

Introduction

Bone marrow mononuclear stem cells have several advantages for clinical applications, as they can be easily obtained and are suitable for autologous transplantation. In this study we evaluated the feasibility, safety and potential efficacy of autologous transplantation of autologous bone marrow mononuclear stem cells in subjects with acute complete SCI.

Methods

We conducted a phase I, randomized controlled study in patients with acute complete (quadriplegia/ paraplegia) traumatic SCI (within 21 days), classified as American Spinal Injury Association (ASIA) grade-A. Patients were randomized to standard therapy arm or a standard therapy plus stem cell arm.

Baseline spinal magnetic resonance imaging (MRI) and Spinal Cord Independence Measure (SCIM) were assessed before and at 6 months and 1 year after treatment. Bone marrow was aspirated and mononuclear stem cells were isolated and characterized by flow cytometry. Bone marrow mononuclear stem cells were injected directly into the spinal cord at the level of the injury following a dural incision after decompression of the cord and instrumentation (if required).

Results

A total of 14 patients were randomized to the stem cell arm (n=7) or the control arm (n=7). Both groups were comparable in level of injury, demographics and follow up period. The mean follow up period was 8 months (range 3-12 months) in stem cell group and 9 months in control group (range 3-12 months). All subjects in stem cell group displayed variable improvements in sensory function and six subjects developed lower limbs motor functional gains, principally in the hip flexors. ASIA grade improved by one grade in 1 patient,by 2 grades in 4 patients and 3 grades in 1 patients. SCIM scores improved by mean of 24 (range 10-43). No patient in control group had any improvement in ASIA grade or sensory function. Intramedullary injection of stem cells was not associated with any adverse events in any patient.

Conclusions

Intramedullary transplantation of autologous bone marrow mononuclear stem cells in subjects with acute complete spinal cord injury is safe, feasible and may promote improvement in motor and sensory function.

Learning Objectives

Stem cell or cell therapy can help to improve quality of life in traumatic spinal cord injury patients.

References

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