Letter: Optimizing Dupilumab Dosing in Atopic Dermatitis: Real-World Evidence

To the Editor:

Dupilumab has demonstrated remarkable efficacy in treating atopic dermatitis (AD). The recommended therapeutic regimen for adults consists of a 600 mg subcutaneous loading dose, followed by a maintenance dose of 300 mg every 2 weeks (Q2W). The SOLO-CONTINUE study[1] found that dose reduction led to decreased efficacy, supporting the approved Q2W regimen. However, recent real-world studies[2–5] suggest that extending the dosing interval may maintain effectiveness in patients with well-controlled AD.

The objective of this study was to evaluate a patient-centered dupilumab dosing regimen in a large, multicenter, real-world cohort, including adult and adolescent patients with moderate-to-severe AD who received standard-dose dupilumab and later transitioned to off-label dose spacing. Clinimetric scores included EASI (Eczema Area and Severity Index), P-NRS (Pruritus Numerical Rating Scale), Sleep Disturbances NRS, and Dermatology Life Quality Index. The Wilcoxon test evaluated differences across follow-ups; significance was set at $P < 0.05$ for all two-tailed analyses.

The population comprised 389 patients, of which 228 (58.6) were males, with a mean (SD) age of 41.3 (18.6). Most patients had an onset under 18 year old (241, 62.0%). Dose spacing was initiated after a mean (SD) of 126.5 (66.6) weeks, mainly due to clinical remission and mainly transitioning to a Q3W or Q4W scheme (Table 1). During the dose-spacing period, good clinical control was maintained in nearly all patients (Table 1). No significant clinical differences were found between Q3W and Q4W at any timepoint. Notably, the use of topical corticosteroids did not increase over time. Only 13 patients (3.3%) switched back to the Q2W regimen due

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The study was approved by the Ethics Committee of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan (Dupi Long Term 20221157_2022; 22-Dec-2022). The patients in this article have given written informed consent to publication of their case details.

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TABLE 1. Reason for Initiating Dose Spacing, Dose Spacing Regimens and Clinimetric Scores Evaluated at Baseline, at the Time of Dupilumab Spacing and After 16, 24, 32, 48 and 72 of Weeks after Dose Spacing

Score	Baseline n = 389	Dupilumab Spacing n = 389	Week 16 n = 207	Week 24 n = 142	Week 32 n = 92	Week 48 n = 97	Week 72 n = 46
EASI							
- Absolute score, median (Q1–Q3)	25.0 (24.0–30.0)	0.0 (0.0–1.0)	0.0 (1.0)	0.0 (1.5)	0.0 (0.0–1.8)	0.0 (0.0–1.0)	0.0 (0.0–2.0)
- % improvement, median (Q1–Q3)	/	100.00 (96.2–100.00)	100.0 (95.8–100.0)	100.0 (95.7–100.0)	100.0 (92.6–100.0)	100.0 (95.5–100.0)	100.0 (95.8–100.0)
- EASI-75, n (%)	/	387 (99.5)	202 (97.6)	138 (97.2)	87 (94.6)	8 (100.0)	43 (95.6)
- EASI-90, n (%)	/	348 (89.5)	186 (89.9)	125 (88.0)	76 (82.6)	89 (91.8)	41 (91.1)
- EASI-100, n (%)	/	266 (68.4)	130 (62.8)	91 (64.1)	57 (62.0)	65 (67.0)	30 (66.7)
	n = *389/389*	n = *389/389*	n = *207/207*	n = *142/142*	n = *92/92*	n = *97/97*	n = *45/46*
P-NRS							
- Absolute score, median (Q1–Q3)	8.0 (8.0–10.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)
- % improvement, median (Q1–Q3)	/	100.0 (87.5–100.0)	100.0 (85.7–100.0)	100.0 (85.7–100.0)	100.0 (88.9–100.0)	100.0 (86.2–100.0)	100.0 (87.5–100.0)
- P-NRS 0/1, n (%)	2 (0.5)	312 (80.2)	162 (78.3)	114 (80.3)	73 (80.2)	77 (79.4)	39 (84.8)
	n = *385/389*	n = *389/389*	n = *207/207*	n = *142/142*	n = *91/92*	n = *97/97*	n = *46/46*
SD-NRS							
- Absolute score, median (Q1–Q3)	7.0 (5.0–9.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
- % improvement, median (Q1–Q3)	/	100.0 (92.6–100.0)	100.0 (89.7–100.0)	100.0 (95.2–100.0)	100.0 (91.7–100.0)	100.0 (94.4–100.0)	100.0 (93.3–100.0)
- SD-NRS 0/1, n (%)	27 (7.2)	368 (95.3)	194 (94.6)	133 (95.0)	86 (93.5)	88 (92.6)	45 (100.0)
	n = *374/389*	n = *386/389*	n = *205/207*	n = *140/142*	n = *92/92*	n = *95/97*	n = *45/46*
MDA, n (%)		294 (75.6)	155 (74.9)	108 (76.1)	67 (73.6)	75 (77.3)	37 (82.2)
DLQI							
- Absolute score, median (Q1–Q3)	17.0 (11.0–22.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)
- % improvement, median (Q1–Q3)	/	100.0 (100.0–100.0)	100.0 (100.0–100.0)	100.0 (100.0–100.0)	100.0 (100.0–100.0)	100.0 (100.0–100.0)	100.0 (100.0–100.0)
- DLQI 0/1, n (%)	4 (1.1)	312 (82.5)	158 (77.8)	119 (85.0)	71 (79.8)	82 (86.3)	34 (82.9)
	n = *367/389*	n = *378/389*	n = *203/207*	n = *140/142*	n = *89/92*	n = *95/97*	n = *41/46*
Use of TCS, n (%)	351 (90.2)	81 (23.0)	51 (27.6)	28 (21.9)	15 (17.6)	13 (16.3)	6 (15.8)
		n = *352/389*	n = *185/207*	n = *128/142*	n = *87/92*	n = *80/97*	n = *38/46*
Reasons for initiating dose spacing, n (%)	Good clinical control, 356 (90.5) Ocular AEs, 12 (3.1) Good clinical control and ocular AEs, 12 (3.1) Patient preference, 3 (0.8) Other AEs, 6 (1.6) • Eosinophilia, 1 (0.3) • Facial redness, 1 (0.3) • Weight gain, 1 (0.3) • Good clinical control and arthralgias, 1 (0.3) • Good clinical control and weakness, 1 (0.3) • Post-injection nausea, 1 (0.03)		Adverse events after dose spacing		/	No improvement (n = 9), subjective improvement without complete remission (n = 12), complete remission (n = 3) / Complete remission Complete remission Weight loss but no return to initial weight Subjective improvement No improvement Subjective improvement		
Dose spacing regimens, n (%)		Q3W, 274 (70.4) Q4W, 86 (22.1) Q5W, 5 (1.3) Q6W, 2 (0.5) Q3W to Q4W, 22 (5.7) Q3W to Q6W, 4 (1.0)					

Patients were assessed at varying intervals, with data aggregated at 16 (±4), 24 (±4), 32 (±4), 48 (±4), and 72 (±4) weeks following dupilumab dose spacing.

At baseline, 21 patients had an SD-NRS of 0, 1 patient had a P-NRS of 0; these patients could not be included in the percentage improvement calculations for subsequent follow-ups.

n, valid data (non-missing data); EASI, Eczema Area and Severity Index; DLQI, Dermatology Life Quality Index; P-NRS, Pruritus-Numerical Rating Scale; SD-NRS, Sleep Disturbance Numerical Rating Scale; MDA, minimal disease activity (EASI-90, P-NRS 0/1, SD-NRS 0/1). EASI-75, improvement of at least 75% from baseline; EASI-90, improvement of at least 90% from baseline; EASI-100, complete remission; Q2W, injection every 2 weeks; Q3W, injection every 3 weeks; Q4W, injection every 4 weeks; Q5W, injection every 5 weeks; Q6W, injection every 6 weeks.

to clinical flares with a median of 22 weeks after the spacing, and 6 (1.5%) patients discontinued dupilumab during the observation period.

Our findings are even more promising than those of Spekhorst et al.,[2] where 21.2% of patients required a return to the standard Q2W dosing, compared to only 3.3% in our

cohort. Similar to their report, we observed no clinically significant differences. However, it is worth noting that our patients had a longer mean treatment duration before dose spacing (126.5 vs 65.5 weeks), which may explain both the lower EASI scores at the start of spacing and the reduced need to revert to Q2W dosing. Additionally, our results align with those of Mastorino et al.[3] regarding EASI scores before and after dose spacing, likely due to a comparable mean treatment duration (28.6 vs 31.5 months). Given the lack of significant clinical differences found between Q3W and Q4W regimens, and only 3.3% of patients who underwent dose spacing returned to the Q2W regimen, it would be reasonable and cost-effective to extend dosing to Q4W for all patients who achieve good control, accepting the minimal risk that a small percentage may require a return to Q2W.

Among patients who underwent dose spacing due to adverse events (AEs) (n = 24), particularly ocular AEs, only 3 achieved complete remission, while the majority (n = 12) reported subjective improvement without full remission, and 9 experienced no improvement. These findings suggest that dupilumab may not be the sole contributor to ocular AEs, or that dose spacing alone may be insufficient to resolve them. However, the following limitations should be acknowledged: the sample size of 24 patients is small, only subjective patient-reported symptoms were evaluated, and data on ophthalmological prescriptions and treatment adherence were not collected.

To summarize, our findings indicate that dupilumab dose reduction can be effective in patients with consistently controlled AD, and the drug may have a disease-modifying effect. However, a randomized, prospective clinical trial is warranted to better define the patient profiles most likely to benefit from this approach and to clarify its impact on AEs.

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