Dupilumab treatment reduces hospitalizations in adults with moderate-to-severe atopic dermatitis: a pooled analysis of data from 7 randomized, placebo-controlled studies

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INTRODUCTION

- Patients with atopic dermatitis (AD) may require inpatient hospital treatment for refractory AD, severe AD flares (exacerbations), and infections.[1]
- Dupilumab, a fully human monoclonal antibody that blocks the shared receptor component for interleukin-4 and interleukin-13, has demonstrated efficacy and was well tolerated in adults and adolescents with moderate-to-severe AD and in children aged ≥ 6 years with severe AD, in several randomized controlled trials (RCTs).[2-8]

OBJECTIVE

- **To compare hospitalization rates of adult patients with moderate-to-severe AD treated with dupilumab vs control by performing a post-hoc analysis of pooled data from 7 placebo-controlled RCTs including 2,932 patients.**

METHODS

- Data were analyzed from the safety populations of 7 placebo-controlled phase 2 and phase 3 RCTs in adult patients with moderate-to-severe AD that compared treatment with dupilumab 300 mg every 2 weeks (q2w) or weekly (qw) vs placebo for 12[2], 16[3-5,9], or 52[6] weeks.
  - 5 of these RCTs were monotherapy studies (NCT01548404[2], NCT02277743[4], NCT02277769[4], NCT01859988[5], NCT02210780[9]), and 2 RCTs required use of concomitant topical corticosteroids (TCS) (NCT02755649[3], NCT02260986[6]).
- We assessed hospitalization rates ("all-cause" and "AD-related"), and length of AD-related hospitalization
- Hospitalization events were identified through a review of serious adverse event (SAE) reports.
  - All-cause hospitalizations were defined as hospital admissions resulting from SAEs due to any reason.
  - AD-related hospitalizations were defined as hospitalizations that were related to AD per the reviewing medical directors' judgement.

METHODS (CONT.)

- Outcomes were compared for patients receiving dupilumab as monotherapy or with concomitant TCS, in the dupilumab 300 mg q2w, dupilumab 300 mg qw, and either posology combined ("dupilumab combined") groups versus controls (patients receiving placebo or placebo + TCS).

RESULTS

Table 1. Baseline demographics and disease characteristics and causes/diagnoses* of hospitalization

	Control (n = 1,091)	Dupilumab 300 mg q2w (n = 746)	Dupilumab 300 mg qw (n = 1,095)	Dupilumab Combined (N = 1,841)
Baseline demographics and disease characteristics†				
Age, y	38.0 (13.6)	38.5 (13.9)	37.6 (13.7)	38.0 (13.8)
Weight, kg	76.5 (18.9)	76.4 (18.0)	76.7 (18.3)	76.6 (18.2)
BMI, kg/m^2	26.4 (6.0)	26.1 (5.4)	26.1 (5.6)	26.1 (5.5)
AD disease duration, y	28.2 (14.6)	28.6 (15.3)	28.2 (14.7)	28.4 (15.0)
EASI	33.1 (13.5)	32.7 (13.0)	31.8 (12.8)	32.2 (12.9)
POEM score	20.3 (5.9)	20.2 (6.0)	20.3 (6.1)	20.3 (6.1)
DLQI total score	14.6 (7.4)	14.6 (7.3)	14.7 (7.5)	14.7 (7.4)
BSA, %	55.0 (22.8)	54.6 (21.9)	52.9 (22.1)	53.6 (22.0)
Hospitalization causes/diagnoses‡				
Hospitalizations	46 (9.0)	17 (5.8)	14 (2.7)	31 (3.8)
Exacerbation of AD§	13 (2.6)	5 (1.7)	1 (0.2)	6 (0.7)
Skin and soft-tissue infections	4 (0.8)	2 (0.7)	2 (0.4)	4 (0.5)
Other causes (non-exacerbation of AD)	33 (6.5)	12 (4.1)	13 (2.5)	25 (3.1)
Acute myocardial infarction	0	0	2 (0.4)	2 (0.2)
Decompensation of mood disorder (anxiety/depression)	0	2 (0.7)	0	2 (0.2)
Suicidal ideation	2 (0.4)	0	0	0

AD, atopic dermatitis; BMI, body mass index; BSA, body surface area; DLQI, Dermatitis Life Quality Index; EASI, Eczema Area and Severity Index; POEM, patient-oriented eczema measure; PY, patient-years; q2w, every 2 weeks; qw, every week; SD, standard deviation.
*Diagnoses were extracted from serious adverse event reports. Only diagnoses with >1 event are shown.
†Values are given in mean (SD).
‡Values are given as events (events per 100 PY).
§Exacerbation of AD includes both "exacerbation of AD" and "exacerbation of AD (erythrodermic AD)".

RESULTS (CONT.)

- A total of 2,932 patients (1,841 dupilumab and 1,091 control) from 28 countries were included in the analysis (29.3% from the USA, 14.9% from Germany, 13.3% from Poland, 10.3% from Canada, 8.5% from Japan, 23.7% from 23 other countries).
- Baseline demographics and characteristics (**Table 1**) were similar between the dupilumab and control groups.
- 77 hospitalization events were identified (31 in the dupilumab group, 46 in the control group).
- Patients who received dupilumab 300 mg q2w (n = 746), qw (n = 1,095), or dupilumab combined vs controls had lower rates of all-cause and AD-related hospitalizations (**Figure 1**), and reduced durations of AD-related hospitalizations (**Figure 2**).

Figure 1. Rates of all-cause and AD-related hospitalizations.

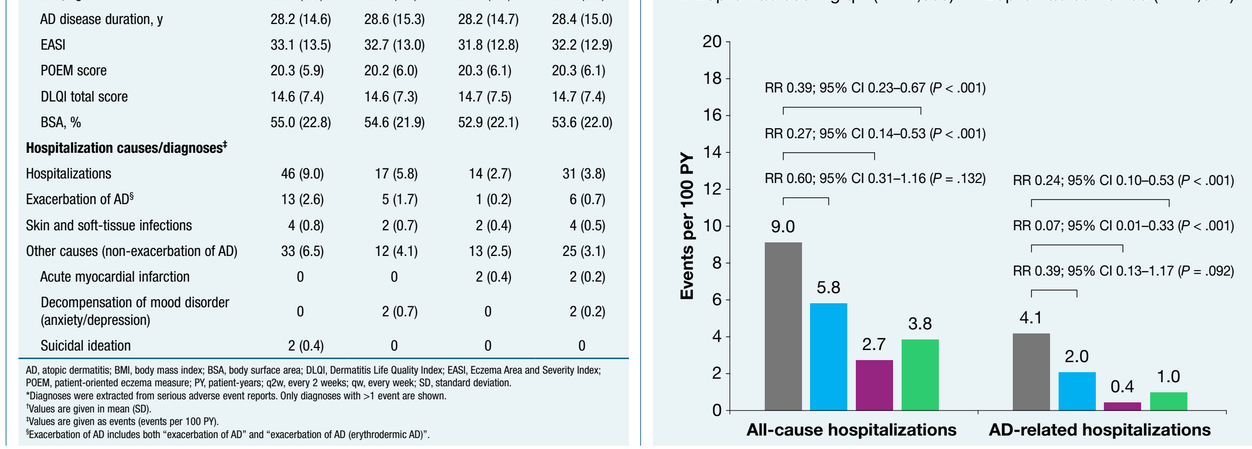
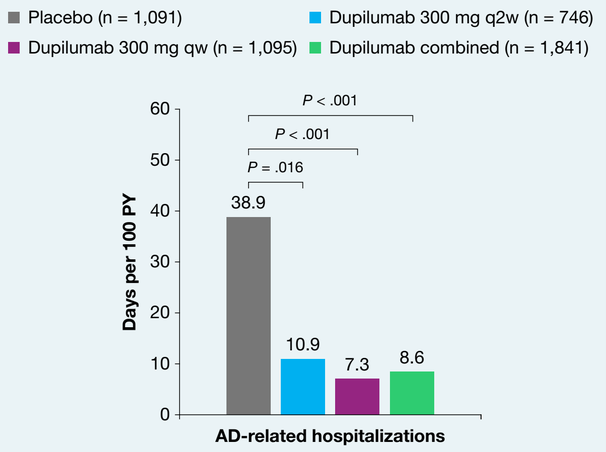


Figure 2. Duration of AD-related hospitalizations.



AD, atopic dermatitis; CI, confidence interval; PY, patient-years; q2w, every 2 weeks; qw, weekly; RR, rate ratio.

CONCLUSION

- **Among adults with moderate-to-severe AD, treatment with dupilumab was associated with significant reductions in all-cause and AD-related hospitalization rates, and shorter duration of AD-related hospitalizations, compared to a control group.**

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