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RESEARCH ARTICLE

Improvements in self-confidence and satisfaction with self-injection after introducing self-injection of dupilumab in patients with atopic dermatitis

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Abstract

Dupilumab was approved for treating adult patients with atopic dermatitis (AD) refractory to topical therapy in Japan in April 2018, and self-injection of dupilumab has been available since May 2019. Subcutaneous self-injection of medication has benefits for patients and the healthcare system. However, anxiety about self-injection, lack of confidence, and the complicated procedure could prevent initiating self-injection. In this study, we assessed the experience of AD patients treated with dupilumab before and after introducing self-injection, utilizing the Self-Injection Assessment Questionnaire (SIAQ). Adult AD patients who received dupilumab by self-injection and had been treated for more than 3 months after initiating self-injection in our hospital from March 1, 2020, to June 19, 2021, were included in this study. Patients rated their perceptions about self-injections using the SIAQ before the first self-injection and 3 months after initiating self-injection. Data were collected retrospectively from their charts. Data on 36 patients were analyzed. The mean age was 34.1 ± 11.5 years. Twenty patients used a prefilled auto-injector, and the others used a prefilled syringe. Scores on self-confidence and satisfaction with self-injection significantly improved after introducing self-injection. Feelings about injections improved in patients over 40 years and in those who felt anxious about self-injection. A strong correlation in scores between satisfaction with self-injection and the ease of use was observed. The results were not affected by clinical severity, gender, or device. Our results could encourage patients who dither to introduce self-injection of dupilumab due to anxiety and/or lack of self-confidence about self-injection to initiate self-injection.

Masahiro Kamata and Takeko Ishikawa contributed to this work equally as a corresponding author.

KEYWORDS
atopic dermatitis, dupilumab, Self-Injection Assessment Questionnaire

1 | INTRODUCTION

Atopic dermatitis (AD) is a chronic inflammatory skin disease with pruritus, characterized by recurrent eczema with exacerbations and remissions, and impairs patients' quality of life. Dupilumab demonstrated good efficacy[1–3] and effectiveness[4–6] for adult patients with moderate-to-severe AD. In Japan, dupilumab was approved for treating adult AD patients in April 2018, and self-injection of dupilumab has been available since May 2019. Subcutaneous self-injection of medication has benefits for patients and the healthcare system. Self-injection at home can release patients from regular clinic visits, leading to higher adherence.[7] However, anxiety against self-injection, lack of confidence, and the complicated procedure could prevent initiation of self-injection.[8] In this study, we assessed the experience of AD patients who were being treated with dupilumab before and after introducing self-injection, utilizing the Japanese version of the Self-Injection Assessment Questionnaire (SIAQ) 2.0,[9,10] which was designed to evaluate the patient's perceptions before and after initiating self-injection, and which was deemed to be suitable for use in clinical studies.

2 | METHODS AND PATIENTS

Adult AD patients who were scheduled to initiate self-injection of dupilumab at our hospital from March 1, 2020, to June 19, 2021, were recruited for this study. Patients rated their perceptions about self-injections using the Japanese version of the SIAQ before the first self-injection (PRE) and 3 months after initiating self-injection (POST). All patients who completed the PRE- and POST-module assessments were included in the analysis. The two modules of the SIAQ were completed by patients while alone in a quiet environment. The detailed questionnaires are described in the previous literature.[9] Briefly, the SIAQ is composed of six concepts (five causal domains including "feelings about injections," "self-image," "self-confidence," "injection-site reactions," and "ease of use," and a determining factor, "satisfaction with self-injection" domain), and comprises two modules (the PRE-self-injection and the POST-self-injection modules). The PRE-module consists of seven items grouped into three domains (feelings about injections, self-confidence, and satisfaction with self-injection domain) and the POST-module consists of 21 items, grouped into six domains (all the domains mentioned above). The respondent rated all items of the PRE-module and 16 of the 21 items of the POST-module on a 5-point scale, and five items of the POST module on a 6-point semantic Likert-type scale. For all items, a score of 1 corresponds to the subject's worst experience and a score of 5 or 6 corresponds to the subject's best experience. Item scores were transformed to obtain a score ranging from 0 (worst experience) to 10 (best experience) for each item. The domain score was the mean of the item scores included in the domain. Domain scores were calculated only if at least half of the domain items were completed.

We also collected the data on the Eczema Area and Severity Index (EASI) and the visual analog scale (VAS) score of pruritus. We compared the domain scores of feelings about injection, self-confidence, and satisfaction with self-injection before (PRE) and 3 months after initiating self-injection (POST). Differences by device, gender, or age were also evaluated. In addition, we calculated their improvement rates, and evaluated correlations between improvement rates of the domain scores and those of the EASI score or VAS score of pruritus. All data were collected retrospectively from their charts.

Regarding statistical analyses, for comparison of two-paired samples, Wilcoxon signed-rank test was used. For comparison of two independent samples, Mann–Whitney *U*-test was used. Correlations were analyzed with the Spearman correlation method. Values of $p < .05$ were considered to represent significant differences.

This study was approved by the institutional review board of Teikyo University (19-237) and was carried out under the principles of the Declaration of Helsinki. Written informed consent was obtained from all of the participants.

3 | RESULTS

Thirty-six adult AD patients (12 females and 24 males) who initiated self-injection of dupilumab and were treated for more than 3 months after initiating self-injection were analyzed. Their demographic and clinical characteristics are shown in Table 1. The mean age was 34.1 ± 11.5 (standard deviation) years. Sixteen patients (44.4%) used a prefilled syringe, and 20 (55.6%) used an auto-injector (prefilled pen). The clinical severity was moderate to severe in all patients (EASI 30.8 ± 10.7), and they suffered from pruritus (VAS 60.7 ± 21.7/100 mm). Three months after initiating self-injection of dupilumab, their symptoms improved (EASI 10.6 ± 5.4, VAS 24.8 ± 19.0/100 mm).

The SIAQ scores before (PRE) and 3 months after introducing self-injection of dupilumab (POST) are shown in Table 2 and Figure 1A. Scores of self-confidence and satisfaction with self-injection significantly improved (from 3.59 ± 2.16 to 5.74 ± 1.94, $p < .01$; from 4.72 ± 1.53 to 6.80 ± 1.31, $p < .01$, respectively), whereas there was no significant difference in scores of feeling about injections between PRE and POST (6.15 ± 2.29, 6.62 ± 2.04, $p = .22$). Scores of self-image, ease of use, and injection-site reaction which were included only in the POST-module were generally high (8.61 ± 2.16, 9.15 ± 0.70, 7.89 ± 1.80, respectively).

Next, we evaluated whether the type of device, gender, or age affected the SIAQ scores (Figure 1B–D, Table 3). The type of device did not affect the results. Regarding gender, there were no differences in the results between male and female patients except that female patients had a slightly lower score on injection-site reaction. As for age, scores of feelings about injection in patients ≥40 years were numerically lower than those in patients <40 years (5.83 ± 2.61, 6.31 ± 2.09, respectively), although there was no significant difference. In patients ≥40 years, the score on feelings about injection significantly improved at the POST evaluation (from 5.83 ± 2.61 to 6.60 ± 2.69, $p = .044$), whereas no significant difference was observed between the scores on PRE- and POST-feelings about injection in patients <40 years ($p = .35$). This indicates that some elderly patients were anxious about injection before introducing self-injection, but that the anxiety was dispelled 3 months after initiating self-injection. We also compared the results between patients with PRE scores <5 and those with PRE scores ≥5 (Figure 1E, Table 4). Regarding scores on self-confidence and satisfaction with self-injection, those scores improved at the POST evaluation regardless of the PRE values. Meanwhile, regarding feeling about injections, patients with PRE scores <5 showed significant improvement at the POST evaluation (from 2.77 ± 1.30 to 4.91 ± 2.34, $p = .022$), whereas those with PRE scores ≥5 did not (from 7.28 ± 1.17 to 7.19 ± 1.56, $p = .79$). This suggests that even if patients are anxious about self-injection, most of them will not feel anxiety 3 months after initiating self-injection.

We examined the association between improvement in eruption or pruritus and the improvement in SIAQ scores. No significant correlations were observed between improvement rates of EASI or VAS score of pruritus and those of SIAQ scores (Figure S1).

Lastly, we assessed what factors contributed most to satisfaction with self-injection at the POST evaluation (Figure 2). The scores of satisfaction with self-injection were strongly and positively correlated with those of ease of use of the device ($r = .71$, $p < .01$), followed by self-confidence ($r = .64$, $p < .01$), and injection-site reaction ($r = .53$, $p < .01$).

TABLE 1 Demographic characteristics and clinical severity of the patients with AD.

Gender	Female, 12 (33.3%); male 24 (66.7%)
Age (years)	34.1 ± 11.5 (standard deviation), range 18–59
Device	Prefilled syringe, 20 (55.6%); Auto-injector (prefilled pen), 16 (44.4%)
EASI at baseline[a]	30.8 ± 10.7
EASI at 3 months	10.6 ± 5.4
VAS score of pruritus at baseline	60.7 ± 21.7/100 mm
VAS score of pruritus at 3 months	24.8 ± 19.0/100 mm

Note: Results are shown as number (%) or mean ± standard deviation.
Abbreviations: EASI, Eczema Area and Severity Index; VAS, visual analog scale.
[a]EASI and VAS scores of pruritis before (baseline) and 3 months after initiation of self-injection of dupilumab, are shown.

4 | DISCUSSION

Self-injection at home is associated with a wide range of benefits including increased flexibility in the time and place of injection administration.[9,11] It offers convenience and enables treatment to fit into the individual's daily life. In addition, patients do not have to take time off from work to come to the hospital for injections.[12] However, some patients hesitate to introduce self-injection because of anxiety and/or lack of self-confidence. According to a previous study in patients with rheumatoid arthritis,[13] younger patients were significantly more confident about self-administering treatment and preferred self-administration, whereas older patients preferred health care staff to administer treatment and more readily identified "contact with other patients/meeting others" and "staff availability if problems arise" as factors influencing their choice. Similarly, our study demonstrated that AD patients older than 40 years old tended to be anxious about self-injection. However, even in patients with anxiety about self-injection, their anxiety was reduced 3 months after initiating self-injection. Regarding self-confidence, their self-confidence improved at the POST evaluation regardless of age, gender, and type of injector. AD patients were more satisfied with self-injection at the POST evaluation than at the PRE evaluation.

TABLE 2 Self-Injection Assessment Questionnaire scores before and 3 months after initiating self-injection of dupilumab in patients with atopic dermatitis.

Domains	PRE (mean ± SD)	POST (mean ± SD)	*p*
Feelings about injections	6.15 ± 2.29	6.62 ± 2.04	.22
Self-confidence	3.59 ± 2.16	5.74 ± 1.94	**.000021**
Satisfaction with self-injection	4.72 ± 1.53	6.80 ± 1.31	**.0075**
Self-image	–	8.61 ± 2.16	–
Ease of use	–	9.15 ± 0.70	–
Injection-site reaction	–	7.89 ± 1.80	–

Note: Bold values represent $p < .05$.
Abbreviation: SD, standard deviation.

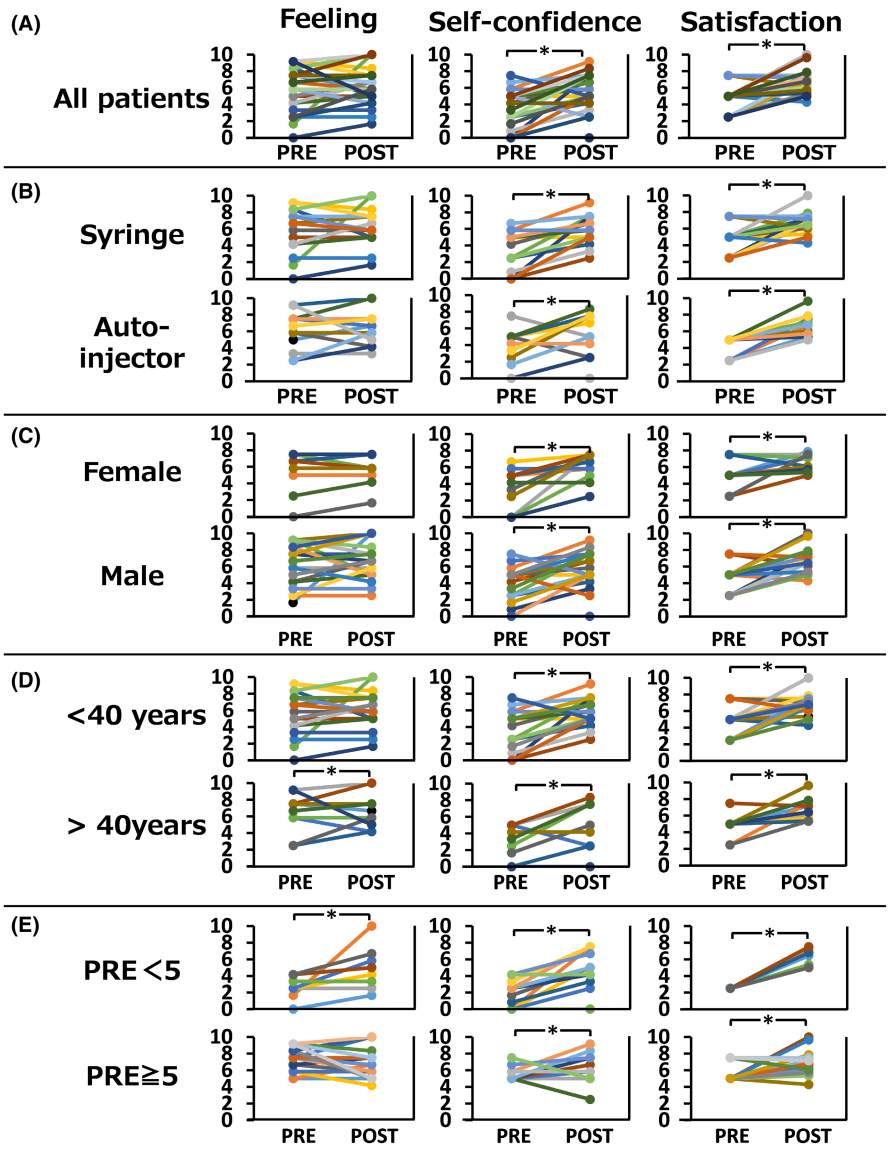

FIGURE 1 Changes in scores on feeling, self-confidence, and satisfaction with self-injection before (PRE) and 3 months after (POST) initiating self-injection of dupilumab (A). Changes in these scores according to the device used (B), gender (C), age (D), or the PRE score (E) are also shown. *$p < .05$.

Our results could encourage patients who dither to introduce self-injection due to anxiety and/or lack of self-confidence about self-injection to initiate self-injection.

The scores on satisfaction with self-injection were strongly correlated with those on ease of use of the device in addition to self-confidence and injection-site reaction. According to the study in patients with rheumatoid arthritis conducted by Frances et al.,[13] patient preferences were related to ease of administration, preparation of the drug and its availability as a prefilled, ready-to-use injectable medicine, reducing the possibility of drug errors. Our data and the previous study indicate that ease of use of the device is one of the most important factors in satisfaction with self-injection. Meanwhile, our study showed no evident difference in satisfaction with self-injection between patients who used a syringe and those who used an auto-injector. The syringe is prefilled with a drug solution, and patients do not need to reconstitute the medicine. Therefore, even a syringe could be easy to use. Furthermore, epidemiologically, most AD patients are young. Therefore, they may be able to learn self-injection with a syringe easily.

Although self-injection at home is available in several biologic agents for psoriasis, data on satisfaction with self-injection are limited in psoriasis patients as in AD patients. To our best knowledge, there is only one article reporting SIAQ in psoriasis patients. Auto-injector usability was evaluated by SIAQ in the clinical trial of secukinumab, an anti-interleukin-17 antibody, in patients with psoriatic arthritis (PsA).[14] Baseline scores of feelings about injections, self-confidence, and satisfactions with self-injection were 8.3 ± 1.8, 6.6 ± 2.7, and 6.6 ± 2.4 in patients who were assigned to secukinumab 300 mg. The patients who were assigned to secukinumab 150 mg, or placebo showed almost the same scores. In our study, baseline values were 6.15 ± 2.29, 3.59 ± 2.16, and 4.72 ± 1.53, respectively. These scores in our study were lower than those in the clinical trial of secukinumab for PsA. It indicates that AD patients may be more anxious, have

TABLE 3 Self-Injection Assessment Questionnaire scores before and 3 months after introducing self-injection of dupilumab by device, gender, and age.

	Syringe $n=20$	Auto-injector $n=16$	p	Female $n=12$	Male $n=24$	p	Age < 40 years $n=24$	Age ≥ 40 years $n=12$	p
Feelings about injections									
PRE	6.00 (2.48)	6.35 (2.02)	.80	5.90 (2.27)	6.28 (2.29)	.60	6.31 (2.09)	5.83 (2.61)	.60
POST	6.58 (2.19)	6.67 (1.83)	.99	6.11 (1.75)	6.88 (2.13)	.45	6.63 (1.62)	6.60 (2.69)	.90
p	.51	.31		.75	.26		.35	**.044**	
Self-confidence									
PRE	3.50 (2.29)	3.70 (2.00)	1.00	3.13 (2.43)	3.82 (1.98)	.48	3.64 (2.18)	3.47 (2.15)	.48
POST	5.75 (1.56)	5.73 (2.34)	.64	5.83 (1.83)	5.69 (1.99)	.80	5.83 (1.97)	5.56 (1.87)	.67
p	**.00045**	**.0075**		**.0057**	**.0011**		**.00044**	**.040**	
Satisfaction with self-injection									
PRE	5.00 (1.77)	4.38 (1.08)	.28	5.02 (1.60)	4.48 (1.44)	.20	4.69 (1.66)	4.79 (1.23)	.82
POST	6.80 (1.39)	6.79 (1.21)	.87	6.55 (0.90)	6.92 (1.46)	.66	6.90 (1.31)	6.58 (1.27)	.44
p	**.0058**	**.00047**		**.026**	**.00011**		**.00020**	**.0046**	
Self-image									
POST	9.13 (1.63)	7.97 (2.53)	.13	8.54 (2.59)	8.65 (1.90)	.70	9.06 (1.58)	7.71 (2.79)	.16
Ease of use									
POST	8.18 (1.45)	7.53 (2.11)	.56	7.43 (1.77)	8.12 (1.77)	.29	8.05 (1.64)	7.56 (2.05)	.61
Injection-site reaction									
POST	9.22 (0.68)	9.06 (0.71)	.49	8.78 (0.68)	9.33 (0.63)	**.025**	9.11 (0.63)	9.23 (0.81)	.38

Note: Results are shown as mean (standard deviation). Bold values represent $p < .05$.

TABLE 4 Comparison of Self-Injection Assessment Questionnaire scores before and 3 months after introduction of self-injection of dupilumab with the boundary of PRE-score of 5 points.

	PRE (mean ± SD)	POST (mean ± SD)	p
Feeling about injections			
PRE < 5 ($n=9$)	2.77 ± 1.30	4.91 ± 2.34	**.022**
PRE ≥ 5 ($n=27$)	7.28 ± 1.17	7.19 ± 1.56	.79
Self-confidence			
PRE < 5 ($n=18$)	1.76 ± 1.47	5.05 ± 2.05	**.00044**
PRE ≥ 5 ($n=18$)	5.42 ± 075	6.35 ± 1.54	**.036**
Satisfaction with self-injection			
PRE < 5 ($n=9$)	2.5 ± 0.00	6.39 ± 0.96	**.0090**
PRE ≥ 5 ($n=27$)	5.46 ± 0.97	6.93 ± 1.39	**.00051**

Note: Bold values represent $p < .05$.

lower self-confidence, and be less satisfied with self-injection than PsA patients. This difference in baseline scores between AD patients and PsA patients might be due to age, ethnicity, or disease. Further studies are needed to clarify this difference. In the clinical trial of secukinumab for PsA, scores of feelings about injections, self-confidence, and satisfactions with self-injection improved (9.0 ± 1.8, 8.7 ± 2.0, and 8.8 ± 1.6 in patients who were assigned to secukinumab 300 mg) 2 weeks after self-injection, namely, after having experienced self-injection twice, although statistical analysis was not conducted. The extent of improvement in scores of feelings about injections (0.7) was small compared with scores of self-confidence (2.1) and satisfactions with self-injection (2.2) as in our study (0.47, 2.15, 2.08, respectively), indicating that patients can easily gain self-confidence and satisfaction by experiencing self-injection whereas it is difficult to relieve anxiety even after experiencing it. However, the small improvement in feelings about injections in the clinical trial of secukinumab for PsA might be due to high scores at baseline (8.3 ± 1.8), and there might be no room for further improvement. Further accumulation of studies is needed to clarify it.

One limitation of this study is the small number of patients since this was a single-center study.

In conclusion, self-confidence and satisfaction with self-injection improved 3 months after initiating self-injection of dupilumab in AD patients. Reduction of anxiety was observed in patients over 40 years old and patients who felt anxious about self-injection 3 months after initiating self-injection. Satisfaction with self-injection was mainly influenced by ease of use of the device, self-confidence, and injection-site reaction. Before initiating self-injection, AD patients tend to be anxious, have low self-confidence, and be less satisfied with self-injection compared with PsA patients. Our results could be helpful for patients who dither to introduce self-injection due to anxiety and/or lack of confidence.

FIGURE 2 Correlations between Self-Injection Assessment Questionnaire domain scores at 3 months after the first self-injection.

0.4≦r≦0.7 0.7≦r≦1.0

Domains	Satisfaction with self-injection	Self-confidence	Feelings about injections	Self-image	Ease of use (of the device)	Injection-site reaction
Satisfaction with self-injection		r=0.64 (*0.000028*)	0.37 (*0.026*)	0.22 (*0.20*)	0.71 (*0.0000015*)	0.53 (*0.00094*)
Self-confidence			0.41 (*p=0.012*)	0.047 (*0.78*)	0.60 (*0.00013*)	0.46 (*0.0051*)
Feelings about injections				0.28 (*0.10*)	0.39 (*0.019*)	0.61 (*0.000077*)
Self-image					0.11 (*0.54*)	0.22 (*0.19*)
Ease of use (of the device)						0.56 (*0.00039*)
Injection-site reaction						

AUTHOR CONTRIBUTIONS

MK designed the study. MI, TI, and MK wrote the first draft of the manuscript. MI and TI performed the statistical analysis and interpretation of the results. All authors contributed to data collection and read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, M.K., upon reasonable request.

ETHICS STATEMENT

Approval of the research protocol: 19-237.

Informed Consent: Obtained.

Registry and the Registration No. of the study/trial: N/A.

Animal Studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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