Profile of Patients with Spasticity

A Research Study
Conducted by WE MOVE

July 2008

Introduction

During a six-week period commencing April 2008, WE MOVE conducted an online research study to develop a profile of patients with spasticity. Commissioned by Avigen, this study consisted of 20 close-ended questions pertaining to: the issues that impact quality of life of patients with spasticity; the types of physicians that treat them; and the varied types of pharmacotherapeutic interventions that they utilize and the side effects that patients experience. The study also sought to identify if a needs exists for a new oral intervention that will not confer or impart any side effects.

Spasticity is an involuntary form of muscle overactivity that can cause discomfort, pain, limited ability to move, skin problems and can affect overall quality of life. People living with spasticity can also feel socially isolated and experience varying levels of anxiety and depression. Spasticity may occur as a result of cerebral palsy, a stroke, multiple sclerosis, traumatic brain or spinal cord injuries, or other causes. Spasticity is actually caused by an injury or damage to the brain or spinal cord. Damage occurs in areas that help control voluntary movements.

Treatment of spasticity typically encompasses many therapeutic approaches and can take the form of injectable therapies, intrathecal baclofen therapy (ITB), oral medications, physical and occupational therapies and surgical interventions. Oral medications can include baclofen, benzodiazepines, gabapentin, dantrolene sodium and imidazolines.

While the benefits of pharmacotherapeutic interventions can positively impact patients and their spasticity, these approaches are not without side effects. Common side effects that can contribute negatively to quality of life can include:

- Hallucinations
- Drowsiness
- Fatigue
- Confusion or inability to think clearly
- Nausea
- Dizziness
- Depression
- Clumsiness
- Memory impairment
- Diarrhea
- Weakness
- Dry mouth

Sample Size & Breakdown

Survey respondents were recruited through www.wemove.org, WE MOVE NEWS, collaboration with the National Stroke Association, Easter Seals, the Spastic Paraplegia Foundation, and the National Spinal Cord Injury Association. In addition, a qualified list of individuals affected by spasticity was purchased by Fieldwork International.

The only screening criterion was a self-reported medical diagnosis of spasticity from the patient's treating physician. No differentiation was made based on a patient's gender or age. The resulting sample size was 810 individuals. An overwhelming majority (56.8%) of survey respondents indicated that their spasticity was related to stroke, followed by 14.3% who had multiple sclerosis. Over nine percent (9.7%) of respondents indicated that their spasticity was related to other conditions, including hereditary spastic paraplegia (HSP) and primary lateral sclerosis (PLS). An additional 9.7% of respondents indicated that their spasticity was a result of a spinal cord injury, followed by 6.8% with a traumatic brain injury and 4.3% with cerebral palsy.

Physician Management

Slightly more than sixty-five percent (65.8%) of study participants indicated that they seek treatment for their spasticity from only one type of physician.

- 53.7% of the survey respondents indicated that a neurologist manages their spasticity. Sixty percent (60.2%) of this group indicated that their neurologist is the only healthcare professional managing their care.
- 31.5% of respondents sought treatment from a physician specializing in physical medicine & rehabilitation (physiatrist); 53.3% used their physiatrist exclusively for their spasticity treatment.
- 26.1% indicated that their family practitioner manages their care, 53.1% of them exclusively.
- 7.0% indicated that they rely on their internist for care. About forty percent (40.4%) of this group are managed exclusively by their internist.

Physician Communication, Understanding of Spasticity and Satisfaction with Their Treatment

Survey respondents were presented with four statements and asked to indicate their level of agreement.

I communicate well with my physician. All my questions are answered and time is taken by my doctor to explain spasticity and its management. Overall, *65.5%* of survey respondents indicated that they *agreed* on some level with this statement. The only group that differed in opinion was those patients affected exclusively by *multiple sclerosis, with 75.5% indicating some level of disagreement*. In addition, patients under the exclusive care of a physiatrist indicated a higher level of agreement with this statement than those under the care of another type of physician.

I fully understand spasticity and its management. Overall, *65.9%* of the survey respondents indicated some level of *agreement*. Once again, the majority of the patients with *multiple sclerosis did not agree with this statement 71.8%*.

I believe that my symptoms from spasticity are well managed and I am satisfied with my health right now. There was not a definite sense of agreement or disagreement with this statement. Only 37.7% indicated some level of agreement, while 49.5% indicated some of disagreement. This overall ambivalence was reflected across the board with all disease states.

I am doing everything that has been recommended to me with regard to managing the symptoms of spasticity. *70.1%* of the survey respondents indicated some level of *agreement* with this statement. Once again, the majority *(71.7%)* of patients with multiple sclerosis indicated a level *disagreement* with this statement.

Impact of Symptoms on Quality of Life

There are a number of symptoms associated with spasticity. Survey respondents were presented with five and asked to identify which aspect of the condition has the most significant impact on their quality of life. These five symptoms presented were:

- Stiffness or limited range of motion in affected muscles
- Abnormal posture
- Pain
- Inability to sleep
- Limitations in activities of daily living (such as bathing, getting dressed, going up/down stairs, etc)

Almost 42% of survey respondents felt that stiffness or limited range of motion most affected their quality of life, followed by limitations in activities of daily living (23.5%). Stiffness was indicated as the most common aspect by patients with all disorders, except those with traumatic brain injury. Twenty-eight percent (28.6%) of traumatic brain injury patients felt that pain has the most significant impact on their quality of life.

Utilization of medication, medical devices or injectable therapies

Slightly over sixty-nine percent (69.3%) of all survey respondents indicated that they do utilize some form of pharmacotherapeutic intervention to help manage their spasticity. Those that do use an intervention, use one or more of the following:

- Baclofen (oral) – 47.6%
  - Most commonly used exclusively by patients with multiple sclerosis, spinal cord injury or traumatic brain injury
- Injectable therapies – 31.4%
  - Most commonly used exclusively by patients with stroke or cerebral palsy
- Benzodiazepines – 18.7%
- Gabapentin – 13.5%
- Imidazolines – 12.8%
- Intrathecal Baclofen – 7.5%
- Dantrolene Sodium – 3.2%

The survey participants were asked how strongly they agree with the following statement: **I believe that the medications, medical devices and/or injectable therapies I utilize manage my symptoms of spasticity effectively.** In reviewing the results, there seems to be sense of overall ambivalence. More that forty-one percent (41.7%) of respondents indicated a level of disagreement, while *46% agreed* with the statement on some level. The majority of patients with multiple sclerosis and traumatic brain injury disagreed with this statement.

The three most commonly identified side effects of the pharmacotherapeutic interventions were drowsiness, fatigue or dry mouth, as identified by 40.5%, 40.5% and 27.3%, respectively. More than twenty-six percent (26.9%) of the survey participants did not experience any side effects. These three side effects are most prevalent in all conditions except in the case of cerebral palsy and traumatic brain injury. Those patients with cerebral palsy indicated that they most commonly experience fatigue, dry mouth and weakness, while patients with traumatic brain injury most commonly experience drowsiness, dry mouth and confusion.

Current or Past Utilization of Oral Medications for Management of the Symptoms of Spasticity

Almost seventy-three percent (72.7%) of the survey participants indicated that they have taken (or currently take) oral medications for the management of their spasticity.

- Baclofen – 52.6%
- Benzodiazepines – 20.5%
- Gabapentin – 15.3%
- Imidazolines – 17.3%
- Dantrolene Sodium – 4.3%

Of the respondents who indicated that they have not or do not take oral medications for the management of their spasticity, fifty-one percent (51.1%) indicated that they were not aware that they could take such a medication, while 32.6% felt that there were other reasons for not taking oral medications. Only 12.2% did not take oral medications because they have taken them in the past and experienced side effects.

Finally, 91.9% of the survey respondents indicated that they would take an oral medication that did not have side effects associated with it for management of their spasticity, if it were available, demonstrating a strong potential demand for such a product.