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Background Vedolizumab is a gut-selective antibody to $\alpha_4\beta_7$ integrin approved for the treatment of moderate-to-severe ulcerative colitis (UC) and Crohn's disease (CD) in adult patients. Only 3% of patients in pivotal trials of vedolizumab were aged 65–80 years and patients aged >80 years were excluded. We analysed post-marketing safety data to investigate whether older patients reported a different safety profile with vedolizumab compared with younger patients.

Methods Adverse events (AEs) were identified from the vedolizumab Global Safety Database (cut-off: 19 May 2017) and classified by MedDRA Preferred Terms. Frequencies of AEs were calculated for patients aged ≥65 years (older) and <65 years (younger).

Results In the context of an estimated 114 071 patient-years of vedolizumab exposure, 1927 older and 12 164 younger patients reported AEs (Table 1). UC and CD were the primary treatment indications. In the older and younger groups, respectively, 51% and 61% of patients reported prior or concomitant exposure to anti-TNFs, 43% and 40% reported concomitant corticosteroids, and 17% and 21% reported a concomitant immunomodulator. Four of the five most commonly reported non-serious AEs were shared by both age groups: fatigue, increased blood pressure, arthralgia and headache (Table 2). The 5th non-serious AE was diarrhoea (older) and exacerbated UC (younger). Serious AEs were reported by 17% and 12% of patients in the older and younger groups, respectively. Serious AEs experienced by the older group (e.g. pneumonia and death) were as expected in that age group. AEs of particular clinical relevance in older patients (e.g. increased blood pressure and heart failure) constituted a small proportion of total AEs in both groups. Despite experiencing an AE, 76% of patients in each group continued vedolizumab.

Conclusion AEs reported more frequently in older patients in the post-marketing setting were events more commonly expected in this group (e.g. pneumonia and death). Other AEs were reported at similar frequencies in both age groups. Most patients reporting AEs continued treatment. Limitations of post-marketing safety reports, including: incomplete data, voluntary reporting and difficulty establishing a causal relationship between drug and event must be considered when interpreting these results.

Table 1. Patient characteristics

		≥ 65 years old (older)	< 65 years old (younger)
Total number of patients (N = 14 091)		1927	12 164
Sex, n (%)	Male	1016 (53)	5144 (42)
	Female	893 (46)	6915 (57)
	Not reported	18 (1)	105 (1)
Median age, years		71	40
Indication, n (%)	UC	988 (51)	5733 (47)
	CD	826 (43)	5737 (47)
	IBD (unspecified)	14 (1)	44 (< 1)
	Other	27 (1)	137 (1)
	Not reported	72 (4)	513 (4)
Treatment history, n (%)[a]	Prior treatment with anti-TNF	941 (49)	6791 (56)
	Concomitant treatment with anti-TNF	13 (1)	292 (2)
	Both prior and concomitant treatment with anti-TNF	19 (1)	343 (3)
	Concomitant treatment with corticosteroids	825 (43)	4891 (40)
	Concomitant treatment with immunomodulator	320 (17)	2569 (21)

[a]Includes all patients for which data were available
CD, Crohn's disease; IBD, inflammatory bowel disease; TNF, tumour necrosis factor; UC, ulcerative colitis

Table 2. Adverse events reported in the post-marketing setting

	≥ 65 years old (older)		< 65 years old (younger)	
Total AEs reported	5025		31 314	
Non-serious AEs, n (%)	4195 (83)		27 400 (88)	
Serious AEs, n (%)	830 (17)		3914 (12)	
Patients continuing treatment despite experiencing an AE, n (%)	9294 (76)		1468 (76)	
Most frequently reported non-serious AEs, n (%[a])	Increased blood pressure[b]	272 (5)	Fatigue	873 (3)
	Fatigue	151 (3)	Increased blood pressure[b]	720 (2)
	Diarrhoea	91 (2)	Headache	715 (2)
	Arthralgia	84 (2)	Arthralgia	608 (2)
	Headache	76 (2)	UC	511 (2)
Most frequently reported serious AEs, n (%[a])	Death	55 (1)	CD	181 (1)
	CD	27 (1)	UC	176 (1)
	UC	22 (< 1)	Intestinal obstruction	75 (< 1)
	Asthenia	16 (< 1)	Colectomy	69 (< 1)
	Pneumonia	16 (< 1)	Abdominal pain	60 (< 1)
AEs[c] of particular clinical relevance to older patients, n (%[a])	Increased blood pressure[b]	279 (6)	Increased blood pressure[b]	734 (2)
	Heart failure	4 (< 1)	Heart failure	9 (< 1)
	Cerebrovascular events	6 (< 1)	Cerebrovascular events	20 (< 1)
	Pneumonia	35 (1)	Pneumonia	107 (< 1)
	Septicaemia	5 (< 1)	Septicaemia	37 (< 1)
	Abscess	18 (< 1)	Abscess	187 (1)
	Pyelonephritis	0 (0)	Pyelonephritis	6 (< 1)
	Gastroenteritis	10 (< 1)	Gastroenteritis	76 (< 1)
	Any infection leading to hospitalization	73 (1)	Any infection leading to hospitalization	365 (1)

[a]As a proportion of all AEs reported in each age group
[b]Includes hypertension
[c]Non-serious and serious
AE, adverse event; CD, Crohn's disease; UC, ulcerative colitis