

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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BACKGROUND AND AIM:

- ▶ Golimumab maintenance dose for patients weighing ≤ 80 kg differs in European Union (EU) (= 50 mg every 4 weeks) and United States of America (US) (= 100 mg every 4 weeks).
- ▶ But is efficacy, safety and drug consumption the same after 1 year of treatment?

MATERIAL AND METHODS:

- ▶ Prospective multicenter study of 29 patients ≤ 80 kg with ulcerative colitis.
- ▶ The same induction of golimumab and different 1 year maintenance regimen:
 - ▶ US (52 %): 100 mg every 4 weeks,
 - ▶ EU (48 %): 50 mg every 4 weeks:
 - ▶ Inadequate or loss of response in EU patients increase to 100 mg every 4 weeks.
- ▶ Co-primary endpoints: endoscopic improvement and clinical remission.

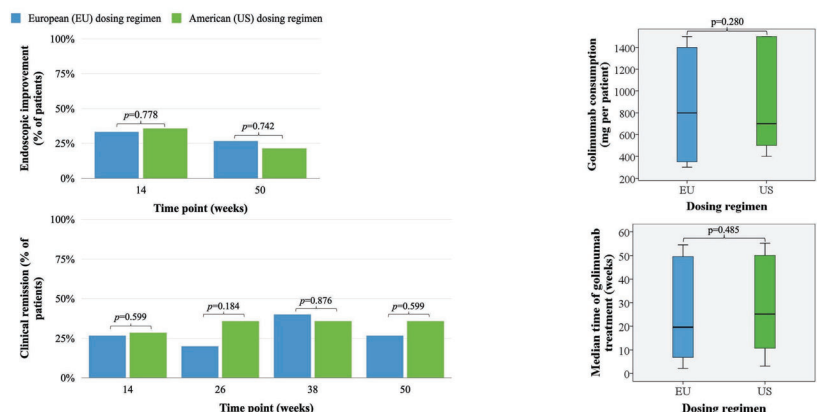
RESULTS:

- ▶ Patient demographic data (Table 1).
- ▶ Endoscopic improvement and clinical remission rates were similar in EU and USA maintenance regimens (Figure 1).
- ▶ 8/14 (57%) of patients in EU regimen needed dose escalation to 100 mg due to inadequate response.
- ▶ Drug persistence and drug consumption were similar in both maintenance regimens (Figure 1).
- ▶ In the US regimen 3 potentially drug-related side effects occurred, none in the EU regimen.

	European (EU) dosing regimen*	American (US) dosing regimen**	All patients	p-value
Number of patients	14	15	29	/
Sex, patient number (%)				
Male	4 (28.6)	5 (33.3)	9 (31.0)	/
Female	10 (71.4)	10 (66.7)	20 (67)	/
Age at diagnosis (years, median with range)	25 (14 – 53)	36 (17 – 66)	31 (14 – 66)	0.012
Montreal disease extent, number of patients (% per group)				
E1 (proctitis)	2 (13.3)	6 (40)	8 (27.6)	/
E2 (left-sided)	10 (66.6)	4 (26.7)	14 (48.3)	/
E3 (extensive)	2 (13.3)	5 (33.3)	7 (24.1)	/
Age at the start of golimumab treatment, median in years (range)	34 (18 – 58)	47 (19 – 71)	40 (19 – 71)	0.007
Treatment at the start of golimumab, number of patients (% per group)				
Aminosalicylates	11 (78.6)	10 (66.6)	21 (72.4)	0.474
Systemic steroids	6 (42.9)	4 (26.7)	10 (34.4)	0.359
Local steroids	1 (7.1)	2 (13.3)	3 (10.3)	0.584
Azathioprine	0 (0)	3 (20)	3 (10.3)	0.077

* EU: 50 mg of golimumab every 4 weeks with option of reactive dose escalation to 100 mg in case of inappropriate response
**US: 100 mg of golimumab every 4 weeks

Figure 1: Efficacy and consumption of golimumab in European vs. American dosing maintenance regimens



*US maintenance dosing regimen for patients ≤ 80 kg: 100 mg golimumab/4 weeks. EU maintenance dosing regimen for patients ≤ 80 kg: 50 mg golimumab/4 weeks with option of reactive dose escalation to 100 mg. EU - European Union, US - United States of America. **Endoscopic improvement: endoscopic Mayo < 2 , **Clinical remission (rectal bleeding score = 0 and stool frequency score < 2)

CONCLUSIONS:

- ▶ EU and US golimumab maintenance regimens resulted in similar endoscopic improvement and clinical remission rates in UC with body weight ≤ 80 kg
- ▶ Due to high dose escalation rates in EU regimen dose consumption was similar in both maintenance regimens.

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