Abstract / Povzetek predavanja

Efficacy and consumption of golimumab is similar with European and American dosing regimens in Ulcerative Colitis: Results of a prospective study

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Slovenian journal of gastroenterology / Gastroenterolog 2025; supplement 2: 38–39

***Keywords**: golimumab, dosing regimens, ulcerative colitis*

BACKGROUND

Golimumab is a subcutaneous TNF-alpha inhibitor approved for ulcerative colitis in European Union (EU) and United States of America (US). Interestingly, maintenance dose for patients weighing ≤80 kg is different in EU and US. In EU, golimumab maintenance dose in 50 mg every 4 weeks with an option of reactive dose escalation to 100 mg every 4 weeks in case of inappropriate response. In US, maintenance dose is 100 mg every 4 weeks for all patients, irrespective of body weight and response to induction. Here we compared efficacy, safety and drug consumption of EU and US maintenance dosing of golimumab in patients weighing ≤80 kg.

METHODS

In this investigator initiated prospective study (ClinicalTrials.gov ID: NCT04156984) we recruited 29 patients with active ulcerative colitis. After common induction (golimumab 200 mg at baseline and 100 mg at week 2) all patients received 1 year of maintenance treatment. First 15 patients received US maintenance regimen with 100 mg golimumab monthly and next 14 patients received EU maintenance regimen with 50 mg golimumab monthly. Those in EU regimen with inadequate response to induction or loss of response during maintenance phase (rectal bleeding score (RBS) > 0 or endoscopic Mayo score (eMayo) ≥ 2) increased dose of golimumab from 50 mg to 100 mg. Co-primary endpoints were endoscopic improvement (eMayo ≤ 1) at weeks 14 and 50 and clinical remission (RBS = 0 and stool frequency score (SFS) < 2) at weeks 14, 26, 38, and 50. Statistical analysis included Chi-square and Mann-Whitney tests.

RESULTS

Endoscopic improvement and clinical remission rates were similar with EU and US maintenance regimens. 8/14 (57%) of patients in EU regimen needed dose escalation to 100 mg due to inadequate response after a median of 8.6 weeks (interquartile range 6 to 14 weeks). Drug persistence and drug consumption was similar in both maintenance regimens. In the US regimen 3 potentially drug-related side effects occurred (one case each: one-dermatome herpes zoster, labial herpes, skin small vessel vasculitis), but none in the EU regimen.

CONCLUSION

In this prospective study, EU and US golimumab maintenance regimens resulted in similar endoscopic improvement and clinical remission rates during the first year of treatment with golimumab in patients with ulcerative colitis weighing ≤80 kg. Due to high dose escalation rates in EU regimen dose consumption was similar in both maintenance regimens.

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