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Combination therapy of Cyclosporine and Vedolizumab is effective and safe for severe, steroid resistant ulcerative colitis patients: Prospective study

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Background: Vedolizumab is an anti-integrin monoclonal antibody approved for use in moderate to severe Ulcerative Colitis (UC). However, concurrent use of calcineurin inhibitors was not studied in the original clinical trials but has subsequently been described. Here we describe the efficacy and safety of cyclosporine in conjunction with vedolizumab for severe, steroid - resistant UC patients.

Methods: This is a prospective study of 17 UC patients treated with cyclosporine in conjunction with vedolizumab at the Military Medical Academy in Belgrade, Serbia. UC patients, not responding to IV steroids for 3 days were treated with IV cyclosporine at doses of 2-4 mg/kg titrated to goal trough level of 300-400. At day 8 after IV cyclosporine was started (defined as week 0), those who responded were prescribed vedolizumab 300 mg IV. After vedolizumab was administered, cyclosporine was continued orally at double the IV dose and discontinued after 8 weeks of cyclosporine use. Vedolizumab was additionally dosed at 300 mg at weeks 2 and 6, followed by 300 mg IV every 8 weeks. Patients are planned to be followed up to 52 weeks. Demographics and disease information were reviewed. Clinical and endoscopic response and remission were the primary endpoints.

Results: 17 patients (mean age 40 (range 20-67 years)); mean disease duration 4.9±4 years with severe, steroid-resistant UC were treated with cyclosporine. Two patients did not respond to I.V cyclosporine and were referred to surgery. 15 (79%) patients (9/15 male) initially responded to I.V cyclosporine (median cyclosporine dose 200 mg (100-300) IV and 400 mg (200-600) oral. At admission, patients' median Lichtiger score was 12 and Mayo endoscopic subscore was 3. At initial follow-up at week 10, 11 (73%) patients achieved a Mayo subscore of ≤1 (decrease from 3 at admission). Patients' mean Lichtiger score decreased to 5 at week 0, CRP decreased to 15.9, 5.8 and 3.8 mg/L at weeks 0, 2, 6, respectively. At week 26, 14/15 patients were in clinical remission and 11/14 are still in endoscopic remission with Mayo subscore ≤1.

Conclusions: This is the first prospective study of cyclosporine and vedolizumab in steroid-refractory severe UC patients. We demonstrate significant effectiveness and safety of this treatment on week 10 and 26 after vedolizumab was started. Further trials are warranted.

Biography

Dino Tarabar graduated from University of Belgrade, School of Medicine in 1984. Specialized internal medicine in 1995 and currently is a subspecialist gastroenterologist/oncologist. He is a full professor and currently deputy chief of the Clinic of gastroenterology at the Military Medical Academy and also heads the department for the treatment of IBD. He is a member of the European Association for the Treatment of IBD (ECCO), a member of the American Association for the Treatment of IBD patients (CCFA), the Association of American Gastroenterologists (AGAF), the European Association for the Treatment of Malignancies (EORTC), the European Society of Medical Oncologists (ESMO). He has published more than 120 papers in domestic and international journals, 30 of which in journals of leading international significance.

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