Spinal Cord Injury

Overview

Spinal Cord Injury (SCI) is an insult to the spinal cord, resulting in temporary or permanent damage to its normal motor, sensory and autonomic function. SCI afflicts about 250,000 Americans, 82 percent of whom are male. Fifty-six percent of injuries occur between the ages of 16 and 30, and the average age of a spinal cord injury patient is 31. SCI ranges from complete injury, where function below the neurological level is lost, to incomplete injury, where some sensation or movement below the level of injury is retained. The severity of the injury in terms of functional loss is dependent on where the injury occurs and how quickly doctors can respond to it. Cervical injuries in the neck will generally result in full or partial quadriplegia, while injuries further down, at or below thoracic spinal levels and at lumbar levels, will result in paraplegia or decreased control of various functions below the point of injury. Typically, death does not result from the injury itself, but from complications, which include skin breakdown, pneumonia, osteoporosis and fractures, urinary tract infections and cardiovascular disease, among others. Treatment is currently limited to anti-inflammatory agents within eight hours of the injury, surgical implants for the stabilization of the spinal cord and intensive rehabilitation to help maintain strength.

Spinal Cord Injury and Regenerative Medicine

SCI generally results in neuron loss and demyelination of the nerve axons at and near the site of injury. It is difficult to treat effectively due to the scarring and toxic environment that also develops around the injury site.

The California Institute for Regenerative Medicine (CIRM), has been at the forefront of this research. Researchers supported by CIRM at University of California, Irvine were the first in the world to develop a method to create large amounts of high purity oligodendrocytes from hESCs. Oligodendrocytes are central nervous system specific cells that produce myelin, the material that insulates the spinal cord and nerve cells, allowing for electric conduction.

StemCells, Inc. is testing its human neural stem cell product (HuCNS-SCs) to treat SCI. In preclinical trials, these stem cells migrated to the injury site, differentiated into neurons and oligodendrocytes, which formed new myelin sheaths around the damaged nerve axons and restored motor function. In February of 2013, StemCells, Inc. announced that the first cohort of patients completed the Phase 1/2 SCI trial which demonstrated a favorable safety profile and gains in sensory motor function compared to pre-transplanted baselines.

Neuralstem's lead cell therapy candidate, NSI-566 is a human spinal cord stem cell derived product. The cells, which are transplanted into the patient's spinal cord are expected to integrate into the patient's neural tissue and create new circuitry to transmit nerve signals to muscles. In preclinical work, NSI-566 made synaptic contact with the host motor neurons and expressed neurotrophic growth factors, which are protective of cells. In January of 2013, Neuralstem received FDA approval to initiate a Phase 1 human trial.

RhinoCyte Inc. is developing an adult autologous stem cell technology that repairs damage resulting from SCI. The autologous cells are cultured from the olfactory regions of the nasal passageways via outpatient surgery, which can then be transplanted into the injury site. Preclinical animal studies have demonstrated positive results. The company hopes to submit an IND in the near future.

Q Therapeutics is hoping to use their Q-cells product to treat SCI. When injected into the CNS, these cells are believed to replicate, migrate and differentiate into oligodendrocytes and astrocytes (glial support cells that provide growth and trophic factors for the oligodendrocytes and neurons). The company is currently conducting preclinical studies in disease models of SCI.

The Miami Project was the first to establish optimal laboratory methods to isolate and expand human Schwann cells, the myelin producing cells of the peripheral nervous system (PNS). They recently received FDA approval to begin a Phase 1 trial evaluating the safety of transplanting human Schwann cells to treat patients with recent SCI.

The New York Neural Stem Cell Institute (NSCI) is developing biodegradable beads that activate the dormant resident, or endogenous, CNS stem cells within the spinal cord to produce the oligodendrocytes needed to reduce CNS scarring. NSCI is hoping to progress toward clinical trials with this product.

InVivo Therapeutics is focusing on the scaffolding technology that could provide structural support and bridge the neural pathways at the site of the injury. They are currently awaiting FDA approval to commence a human clinical trial in 2013.

Spinal Cord Injury: Economic Impact

The cost of healthcare attributable to SCI varies greatly according to the severity of the injury, but leaves families of patients with an extremely heavy cross to bear.

$321,720–$985,774
Average yearly expenses during the first year of treatment and care (from incomplete motor function to high tetraplegia).[1]

$39,077–$171,183
Average yearly expenses for each subsequent year.[1]

[1] National Spinal Cord Injury Statistical Center, "Paralysis Research Center: The Costs of Living with SCI," Christopher & Dana Reeve Foundation website, http://www.christopherreeve.org/site/c.mtKZKgMWKwG/b.5193227/k.AFB/Costs_of_Living_with_Spinal_Cord_Injury.htm