

O-03

The Sodium-Glutamate Antagonist Riluzole Enhances Recovery After Acute Spinal Cord Injury: Results from the RISCIS Randomized Controlled Trial Using a Global Statistical Analytic Technique

Michael Fehlings^{1,2}, Karlo Pedro¹, Mohammed Alvi¹, James Harrop³, Bizhan Arabi⁴, Kevin Thorpe⁵, Peng Huang⁶

¹Toronto Western Hospital, Neurosurgery, Toronto, Canada

²University of Toronto, Neurosurgery, Toronto, Canada

³Thomas Jefferson University, Neurological Surgery, Philadelphia, PA, United States

⁴University of Maryland, Neurosurgery, Baltimore, MD, United States

⁵University of Toronto, Dalla Lana School of Public Health, Toronto, Canada

⁶Johns Hopkins University, Biostatistics, Baltimore, MD, United States

Background: In clinical trials, single-scale outcome measures often fail to capture the heterogeneity of treatment effects, limiting statistical power to detect intervention efficacy. A multidimensional approach that integrates functional and quality-of-life measure may provide a more robust assessment.

Research Question: Can a composite outcome measure improve the representation of spinal cord injury (SCI) outcomes?

Design: Multivariable analysis of the RISCIS (Riluzole in SCI) Study

Methods: Data from 131 randomized patients in RISCIS were analyzed. Outcomes at six months included AIS motor score (neurological status), Spinal Cord Independence Measure (SCIM) (functional status) and SF-36 PCS (quality of life). A global statistical method using the modified O'Brien's rank sum test was applied to compute a global treatment effect (GTE) across these outcomes.

Results: In the RISCIS trial, unadjusted mean difference (MD) showed a favorable trend for riluzole compared to placebo across AIS motor score [MD 2.86, $p = 0.2864$], SCIM [MD 6.02, $p = 0.0921$], and SF-36 PCS [MD 2.0, $p = 0.1372$]. Combined analysis of all three scales revealed a significant GTE favoring riluzole over placebo ($GTE = 0.101$, $p = 0.0396$). Riluzole treatment was associated with a 55% higher probability of functional improvement compared to placebo drug.

Discussion: A multidimensional assessment of SCI outcomes enhances the ability to detect treatment effects. Riluzole demonstrated a significant global benefit in acute traumatic SCI when motor recovery, functional independence, and quality of life were evaluated simultaneously.

Figure 1. Boxplot of individual outcome scale (change from baseline to 6 months) compared between placebo and riluzole group. A. SCIM, B. TOTM, and C. SF-36 PCS.

Fig. 1

Figure 1. Boxplot of individual outcome scale (change from baseline to 6 months) compared between placebo and riluzole group. A. SCIM, B. TOTM, and C. SF-36 PCS. The boxplot representing mean rank sum used for the GST analysis was added for comparative purpose. P values were computed from Wilcoxon rank sum test

