Traumatic Optic Neuropathy Treatment Trial (TONTT): A Prospective Multicenter Semi-experimental Trial

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Background/Aim: IV Erythropoietin (EPO) was firstly reported by our group in 2011. This multicenter trial was designed to compare its effect with IV steroid and observation (ClinicalTrial.gov, NCT01783847, 02/01/2013) in patients with TON.
Method: Included were age ≥ 5 years and trauma treatment interval of ≤ 3 weeks. BCVA, Color, and RAPD were recorded pre- and 1, 2, 3, 7, 14, 30, and at least 90 days after treatment. There were 3 groups: EPO (20,000 units/ day for 3 days), methyl prednisolone (250 mg 4 times daily for 3 days), and observation. Systemic examination and blood tests were performed pre-treatment and 3 and 7 days after treatment. Improvement was assessed based on ≥0.3 LogMAR decrease in BCVA and Improvement percentage (Formula).
Results: Out of 120 patients, 100 (EPO: 69, Observation: 16, and steroid: 15) were included in the analysis. No variable was significantly different between three groups before treatment. All 3 groups showed a significant improvement of BCVA which was not (adjusted for pretreatment BCVA) significantly different between the groups. EPO group showed an insignificantly better improvement. Improvement of vision was observed in 27% of 41 patients with NLP which was not significantly different between three groups. While color vision significantly improved just in the EPO group, RAPD was improved in all three groups. Patients with age > 25 years, male gender, earlier treatment (≤ 3 days), and car accident showed a better outcome in which earlier treatment was significant (P= 0.02). Whereas, initial VA of NLP, ethmoid and sphenoid fracture showed a worse outcome in which initial NLP vision reached the significance (P=0.001). No side effect was observed in any group.
Conclusion: A significant improvement of BCVA was observed in all 3 groups with no significant difference. Color vision improvement was only significant in the EPO group. Initial VA of NLP and late treatment (>3 days) were significant risk factors for visual improvement.