favor of pathological changes mediated by interneurons rather than by monosynaptically evoked stretch reflexes (based on information of group II afferents) as the main cause of exaggerated stretch reflexes associated with spasticity (6).

Spasticity Measurement

Spasticity manifests clearly as hypertonia. Thus the degree of resistance to passive movement (tone) and available range of movement in a limb provide some measure of spasticity.

The Ashworth scale and the modified Ashworth scale are widely used to quantify spasticity. The resistance of a muscle to passive movement is graded. The dynamic muscle length is assessed by the modified Tardieu scale, which determines the point of resistance to a rapid velocity stretch (7).

A number of more objective biomechanical measures have also been developed to assess muscle tone. Their use is not routine. In the pediatric population it is largely limited to research-oriented projects (8,9). In gait analysis indications of spasticity can be found in raw EMG data (reflex activity in EMG data, EMG while walking at different velocities, clonus activity) and in the discrepancy between kinetic data and EMG data (premature and/or prolonged EMG).

Interventions

A variety of antispasticity interventions are available to improve motor functions in children with spasticity (4,10).

Therapists provide a range of motion exercises, strengthening regimens, and facilitatory/inhibitory exercise programs. The use of stretching casts is beneficial in the reduction of both muscle tone and contracture, and has a beneficial effect on gait. Day and night orthoses are prescribed to help delay the development of contractures, enhance function, provide biomechanically optimal alignment, and allow for proprioception. The use of orally administered medications in the treatment of spasticity can be helpful in selected patients when a generalized reduction in muscle tone is desired. These medications exert their effect by inhibiting excitatory neurotransmitters or augmenting inhibitory neurotransmitters at the level of the spinal cord. Neuromuscular blockade includes chemical denervation by phenol injections and by botulinum toxin A (BTX-A) injections. In recent years, most chemodenervation in children with spasticity has been performed with BTX-A, which is a neurotoxin affecting the neuromuscular synaps (motor endplate) by inhibiting the release of acetylcholine. When injected intramuscularly, BTX-A reduces spasticity for a period of 3 to 6 months. Selective dorsal rhizotomy (SDR) is a surgical intervention in the treatment of lower extremity spasticity. About 20% to 40% of the posterior rootlets from L1 to S1 are sacrificed,

depending on the degree and pattern of abnormal responses demonstrated at intraoperative electric stimulation. The success of SDR is highly dependent on patient selection. Controlled intrathecal baclofen administration is used for the treatment of generalized spasticity that impedes independent function or significantly impairs the ability of caregivers to assist the patient. Baclofen is administered intrathecally by means of an implantable subcutaneous pump, connected to the intrathecal space by a catheter.

Conclusion

In view of the complexity of motor disorders in children having cerebral palsy and who also have a variety of neurologic deficits compounded by the effect of growth on the pathological process, a multidisciplinary team evaluation using standardized and objective measurements (clinical examination and gait analysis) is essential to define the optimal treatment strategy.

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Variability in Gait Analysis Data in Spastic Children

Y. J. M. Janssen-Potten^{*†}, M. L. P. Coenen^{*‡},
E. A. A. Rameckers^{*‡}, L. A. W. M. Speth^{*‡}, J. S. H. Vles^{*}
^{*}Department of Neurology, University Hospital, Maastricht, The Netherlands, [†]Institute for Rehabilitation Research, Hoensbroek, The Netherlands, [‡]Rehabilitation Foundation Limburg, Hoensbroek, The Netherlands

Introduction

While there are several studies evaluating intra- and inter-subject variability in normal gait, there is only a limited number of studies regarding the reproducibility of spastic gait (1). Clinical gait analysis is used in selecting interventions for gait improvement in cerebral palsy. Because intervention studies give conflicting outcomes that might be caused by the variability of gait in children with cerebral palsy, we assessed this variability as measured in our clinical gait laboratory (study 1).

Although instrumented three-dimensional gait analysis (3-DGA) has shown to give reliable and valid results, its complexity, cost, and impracticality for most clinicians as an everyday assessment tool have prevented widespread clinical application (2). In younger children 3-DGA may not always be appropriate because of their small size and varying levels of cooperation (3). In our laboratory we depend on visual assessment to evaluate children's walking patterns and treatment outcomes. Therefore results on observer agreement are also presented (study 2).

Methods

Patients

Fifteen ambulatory children with cerebral palsy (CP) were included in this study: 12 boys and 3 girls, aged 4-11 years. MRI scans showed characteristic abnormalities. The children had a spastic diplegia of the lower extremities according to Hagberg. All of them walked in a flexion pattern with a unilateral or bilateral incomplete knee extension during stance phase, with or without ankle foot orthoses. These children did not have any surgical intervention or botulinum toxin A (BTX-A) treatment in the previous 6 months. Three children used a posterior walker during gait analysis, one child an anterior walker and one child a tripod. The children were dressed in their underwear and walked barefoot in a self-selected pace.

Procedure and Equipment

Gait analysis (GA) consisted of split-screen video recordings, dynamic EMG measurements, and ground reaction force recordings. The data were combined in the multimedia program SYBAR (Noldus, Wageningen,

The Netherlands) used for observational gait analysis. Kinematics of hip, knee, and ankle joint were estimated in the coronal and sagittal plane, in eight different phases of the gait cycle as defined by Perry (4). Gait evaluation was performed according to a predefined protocol.

Raters

Two licensed physical therapists evaluated the video recordings. These observers work in a pediatric facility and have more than 5 years' experience in observing gait and reviewing gait in the CP population. They were trained in the use of the evaluation protocol. The video recordings were evaluated in random order at the individual facilities for the convenience of the raters.

Results

Study 1

Preliminary results revealed that, even in a select group of CP children, the kinematics varied considerably from one subject to another. For example, knee flexion during stance phase ranged from 5 to 60 degrees.

Study 2

Possible levels of agreement were exact agreement, one-rater level disagreement, two-rater levels disagreement up to 11-rater levels disagreement. However, the largest disagreement between the observers proved to be five-rater levels.

From the ratings of all 38 gait parameters of the observation protocol by the two observers the total agreement and one-rater level disagreement covered almost all 38 gait parameters. Foot clearance was the easiest parameter to score, whereas the ankle parameters were the most difficult ones to score.

Discussion

Study 1

Part of the variability in kinematics as shown in this study is most probably caused by the fact that the kinematics are based on (subjective) observations. The inter-subject variability might also be partially explained by immature motor patterns (eight children being younger than 7 years), restrictions in range of motion due to spasticity, and differences in gait velocity.

Study 2

In this study split-screen video recordings with slow-speed viewing capabilities were assessed by two experienced therapists according to a protocol. The majority of the scores showed a high level of agreement between the observers, although there was a small number of scores showing total disagreement, primarily for parameters with only three-rater levels, like lordosis and pelvic tilt. Clear definitions of how to score these parameters appeared to be the problem.