ORIGINAL ARTICLE

Impact on quality of life of an intervention providing additional information to patients with allergic contact dermatitis; a randomized clinical trial

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Abstract

Background Allergic contact dermatitis can negatively impact an individual's daily life in terms of work and interpersonal relationships. Patch-tested individuals show an improved quality of life (QoL).

Objectives We aimed to assess the impact on QoL after patch testing and what value an intervention would have on QoL.

Methods Dermatology Quality of Life Index (DLQI) were assessed in participants with positive patch test reaction. The participants were randomized, in parallel design, into two groups that received either standard information (controls, n = 70) or a reminder letter in addition to standard information (intervention group, n = 66), ClinicalTrials.gov NCT01953380.

Results The response rate was 74% (n = 136). The DLQI score was significantly lower 1 year after patch testing in comparison with baseline in the entire group (mean DLQI 6.3 and 4.5 respectively, 95% CI 0.93-2.72, P < 0.001). However, linear regression analyses showed no significant differences in DLQI score at follow-up between the intervention and control groups. Neither age nor gender had impact on DLQI score.

Conclusion There was an improvement of QoL at follow-up in the entire group. However, the intervention performed did not show any significantly greater improvement concerning QoL. Further research is needed to understand what factors apart from patch testing and medical care may affect QoL in patients with contact dermatitis, and what interventions are needed to improve QoL.

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Conflicts of interest

Andreas Sonesson has received consulting and lecturing fees from SanofiGenzyme, Abbvie, Pfizer and LeoPharma. The payments were made to AS's institution. KM, AD and ÅS have no conflicts of interest to declare.

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Introduction

Contact dermatitis (CD) is one of the most common dermatological conditions.¹ Atopic dermatitis and CD can cause a chronic recurrent and potentially therapy-resistant eczema that can significantly impair the patients' quality of life (QoL), affecting both daily functioning and interpersonal relationships.² Over the past few decades, there has been a greater focus on QoL in patients with dermatologic diseases and QoL assessments have

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become an important outcome variable in dermatologic research.²

The overall analysis of the severity of the dermatitis is often based on external signs of eczema and the clinical evaluation. However, this assessment does not include the associated social and personal factors that may burden the patient. This may vary between individuals and is not necessarily correlated with the clinical appearance of the eczema. It is important to separate the severity of the dermatitis from the impact on QoL when assessing clinical response to therapies.³ Allergic contact hand

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dermatitis has a more serious impact on a patient's overall QoL compared with other types of hand eczema.⁴

The Dermatology Quality of Life Index (DLQI) is a dermatology-specific assessment tool intended to measure the subjective symptoms of having a skin disorder. DLQI has been widely used as a measurement of QoL in individuals with atopic dermatitis and hand eczema.^{5,6}

Patch testing in patients with CD has previously shown to have a high cost–benefit ratio and is well accepted by patients.⁷ Few studies have focused on allergic CD and the impact of patch testing on QoL.

One study found an improvement of OoL in patients with allergic CD who underwent a patch test, regardless of the results of the patch test.⁸ Similarly, another study with the same followup period found greater improvement in DLQI in patients with a positive patch test.⁹ Moreover, Thomson et al. showed a significant improvement in the DLQI score in patients with a positive patch test, which could not be seen in patients who had a negative patch test result. Interestingly, the patients in the study received a letter soon after patch testing containing written information about the specific allergen they tested positive for and most patients were able to remember to avoid these tested allergens.¹⁰ In addition, Woo et al.¹¹ found an improved QoL at 6-week follow-up in patients with eczema who had showed positive patch-tested results of a relevant allergen. In this study most patients had changed their lifestyle to avoid the allergen, and patients with a negative patch test result showed almost the same improvement in QoL. Another study found an improvement in DLQI score in all patients with hand eczema, regardless of a positive or a negative patch test result, at 6-week follow-up. But the improvement was greater in the group of patients with a positive patch test than in patients with a negative patch test.¹²

A Swedish intervention study examined patients' ability to recall their patch test results at a 10-year follow-up period. They found that QoL improves over time after a patch test, but it could not be associated with the outcome of the patch test nor with the patients' recollection ability.¹³

In this study we wanted to examine whether the QoL over time (1 year after patch test) would improve in patients with allergic CD and if the QoL would be affected by an intervention executed after patch testing, providing more information about the diagnosed allergens. Additionally, we investigated whether there was a difference in the studied patients associated with age or gender.

Methods and materials

From 2013 to 2016, a total of 396 consecutive patients at the Department of Dermatology and Venereology at Lund University Hospital, who were suspected of having allergic CD at the time of patch testing and were aged 18 or over, were included in an intervention study (ClinicalTrials.gov NCT01953380) of allergic CD and the patients' recollection of allergen

information.¹⁴ In this study DLQI was assessed among the participants as a secondary outcome measure. All patients were patch tested so as to meet the Swedish baseline series criteria of 2014 and the result was assessed as positive or negative. Of these, 46% (184 of 396) were diagnosed with one or more positive patch test reactions and were randomized into two groups, as previously described.¹⁴ Patients with a negative patch test result were excluded. The randomisation was performed by using the R software (www.r-project.org), in block size of eight, and stratified according to gender. Of the eligible patients, 74% (136 of 184) correctly filled out the DLQI questionnaires and were included in this study.

Both groups received physician advices, including the same information both orally and in writing at baseline during their visit at the dermatologic clinic according to local routine, including patch test results, information on the diagnosed allergen and how to discover and avoid allergen-containing substances in the patients' environment, prepared by the Swedish Association of Dermatology and Venereology, https://ssdv.se/ svenska-saellskapet-foer-arbets-och-miljoedermatologi-ssamd/ radlappar. Additionally, the intervention group received a letter by post after 3 months, where they received the same information as in the initial visit. After 12 months a questionnaire, including DLQI, was sent by post to both groups. The investigators were blinded regarding the intervention group throughout the study.

The DLQI was developed in 1994 and is a reliable and validated instrument for assessing QoL in the dermatologic patient.^{5,6} DLQI consists of a 10-item questionnaire covering the impact of dermatitis during the past week with regards to six aspects of daily life: symptoms and feelings; daily activities; leisure, work and school; personal relationships and treatment. Each question is rated from 0 (not at all) to 3 (very much). DLQI is calculated by summing up the score of each question, with a maximum score of 30 and a minimum score of 0; the lower the score, the better the patient's QoL is.^{5,15} As a means of interpreting what DLQI score is clinically meaningful, one study proposed that a score <5 was considered a small impact on a patient's life, scores 6-10 would mean a moderate impact and a score >10 would indicate a very large or extremely large impact on QoL.¹⁶ A DLQI score under 5 has been somewhat commonly accepted as a value representing passable QoL.¹⁷

The questionnaires at baseline were completed at the department before patch testing was executed. Demographic information including diagnosis, job, prior skin problems, allergies, atopy and self-scoring of eczema severity were analysed and used as baseline characteristics in the two groups. The follow-up questionnaires were sent to the participants and returned to the department once answered. DLQI was measured by separate standard questionnaire on both occasions. Information on the patients' recollection of the contact allergy test results has previously been published.¹⁴ The study was approved by the Regional Ethics Examination board of Lund, Sweden (entry no. 100/2013), and the participants gave informed consent complying with the Helsinki Declaration.

Statistics

Two linear regression models were estimated to compare the DLQI score at follow-up between the groups. The first model was adjusted for DLQI at baseline and the second model was adjusted for DLQI at baseline, gender and age groups. The White estimator (HC3) was applied due to signs of heteroscedasticity. Sample size was calculated as previously described.¹⁴

A paired *t*-test was performed to test for differences in DLQI at baseline compared with DLQI at follow-up in the entire group. A *P*-value <0.05 was considered to indicate significance. The statistical analysis was performed in R version 4.0.2.¹⁸ The sandwich package¹⁹ and lmtest package²⁰ was used for linear regression with heteroscedasticity consistent standard errors.

Results

Among the included individuals, 184 patients with eczema tested positive for a least one allergen and 136 patients completed the DLQI questionnaire both at baseline and at follow-up, i.e., the response rate was 74% (136 of 184). The response rate was similar in both groups (76 and 72% in the control group and intervention group, respectively). The responders and dropouts were considered similar regarding age and gender distribution (Table 1). Among the included participants, 54% (99 of 184) of the participants stated that they suffered from hand eczema, 44.5% (82 of 184) did not suffer from hand eczema, and 1.5% (3 of 184) participants gave no answer. Moreover, 93% (172 of 184) of the participants answered the question if they had noticed if contact with materials or chemicals, associated to the participants work, worsen the dermatitis. Thirty-four percent (59 of 172) stated contact with materials or chemicals at work was associated with worsening of the dermatitis, 45% (77 of 172) did not have such association and 21% (36 of 172) did not

Table 1	Comparison of	responders and	dropouts
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Background variable	Measure	Responders (<i>n</i> = 136)	Dropouts (<i>n</i> = 48)
Age	Median	48.0	42.5
	First quartile	34.0	27.5
	Third quartile	60.0	61.25
	Min	18.0	18.0
	Max	87.0	84.0
Age group	<40	47 (35%)	23 (48%)
	40–60	59 (43%)	12 (25%)
	>60	30 (22%)	13 (27%)
Gender	Female	105 (77%)	37 (77%)
	Male	31 (23%)	11 (23%)

know. There were no differences between the intervention group and the control group regarding gender, age or DLQI at baseline (Table 2).

The distribution of DLQI in the intervention group and the control group at baseline and at follow-up is presented in Fig. 1. To test for differences in DLQI at baseline and DLQI at follow-up in the entire group, a t-test was performed. The results showed a significant difference in DLQI score at baseline (mean = 6.32) and follow-up (mean = 4.5), (95% CI: 0.93-2.72, *P*-value <0.001).

Moreover, we investigated how the DLQI scores among the participants were distributed using a cut-off value of a DLQI score of 5, in accordance with previous reports¹⁶ (Fig. 2). Ten individuals in the control group (14%) reported a DLQI score of 10 or more at follow-up vs. six patients (9%) in the intervention group. Twenty-four patients in the control group (34%) and 16 in the intervention group (24%) reported a DLQI score over 5 at follow-up. Four patients in the control group had a DLQI score over 20 at follow-up, which no one had in the intervention group. There was a smaller dispersion of DLQI scores in the intervention group at follow-up compared with the control group (Figs 1 and 2).

Two linear regression models were estimated to compare DLQI at follow-up between the groups. The first model was adjusted for DLQI at baseline and the second model was adjusted for DLQI at baseline, gender and age groups. Although

Table 2 Characteristics of the participants

	Measure/ category	Intervention group (<i>n</i> = 66)	Control group (<i>n</i> = 70)	Both groups (<i>n</i> = 136)
Age group	<40	25 (37.9%)	22 (31.4%)	47 (34.6%)
	40–60	23 (34.8%)	36 (51.4%)	59 (43.4%)
	>60	18 (27.3%)	12 (17.1%)	30 (22.1%)
Age (years)	Min	18	18	18
	First quartile	34	35.25	34
	Median	47.5	48.5	48
	Third quartile	62	58.5	60
	Max	87	79	87
Gender	Male	15 (22.7%)	16 (22.9%)	31 (22.8%)
	Female	51 (77.3%)	54 (77.1%)	105 (77.2%)
Dermatology	First quartile	2.25	2	2
Quality of Life	Median	5	4.5	5
Index (DLQI) baseline	Third quartile	8.75	8	8.25
Daseillie	Mean	6.14	6.50	6.32
	SD	4.62	5.92	5.31
DLQI follow-up	First quartile	1.25	1	1
	Median	3	3	3
	Third quartile	5	7	6
	Mean	4.06	4.91	4.50
	SD	4.05	5.49	4.85

SD, Standard deviation.



Figure 1 The distribution of Dermatology Quality of Life Index at baseline and follow-up.



Figure 2 The detailed distribution of Dermatology Quality of Life Index among the participants at baseline and follow-up, in the control group (blue dots) and intervention group (orange dots). A cutoff DLQI score of 5 is indicated by a dashed line.

the DLQI was on average slightly lower at follow-up in the intervention group compared with the control group (Table 2), the difference in DLQI between the groups was not statistically significant according to any of the regression models (Table 3). There were no signs of confounding from age or gender.

Discussion

The aim of this study was to evaluate changes in QoL in an intervention study conducted previously at the Department of Dermatology and Venereology at Lund University Hospital.¹⁴ There was a significant decrease in DLQI scores in both the control and the intervention group. However, the intervention group did not show a statistically significant lower DLQI score in comparison with the control group at follow-up.

One year after patch testing the mean DLQI in the entire group had changed from a DLQI score of 6.3 at baseline to 4.5 at follow-up. Although it could be questioned if this decline in DLQI reflects a change in QoL of clinical relevance, it might represent a shift from a moderate impact to a small impact on a patient's QoL.¹⁶ According to guidelines,²¹ patch testing in general requires at least 3 visits; the first contact is for diagnosing the eczema and deciding that a patch test is indicated, followed by the placement of tests on the patient's back. The second and third visits to the dermatologist are for reading, analysing and giving information about the patch test results. In all contacts with the health care personnel the patients will have the opportunity to talk and discuss diagnosis, symptoms and treatment response, thus promoting the patient's feeling of being well taken care of. Furthermore, these clinical visits would probably have led to improvement of the patients' knowledge as well as improved management of eczema and the skin barrier. Previous studies have reported an improvement in QoL in patients after patch testing.²² It has been shown that QoL improves over time after patch testing both at a shorter^{8–12} and a longer follow-up period.¹³ An improvement in life quality after patch test could be seen in patients with a positive patch test as well as patients with no contact allergies.^{8,10,11} The question is whether the improvement of QoL is due to patch testing alone or dependent on the outcome of the patch test. Others have hypothesised that the increased attention by medical staff itself might improve the QoL.^{10,11} One might be tempted to speculate that an even further improvement on QoL could be achieved with an intervention, such as providing more information about the diagnosed allergens, after the patient has been treated and tested at the

Table 3 Linear regression analyses for Dermatology Quality of Life Index (DLQI) at follow-up among the intervention group and the controls

Variable	Model 1		Model 2	
Control group	Reference category (95% CI)	<i>P</i> -value	Reference category (95% CI)	P-value
Intervention group	-0.70 (-2.17; 0.77)	0.35	-0.68 (-2.27; 0.92)	0.40
DLQI baseline	0.42 (0.18; 0.66)	<0.001	0.42 (0.17; 0.67)	<0.001
Age < 40	_	-	Reference category	
Age 40–60	_	-	0.39 (-1.31; 2.09)	0.65
Age > 60	_	-	0.42 (-1.67; 2.51)	0.69
Gender male	_	-	Reference category	
Gender female	_	-	-0.30 (-1.81; 1.21)	0.70

dermatological clinic. However, this study failed to show such an effect.

The limitation of the study was the small sample size. It was likely underpowered to demonstrate differences in QoL due to the intervention. However, the study had few non-responders. The responders and non-responders were comparable regarding age and gender and therefore it is unlikely that there were biases concerning these variables. Occupational cause might influence DLQI, as reported elsewhere,²³ however, the impact of occupational cause was not analysed in this study but is an interesting question for further research. It is previously known that the prevalence of contact allergy is higher among the female population,²⁴ which is in line with our study population where the female: male ratio was roughly estimated at 3:1. Moreover, the patients included in the study were diagnosed by multiple dermatologists with some risk of interobservational bias. Unfortunately, we have no data of additional visits at the clinic during the follow-up period. This might have affected the outcome of the study. However, the study was randomized and blinded, the visits or treatments during the follow-up period would probably have been equally distributed between the groups. Nevertheless, such factors must be considered, when interpreting the result regarding an interventional study. Moreover, the relevance of the positive patch test to the clinical scenario can be past, present, or unknown.²⁵ It is likely that the degree of relevance, concerning positive patch test reactions, might be correlated to effects on DLQI among the participant, which have been reported elsewhere.¹⁰ In this study we have no data available concerning the degree of relevance of the positive test results diagnosed, and associations to DLQI among the participants; however, further research is needed to elucidate this question.

A previous study on patients with hand eczema found that factors like age and male sex would affect QoL in a negative way.²⁶ We did not observe any impact of gender or age in this study concerning DLQI. Several studies have shown an improvement in QoL after patch testing, but somewhat surprisingly, even patients with a negative patch test result reported an improved QoL.^{8,9,11–13} Although we did see a tendency toward a greater improvement in DLQI in the intervention group vs. the control group at follow-up, there was no significant difference in the DLQI scores between the groups. However, since the control group in this study already showed an effect on DLQI at followup, it may have been more difficult to demonstrate a significant effect from the intervention. Generally, it can be assumed that the knowledge of contact allergy and the avoidance of allergens decreases the risk of chronic hand eczema and thus improves QoL, explaining the observed decrease in DLQI in both groups in this study. Nevertheless, the results revealed a certain number of participants reporting a DLQI score > 10, which indicates a very large or extremely large effect on QoL, probably consisting of a subpopulation of the participants with severe refractory dermatitis. Even so, a greater improvement in QoL in patients with severe chronic CD compared with mild disease are reported elsewhere.⁸

It would seem plausible that dermatitis affecting a visible location on the body may affect QoL negatively. However, a study failed to prove that QoL differs according to which body site is affected by eczema.¹⁰ On the other hand, another study found that facial eczema was associated with increased impairment of QoL.²⁷ How the location of CD affects patients' QoL is an interesting question to investigate further.

More attention should be paid to the importance of advice from trained dermatologists who educate the patient and give explanations of the possible sources of the contact allergens involved, based on home-related and work exposures. At the moment of diagnosis both oral and written information should be given.²⁸ Concerning patients with hand eczema, repeated information, education and preventive measures are beneficial.^{29,30} Oral information may be a better instrument for ensuring the patients' understanding and making interventions in their lifestyle.³¹ Woo et al.¹¹ proposed that written information was inferior to oral information when wanting to achieve the patients' comprehension of their disease. Fisker et al.³² showed that a 2-h education program in group form for patients with occupational hand eczema did not influence the patients' QoL, although the patients in the intervention group did learn better skin care. Moreover, it should be taken into account that a recent study have reported positive effects on the QoL by interdisciplinary inpatient rehabilitation measures, including patient education, that is, tertiary individual prevention, in patients with occupational hand eczema.³³ Physicians should be aware of that information about CD exist on social media platforms and are utilized and shared both by patient, physician and industry groups.³⁴ However, knowledge of the skin barrier and changes in lifestyle due to a contact allergy may lead to better compliance but may not necessarily lead to an improvement in life quality. Implementing behavioural changes in the daily life of patients with CD may be seen as an extra burden to the patient. The improvement of QoL in patients with allergic CD may not solely depend on recalling an allergen and understanding the lifestyle changes that should follow.

Conclusion

We did not find a significant difference in QoL in the intervention group who received additional information on their diagnosed allergen(s) compared with the control group. We could confirm that patients with a contact allergy who underwent patch testing showed an improved QoL over time. Further research is needed in order to understand which factors, apart from patch testing and medical care, may affect QoL in patients with CD, and what interventions are needed to improve QoL in this patient group.

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Data availability statement

Data and protocols are available in a repositor on request from corresponding author.

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