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Current Status of SCI Research:

Why Capacity is Important

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Current Status of SCI Research: Why Capacity is Important

Never before have so many interventions been under investigation for treating spinal cord injury (SCI). A number of these treatments are nearing clinical trials. The lack of sufficient numbers of institutions capable of conducting clinical trials in SCI threatens to slow progress. Measures to increase capacity for clinical trials in SCI are needed.

There are approximately 250,000 people in the United States living with an SCI. Every year, another 11,000 people sustain an SCI.[1] Although these numbers are small compared to other health conditions or injuries, the economic consequences of SCI are great – estimated at over $7.7 billion per year.

Great strides have been made in caring for those with traumatic SCI, resulting in increased survival and greater life expectancy after SCI. However, little progress has been made in reducing the neurological deficit or the resulting disability. Functional expectations today vary little from those published decades ago. This may soon change. The past decade has seen enormous advances in the area of spinal cord regeneration and neuroprotection. In the 1990s, clinical trials of methylprednisolone and GM-1 ganglioside provided hope for improving function for those with SCI. Results, however, were modest at best. Now, a number of new interventions for acute SCI are ready or nearly ready for clinical trials. But, because of the relatively low incidence of SCI and the specialized nature of some of the newer treatments, the research community may not have the capacity to conduct clinical trials of these interventions.

Many of the treatments being evaluated or developed for acute SCI involve surgical procedures to place cells or substances within or near the injured spinal cord segment in order to promote axonal regeneration and tissue sparing. For acute SCI, transplantation of specialized cells into the spinal cord is often performed in combination with nerve growth factors.[2] Interventions are being developed for chronic SCI, as well. In addition to pharmacological treatments, researchers are considering combining some of the strategies used for acute SCI with rehabilitation training.[3] Also being conducted are trials of rehabilitation interventions, such as combining a body weight support harness with treadmill training to improve ambulation.[4]

Given the number of acute and chronic interventions for SCI undergoing or nearing clinical trials, the availability of research capacity in SCI is critical. Clinical trials in acute SCI require enormous resources. Because of the relatively low incidence of traumatic SCI, multicenter studies are necessary. The Sygen (GM-1 ganglioside) study required five years for the 28 participating centers to recruit 760 subjects.[5] Less than 25% of patients screened met the inclusion criteria for the study. The Sygen trial included both complete and incomplete injuries.

Due to concerns about safety and possible neurological deterioration, initial studies involving transplants will involve only patients with complete injuries. Even at a busy center such as ours, which sees over 150 patients per year with acute SCI, less than 10 patients per year would likely qualify for an acute intervention trial limited to those with complete injuries. Although able to draw from a larger pool of patients, recent pharmacological intervention studies in chronic SCI have been international in scope in order to recruit subjects in a reasonable time frame.

The Model SCI Systems make up a core group of centers with a long history of collaborative research.[6] Our Center has been involved in a number of clinical trials, such as a phase I clinical trial of Neotrophin in acute SCI, a trial of 4-aminopyridine (a potassium channel blocker) in chronic SCI, and the recently completed body weight-supported treadmill ambulation training trial in acute SCI.

The ability to conduct a clinical trial requires a core infrastructure of research staff and strong clinical programs to attract and effectively manage patients. Most centers will only be able to participate in one acute and one or two chronic trials at a time if they are to effectively recruit subjects. Target start dates of clinical trials are often missed due to regulatory delays and logistical difficulties. As a result, there will be gaps in funding for research staff involved in clinical trials. In the face of shrinking discretionary dollars at academic institutions, funding to establish and maintain capacity for clinical trials is needed. Currently, the National Center for Medical Rehabilitation Research (NCMRR), National Institutes of Health (NIH), funds a traumatic brain injury clinical trials network for the purpose of maintaining research capacity. It has been suggested that such a network be established for SCI clinical trials as well, perhaps with collaborative funding from NCMRR, the National Institute on Disability and Rehabilitation Research (NIDRR) and the Paralyzed Veterans of America.[7]

Hopefully, sufficient resources will be dedicated to improving capacity for SCI clinical trials, so that the promise of basic research can be tested and advances made to restore function to those with SCI. It would be a tragedy if progress toward a cure for SCI were hindered because not enough centers caring for those with SCI had the means to participate in clinical trials.

Jefferson is home to the Regional Spinal Cord Injury Center of the Delaware Valley (RSCICDV), a collaboration between Thomas Jefferson University Hospital and Magee Rehabilitation Hospital. The RSCICDV has been continuously funded as a Model SCI System since 1979 by the National Institute on Disability and Rehabilitation Research, Department of Education. This is one of only 16 such centers in the United States. Our Center has treated over 3,000 people with SCI and admits more than 150 new injuries each year. Visit our website at http://www.spinalcordcenter.org/index.html for more information on the RSCICDV.

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