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Introduction

Atopic dermatitis is a skin condition that occurs in patients with a complex, genetically determined syndrome known as atopy, which includes the tendency to develop eczema and other skin lesions, bronchial asthma, and allergic rhinoconjunctivitis. Its prevalence is estimated to be between 5% and 20% in developed countries. A recent study conducted in Madrid, Spain, among school children aged between 3 and 16 years over the period of a year reported a prevalence of 9.95%. Fifty percent of patients with atopic dermatitis develop lesions within a year of birth and 80%-90% develop them by the age of 5. The primary cutaneous manifestations are dry skin and eczema, accompanied by pruritus. The majority of patients develop a mild (84%) or moderate (14%) form of the disease. Treatment is based on controlling the factors that trigger and perpetuate the dermatitis, restoring the epidermal barrier through correct moisturizing, and reducing the cutaneous inflammation.

The cause of atopic dermatitis is still unknown. In addition to the complex immunological reactions that constitute the underlying etiopathogenic mechanisms, there is a considerable psychological component, which is exacerbated by the chronic nature of the disease. Psychosomatic factors have long been suspected to have an impact on atopic dermatitis and several studies have found an association between the disease and anxiety states. Atopic dermatitis has a considerable social and familial impact as it can cause stress not just in young patients but in their parents as well. Uncertainties regarding disease course become particularly pronounced when young children are involved, resulting in increased anxiety levels. Caring for young patients with moderate to severe atopic dermatitis, for example, has been seen to have a greater impact on the family than caring for children with type I diabetes mellitus. Impaired quality of life, measured using the Children’s Dermatology Life Quality Index, has also been reported in over 60% of pediatric patients with moderate to severe disease. Evidence of impaired quality of life included pain and itching and difficulty dressing and sleeping.

Providing patients with information about disease course and preventive measures has proven to be beneficial in terms of reducing anxiety levels in patients with atopic dermatitis. For example, in a comprehensive study of preventive dermatological and psychological approaches in patients with atopic dermatitis, found that an intervention based on providing patients with information about the disease, the influence of varying factors, and basic skin care,
led to a considerable reduction in anxiety levels, measured by the State Trait Anxiety Inventory (STAI). This intervention strategy had the same effect on anxiety levels as an intervention program based on disease information and education and a cognitive-behavioral program. Other studies have shown that interventions designed to help patients with atopic dermatitis to modify their behavior or habits can be more beneficial than the use of certain drug therapies such as corticosteroid therapy. Ennstaughton, in his contribution to the consensus meeting on atopic dermatitis held in Rome, Italy in 1999, indicated that behavior-modification strategies should be simple and based on actions such as self-observation and the recording of symptoms such as itching, dryness, and redness.

Knowing that we were likely to find an association between the emotional state of patients with atopic dermatitis and disease course, we wished to test the hypothesis that an intervention based on educating and informing patients about clinical and preventive aspects of the disease could improve their emotional state.

Objectives

Based on the above hypothesis, the following objectives were set:

1. Primary objective: to study the impact of an education–information intervention on the emotional state (anxiety levels) of patients with atopic dermatitis.

2. Secondary objectives: a) to study the association between clinical features of atopic dermatitis and the emotional state of patients during the baseline visit; b) to compare the emotional state of parents of children with atopic dermatitis in a control group and an intervention group; and c) to compare disease progression over a follow-up period of 6 months in the 2 groups based on number of outbreaks, itch intensity, and overall disease severity measured using the Investigator’s Global Assessment (IGA) scale, and to explore the association between disease progression and the emotional state of the patients and their parents at the end of the study.

Materials and Methods

Study Design

We conducted a prospective, parallel-group, multicenter study in which investigators were assigned randomly to either a control group or an intervention group.

1. Control group. The patients in this group were managed in accordance with the investigator’s standard clinical practices.

2. Intervention group. The patients in this group were also managed in accordance with the investigator’s standard clinical practices but in addition they were provided with purpose-designed educational material and information.

The intervention material included:

1. An information leaflet given to each patient by the investigator at each 3-month visit during the monitoring period. This leaflet contained information about important everyday patient-oriented aspects of atopic dermatitis.

2. A diary for recording itch and redness intensity with instructions on usage; symptom intensity was recorded using a visual analog scale ranging from 0 to 10.

3. A calendar card showing the dates of future visits within the study program.

Study Conduct

Three visits were held during the study period. These included a baseline visit and 2 follow-up visits (at 3 months and 6 months). Relevant clinical data (disease severity [IGA], itch intensity, and location of lesions) were recorded and the patients’ emotional states were evaluated on the basis of STAI scores. The STAI for children was administered where appropriate and both the state and trait anxiety scales (STAI-S and STAI-T, respectively) were evaluated. To study the association between clinical features of atopic dermatitis and the emotional state of patients at baseline and throughout the study, we analyzed state rather than trait anxiety levels. All statistical calculations were carried out using the PASS statistical package, version 2002. (NCSS/PASS; Number Cruncher Statistical Systems, Kaysville, Utah, USA).

Results

A total of 1247 patients were recruited with the collaboration of 158 participating investigators. The patients were distributed as follows: 683 (54.7%) in the control group and 564 (45.2%) in the intervention group. The mean (SD) age of the patients was 19.7 (15.3) years in the control group and 19.1 (16.3) years in the intervention group. There were no statistical differences between the groups in terms of the proportion of men and women or the educational level.

The percentage of patients with concomitant skin disease was 26.8% in the control group and 26.6% in the intervention group, and the most common concomitant disease was viral skin infection (affecting 11% of the control group and 12.1% of the intervention group).
There were no statistically significant differences between the groups for either the age at which the first episode of atopic dermatitis occurred or the duration of the most recent outbreak. There was a statistically significant difference, however, for the number of outbreaks that had occurred in the preceding 6 months. The mean (SD) was higher in the control group (3.0 [2.6]) than in the intervention group (2.6 [3.0], \(p<.05\)) (Table 1). The most affected areas of the body were the hands and feet in both groups (over 85% of patients in each group). The difference in itch intensity between the 2 groups was also statistically significant, with the intervention group scoring higher than the control group for severity of baseline signs and symptoms (1.8 [0.8] vs 1.7 [0.8], \(p<.05\)) (Table 2).

On analyzing the association between the clinical features of atopic dermatitis and a history of stressful situations or psychological disorders by study group, we found a statistically significant difference for itch severity between patients who had a history of stress or psychological disease and those who did not. The decrease in anxiety levels (state and trait) over the course of the study was statistically significant for patients aged between 9 and 15 years in both groups (\(p<.05\)), although the differences between the 2 groups were not statistically significant (\(p>.05\)) (Figure 1).

A greater percentage of patients completed the study in the intervention group than in the control group (83.1% vs 76.1%, \(p<.005\)). A significant decrease in anxiety levels (state and trait) was observed in patients aged over 15 years in both groups (\(p<.05\)). This implies that the intervention group experienced a greater decrease in anxiety levels as their baseline scores were higher (Figure 2).

With respect to the impact of our intervention on the emotional state of parents of patients younger than 9 years, we observed a significant decrease in both state and trait anxiety levels over the course of the study in both groups (\(p<.05\)). The differences between groups, however, were not statistically significant (\(p>.05\)). (Figure 3).

We found an association between the patients’ emotional state at baseline (measured on the STAI-S scale) and 3 clinical features of atopic dermatitis: presence of the symptom “change in skin temperature,” IGA rating, and itch intensity score (linear regression analysis, \(p<.05\)).

The IGA score was the only clinical variable that was associated with the patients’ emotional state throughout the study (\(p<.001\)) (Table 3).

On analyzing disease progression over the 6 months, we observed a considerable reduction in the 3 factors analyzed (number of outbreaks, itch intensity, and overall disease severity) in both groups (\(p<.05\)). Statistically significant differences between the 2 groups were found for number of outbreaks at baseline, IGA score at 3 months, and itch intensity score at baseline and 3 months (\(p<.05\)).

Discussion

Although the entity now known as atopic dermatitis was first described by Robert Willan as far back as 1808, the concept of “atopic” was not introduced until 1923, when the term “atopy” was proposed by Coca and Cooke to group together different clinical skin, lung, and nasal

<table>
<thead>
<tr>
<th>Table 1. Clinical History of Atopic Dermatitis by Study Group</th>
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<tbody>
<tr>
<td><strong>Control Group</strong></td>
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<tr>
<td>Age of first episode of atopic dermatitis, y</td>
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<td>Outbreaks in past 8 months, No.</td>
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<tr>
<td>Duration of last outbreak, d</td>
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*Statistically significant differences between the 2 groups (\(p<.05\)).

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<tr>
<th>Table 2. Baseline Signs and Symptoms of Atopic Dermatitis by Study Group</th>
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<td><strong>Signs and Symptoms of Atopic Dermatitis</strong></td>
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<tr>
<td><strong>Control Group</strong></td>
</tr>
<tr>
<td>No. of outbreaks</td>
</tr>
<tr>
<td>SD</td>
</tr>
<tr>
<td>No.</td>
</tr>
<tr>
<td>Investigator’s Global Assessment</td>
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<tr>
<td>SD</td>
</tr>
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<td>No.</td>
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<tr>
<td>Itch scale</td>
</tr>
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<td>SD</td>
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<td>No.</td>
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</table>

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Abbreviations: m indicates mean; max, maximum; med, median; min, minimum.

Guerra-Tapia A et al. Observational Study to Evaluate the Impact of an Educational/Informative Intervention in the Emotional Status (Anxiety) of Patients With Atopic Dermatitis (Cuida-DeL)
hypersensitivity manifestations (including atopic dermatitis). It was not until many years later, however, that the psychological component of atopic dermatitis—which is capable of triggering and perpetuating symptoms—received the attention it deserved. Its impact on quality of life is so great that in one study it was seen to be greater than that of diabetes in children.\textsuperscript{14} Anxiety exerts a 2-way effect: when present, it has a negative effect by exacerbating the hypersensitivity reaction, and when absent, it leads to an improvement of symptoms. Likewise, clinical deterioration increases anxiety while clinical improvement enhances patients’ emotional well-being. Anxiety also has an impact on parents of patients under 9 years old, and psychological intervention has been shown to improve the quality of life of these patients.\textsuperscript{15}

Psychological support, for example, can take the form of an educational/informative intervention based on providing patients with information about clinical and

\begin{figure}
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\includegraphics[width=\textwidth]{figure1.png}

\caption{Progression of anxiety (state and trait) in children by study group}
\end{figure}
preventive aspects of atopic dermatitis in an effort to improve their emotional well-being. One such intervention study, for example, found a greater decrease in anxiety levels (measured by the STAI-T) after a year in patients who had participated in the education and information program than in those who had not (decrease of 3.1 points in the intervention group compared to a decrease of 0.1 points in the control group). This study is used as a reference when measuring the effect of education and information on the results of the trait anxiety test. Although the ultimate aim of our study was similar to that of the above study, both our design (graphic and written rather than face to face intervention) and observation period (6 months rather than a year) were different. We should also remember that trait anxiety is the most stable of the 2 types of anxiety studied and that because state anxiety is associated with temporary conditions or situations, it should be more sensitive to the effects of intervention. In view of this, and given the nature

Figure 2. Progression of anxiety (state and trait) in adults by Study group.
of our intended intervention, we established a minimum detection level of 2 points for the STAI-T score at 6 months. We worked on the assumption that we would obtain a mean STAI-T score of 48.3 (10.1) for the control group and 46.3 (10.1) (2 points less) for the intervention group. We took the highest SD value recorded for both groups in the reference study, and, assuming greater variability, took a more conservative approach with the results. On the basis of the above assumptions, we needed a sample of 1194 patients (597 per group) for a statistical power of 90% and a significance level ($\alpha$) of 5%, assuming a 10% loss.

The clinical evaluation (IGA) conducted at the beginning of the study revealed mild to moderate disease and pruritus in both groups. Approximately 28% of the patients in both groups reported having experienced a stressful situation that had modified their emotional state.
The difference in the percentage of patients who had left school early between the 2 groups was statistically significant (23.9% in the control group compared to 16.9% in the intervention group).

With respect to the main aim of the study, we found no statistically significant differences between the groups in terms of emotional state (anxiety) measured by the STAI.

We did, however, find statistically significant differences between the 2 groups for adult patients (older than 15 years) when we analyzed the decrease in anxiety levels from baseline to month 3 (for direct scores but not for corrected scores). Patients in the intervention group had significantly higher levels of state and trait anxiety than those in the control group at baseline but these differences were not noticeable by the end of the study.

In general, we observed considerable decreases from baseline in STAI scores for both children and adults throughout the study, with both the intervention group and the control group showing improvement (probably because the patients knew that they were receiving emotional support from the specific tests they completed at each visit).

We did not find any statistically significant differences between the control and intervention group for other age groups (created in accordance with the criteria followed when administering the STAI: parents answered the questionnaire when the patient was under 9 years old, patients aged between 9 and 15 answered the STAI for children, and patients over the age of 15 years answered the STAI for adults). We did, however, find statistically significant differences within these groups for improvement from baseline to month 6.

Our study has certain limitations. Although the investigators were randomly assigned to either an intervention group or a control group, it appears that selection bias may have occurred when forming these groups. This would explain the differences between the baseline levels of anxiety in the adult patients, that is, the investigators may have tended to assign patients who were more worried about their disease to the intervention group rather than the control group.

Another possible limitation is the type of education intervention chosen. The informative/educational messages delivered by the 3 purpose-designed leaflets were probably not powerful enough to create a detectable difference between the 2 groups in terms of the main test variable (anxiety). The intervention strategy used by Ehlers et al— in which patients were educated and informed by nurses in a face-to-face situation—yielded positive results in terms of improved emotional state measured by the STAI. Thus, the ability to modify habits related to health and prevention hinges on the design of the intervention variable. In the present study, the effect of our strategy was probably diluted by the fact that we are living in an information era with ready access to knowledge. This would explain why patients in both groups judged themselves to be well informed about atopic dermatitis.

The improvement in the emotional state of patients with atopic dermatitis is significantly associated with clinical improvement measured by IGA. Our study, however, did not analyze drug use, a variable which probably exerted an effect on clinical and therefore emotional improvement.

### Conclusions

The intervention we designed—which was based on providing patients with information about how to prevent atopic dermatitis—does not appear to have had a significant impact on the improvement of the patients’ emotional state.

There was, however, a noticeable clinical improvement over the course of the study—both in terms of IGA rating and itch intensity—that was accompanied by an improvement in the patients’ emotional state. The lack of data regarding drug treatment prevented us from analyzing the possible role of drugs in the clinical improvement observed.

It seems clear, however, that emotional improvement only occurs when there is clinical improvement, regardless of whether or not patients have taken part in an education program.

Two symptoms that had a significant influence on the emotional state of the patients were a sensation of increased skin temperature and itching.

Patients in the intervention group rated their knowledge of atopic dermatitis more highly than those in control group. Although the difference was only slight, it was statistically significant.

Adherence to the program was greater in the intervention group than in the control group.

### Conflicts of Interest

This study was sponsored by Novartis Farmacéutica.

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**Table 3. Association Between Clinical Features of Atopic Dermatitis and Improvement in Patients’ Emotional State Over the Course of the Study**

<table>
<thead>
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<th>P</th>
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<tr>
<td>Progression According to Investigator’s Global Assessment</td>
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<td>&lt; .001</td>
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<tr>
<td>Improvement</td>
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