

DUPIXAM: An SNDS (Système National des Données de Santé) Study to Characterize Patients Treated with Dupilumab for Moderate-to-severe Atopic Dermatitis in France

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CONTEXT AND OBJECTIVES

- On March 5th, 2019, dupilumab was granted reimbursement in France to treat adult patients with moderate-to-severe atopic dermatitis (AD), who were intolerant, contraindicated or failed a treatment with cyclosporine (CyA).
- In this context, Sanofi, upon request from the French HTA, conducted two studies to characterize French adult patients treated with dupilumab for moderate-to-severe AD and their previous therapeutic pathway.
- The first study called MOVE was an observational, multicenter, cross-sectional study conducted between 2019 and 2021 and included 594 patients in about 30 centers.
- The second study, DUPIXAM was an SNDS (Système National des Données de Santé - exhaustive claims database including 99.8% of patients treated within the national healthcare system) study on all patients who started a treatment with dupilumab 300mg between 2019-2020 for AD.
- Thanks to the exhaustiveness of the SNDS, DUPIXAM had to be conducted to show representativity of the MOVE study that included a smaller sample of patients, through a linkage process.
- The two studies, conducted in parallel, represented an innovative solution aimed to show robust data on all patients starting a treatment with dupilumab in France for atopic dermatitis by allying solid quantitative data from DUPIXAM to fine qualitative information from MOVE.

METHODS

- All patients who received dupilumab 300mg for moderate-to-severe AD, starting on March 5th, 2019, were first identified and categorized in each indication of interest.
- Indeed, between 2018 and 2020, dupilumab was granted reimbursement in three indications: AD, asthma and chronic rhinosinusitis with nasal polyps (CRSwNP). Because of the absence of diagnosis coding for outpatient consultations in the database, an algorithm was created to identify the patients who were treated with dupilumab specifically for AD (figure 1).
- When identified, the AD patients were characterized through their demographics, comorbidities, concomitant treatments, previous therapeutic journey: topicals and systemic treatments to treat moderate-to-severe AD, inpatient and outpatient consults.
- DUPIXAM patients were eventually linked to the MOVE patients using five variables of interest, in order to 1-validate the algorithm of DUPIXAM, and 2- show accuracy and robustness of the data collected in MOVE

RESULTS

- The results of the study are shown in table 1 and 2.
- Patients treated with dupilumab without previously receiving CyA tended to be older and presented more comorbidities and/or had already received a treatment with methotrexate.
- Besides, the linkage with the MOVE study using 5 variables, with a 92% sensibility, showed robustness of the data collected by physicians on a sample of patients with regards to the total French population. The linkage of DUPIXAM and MOVE showed representativity of the MOVE study and accuracy of the diagnosing algorithm developed for DUPIXAM.

Figure 1: Flow-chart of patients treated with dupilumab for atopic dermatitis

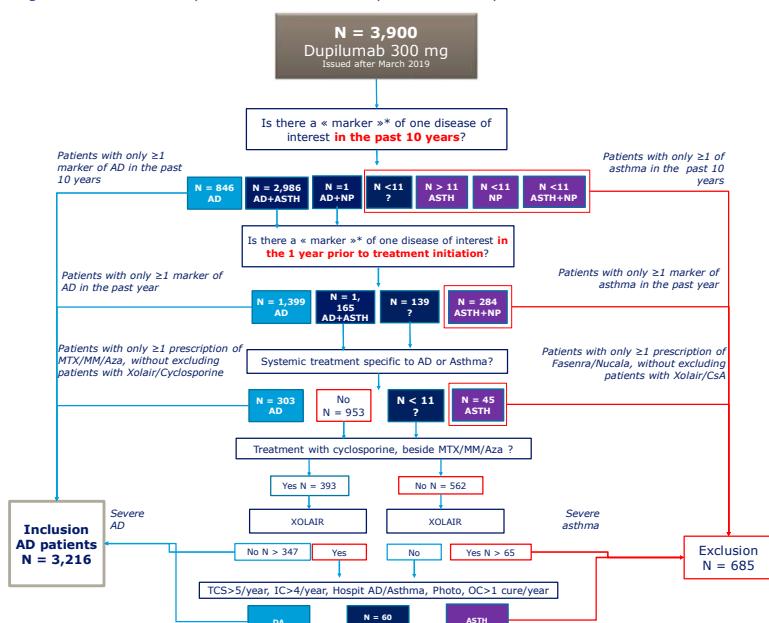


Table 1: DUPIXAM patients characteristics, linked vs non-linked to MOVE

	Linked to MOVE N = 305	Non-linked to MOVE N = 2,936
Demographics		
Age (mean ± SD)	38,4	43,3
Male	40,2 ± 17,1	45,8 ± 19,6
Female	36,4 ± 15,5	40,6 ± 17,7
Female, n (%)	142 (46,6)	1,389 (47,3)
Prescribing centers, n (%)		
CHU	138 (45,2)	1,658 (56,5)
CH	102 (33,4)	781 (26,6)
HIA	41 (13,4)	65 (2,21)
Private hospitals	18 (5,90)	124 (4,22)
Other	< 11	308 (10,5)
Healthcare resource use		
At least 1 hospitalization for AD	31 (10,2)	491 (16,7)
Systemic treatment (at least 1 delivery)		
Cyclosporine	161 (52,8)	1,381 (47,0)
Methotrexate	52 (17,0)	698 (23,8)
Mycophenolate mofetil	-	13 (0,4)
Azathioprine	< 11	56 (1,9)
Topical agents		
Topical corticosteroids	284 (93,1)	2,747 (93,6)
Tacrolimus	107 (35,1)	893 (30,4)
Emollients	65 (21,3)	734 (25,0)

Table 2: Medical history and precautions regarding other treatments in AD

	N = 3,216 (n, %)
Age ≥ 65 y.o	518 (16,1)
Active or History of Cancer	151 (4,7)
Ongoing infection	1,134 (35,3)
Moderate-to-severe liver failure	< 25
Cardiovascular risk	1,703 (53,0)
High blood pressure	809 (25,2)
Diabetes	442 (13,7)
Dyslipidemia	288 (9,0)
Renal failure (defined as ≥4 creatinine dosage/year)	670 (20,8)
Sleep Apnea	165 (5,1%)

CONCLUSION

DUPIXAM was the first study to profile exhaustively French patients with moderate-to-severe AD who were treated with a biologic agent. The study showed that the majority of patients with AD, who were treated with dupilumab, were ineligible to many other agents available on the market to treat moderate-to-severe AD, mostly due to contraindications of age and medical history.

DISCLOSURES Noémie ALLALI, Anne-Lise VATAIRE and Claire THENIE are Sanofi employees and may hold shares and/or stock options in the company. Emmanuel OGER has declared taking part in an advisory board with Novartis. This study was funded by Sanofi.