Acidic fibroblast growth factor for repair of human spinal cord injury: A clinical trial - Clinical article.

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Abstract:

Object. The study aimed to verify the safety and feasibility of applying acidic fibroblast growth factor (aFGF) with fibrin glue in combination with surgical neurolysis for nonacute spinal cord injury. Methods. This open-label, prospective, uncontrolled human clinical trial recruited 60 patients with spinal cord injuries (30 cervical and 30 thoracolumbar). The mean patient age was 36.5 +/- 15.33 (mean +/- SD) years, and the male/ female ratio was 3:1. The mean time from injury to treatment was 25.7 +/- 26.58 months, and the cause of injury included motor vehicle accident (26 patients [43.3%]), fall from a height (17 patients [28.3%]), sports (4 patients [6.7%]), and other (13 patients [21.7%]). Application of aFGF with fibrin glue and duraplasty was performed via laminectomy, and an adjuvant booster of combined aFGF and fibrin glue (2 ml) was given at 3 and 6 months postsurgery via lumbar puncture. Outcome measurements included the American Spinal Injury Association (ASIA) motor scores, sensory scores, impairment scales, and neurological levels. Examination of functional independence measures, visual analog scale, MR imaging, electrophysiological and urodynamic studies, hematology and biochemistry tests, tumor markers, and serum inflammatory cytokines were all conducted. All adverse events were monitored and reported. Exclusions were based on refusal, unrelated adverse events, or failure to participate in the planned rehabilitation. Results. Forty-nine patients (26 with cervical and 23 with thoracolumbar injuries) completed the 24-month trial. Compared with preoperative conditions, the 24-month postoperative ASIA motor scores improved significantly in the cervical group (from 27.6 +/- 15.55 to

37.0 +/- 19.93, p < 0.001) and thoracolumbar group (from 56.8 +/- 9.21 to 60.7 +/- 10.10, p < 0.001). The ASIA sensory scores also demonstrated significant improvement in light touch and pinprick in both groups: from 55.8 +/- 24.89 to 59.8 +/- 26.47 (p = 0.049) and 56.3 +/- 23.36 to 62.3 +/- 24.87 (p = 0.003), respectively, in the cervical group and from 75.7 +/- 15.65 to 79.2 +/- 15.81 (p < 0.001) and 78.2 +/- 14.72 to 82.7 +/- 16.60 (p < 0.001), respectively, in the thoracolumbar group. At 24-month follow-up, the ASIA impairment scale improved significantly in both groups (30% cervical [p = 0.011] and 30% thoracolumbar [p = 0.003]). There was also significant improvement in neurological level in the cervical (from 5.17 +/- 1.60 to 6.27 +/- 3.27, p = 0.022) and thoracolumbar (from 18.03 +/- 4.19 to 18.67 +/- 3.96, p = 0.001) groups. The average sum of motor items in functional independence measure also had significant improvement in both groups (p < 0.05). The walking/wheelchair locomotion subscale showed increased percentages of patients who were ambulatory (from 3.4% to 13.8% and from 17.9% to 35.7% in the cervical and thoracolumbar groups, respectively). There were no related adverse events. Conclusions. The use of aFGF for spinal cord injury was safe and feasible in the present trial. There were significant improvements in ASIA motor and sensory scale scores, ASIA impairment scales, neurological levels, and functional independence measure at 24 months after treatment. Further large-scale, randomized, and controlled investigations are warranted to evaluate the efficacy and long-term results.