

Quality of life of children with atopic dermatitis and their families

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Purpose of the review

Over the last few years major advances have been made in the conceptualization of quality of life and new instruments have been developed for assessing the construct in paediatric atopic dermatitis. This review looks at these developments and reports on recently published articles on the impact of the condition on affected children and other members of their family.

Recent findings

During the period of the review only one article addressing the impact of treatment for paediatric atopic dermatitis on quality of life could be found. This showed the benefits to the quality of life of parents of treating their children with pimecrolimus cream.

Summary

Given the prevalence of paediatric atopic dermatitis and its impact on affected children and their families it is surprising that so little attention has been devoted to the impact of treatment on quality of life. Where standardized measures are included in studies they generally assess outcomes that are of interest to physicians rather than to patients and their carers.

Keywords

activities, atopic dermatitis, functioning, impairment, quality of life

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Introduction

Paediatric atopic dermatitis is a common skin condition affecting 12–15% of children in early childhood [1]. Symptoms vary from individual to individual and, while the condition is mild for most, there is a tendency for it to remit and exacerbate unexpectedly. Consequently, the disease often has a major impact on the child and his/her development [2,3]. In addition, the child is not the only person affected, as the well being of the entire family is likely to be disrupted [4–6].

The importance of showing the benefits of new pharmaceutical products in terms of patient-reported outcomes is now well recognized. It is no longer sufficient to establish safety and efficacy in order to market products. Given the potential widespread and devastating impact of this common childhood disease, quality of life (QoL) is clearly a crucial outcome.

Quality of life and its assessment

There are several different types of patient (or carer) reported outcomes (PROs) and it is crucial to know which type of outcome is being assessed by standardized ques-

tionnaires. In fact, relatively little of the information collected with such measures in clinical studies informs on a patient's or carer's QoL.

- (1) Impairment is any loss or abnormality of psychological, physiological or anatomical structure or function and equates to symptoms. Examples of impairment are anxiety, depression, pain, itch and problems with sleep [7].
- (2) Activity is the ability of an individual to function as expected. This may refer to physical, emotional, social or other types of functioning. Examples include dressing, walking, personal care or taking part in sports [7].
- (3) Health-related quality of life (HRQL) equates primarily to a combination of impairment and disability. There is general agreement that HRQL is multi-dimensional, although there is no formal consensus on the domains that should be included [8]. In fact, HRQL focuses on those aspects of life that are considered to be the province of health professionals. Consequently, the main value of HRQL measurement is in the assessment of health status, impairment and activity.

Limiting consideration of outcome to such 'health-related' aspects fails to take into account patients' response to ill health and its treatment. Lipowski [9] argued that how a person experiences the pathological process, what it means to him or her and how this meaning influences his or her behaviour are all integral components of disease viewed as a total human response.

QoL goes beyond the assessment of impairment and activity. While the consequences of disease and its treatment represent one group of influences on QoL there are many more including; personality, economic status, environment, social relationships and culture. The extent to which impairment or activity influence QoL is dependent on other influences, for example, the impact of a skin disease will depend on whether the lesions are hidden by clothes, the climate, the quality of personal relationships, stage of life and many other factors. Patients may give up activities that become problematic, such as swimming or sun bathing and take up other leisure activities in order to maintain their QoL. Activity-based outcome measures are unable to cope with such adaptation making it difficult for severely ill or disabled patients to show improvement, even following effective interventions.

In the field of health research, the most widely implemented approach to the measurement of QoL, as opposed to HRQL, is needs based [10]. Proponents of the approach argue that individuals are driven or motivated by their needs and that the fulfilment of these provides satisfaction. Consequently, life derives its quality from the ability and capacity of the individual to satisfy certain human needs. QoL is good when most needs are fulfilled and poor when few needs are satisfied. For example, the function of walking may lead to the satisfaction of several needs including; gaining exercise and pleasure, socialization needs, purchasing essential food, communication needs (posting letters) or obtaining medical advice.

Standardized outcome measures used in childhood atopic dermatitis

Measures such as the children's dermatology life quality index (CDLQI) [11], the dermatology family impact

questionnaire (DFI) [12], the infants' dermatitis QOL index (IDQOL) [13], the quality of life of parents of children with atopic dermatitis (QLPCAD) [14] and the childhood atopic dermatitis impact scale (CADIS) [15] have been developed to assess outcome in clinical studies. Unfortunately, the content of these measures is not based on an underlying theoretical model of QoL and, consequently, the measures assess a mixture of constructs – primarily symptoms (impairment) and functioning (activity). The outcomes covered by these measures are shown in Table 1. It is clear from the table that the measures assess HRQL and not QoL. Consequently, they are likely to miss those issues that are of greatest concern to the patient and to the parent of the affected child.

The CADIS attempts to assess the impact of atopic dermatitis on both the child and the parent in the same measure – adding together these outcomes to produce a total score. This approach equates to adding together apples and houses. Such compound measurement provides invalid scores and, unfortunately, applies to all of the above measures except the QLPCAD, which is the only one that does not quote a total score (i.e. the measure provides a profile of outcomes). Modern psychometric approaches emphasize the importance of establishing the unidimensionality of outcome scales to avoid such compound assessments.

Measuring quality of life associated with paediatric atopic dermatitis

A particular problem for trials of paediatric atopic dermatitis is that a high proportion of study participants are too young to provide information about their quality of life. For this reason McKenna and colleagues [16] developed the parents index of quality of life in atopic dermatitis (PIQoL-AD). This is a needs-based measure of QoL that assesses the impact of the child's atopic dermatitis on their main caregiver. Example items from the PIQoL-AD are as follows:

- (1) I have to be careful what he wears.
- (2) I never get a good night's sleep.
- (3) I feel I have little freedom.

Table 1 Constructs assessed by outcome measures used in paediatric AD

Measure	Age of affected child (years)	Total score quoted	Child's impairments	Child's activities	Adult's impairments	Adult's activities
IDQOL	< 4	Yes	✓	✓		
CDLQI	4–16 ^a	Yes	✓	✓		
DFI		Yes			✓	✓
QLPCAD		No			✓	✓
CADIS	≤ 6	Yes	✓	✓	✓	✓

AD, atopic dermatitis; CADIS, childhood atopic dermatitis impact scale; CDLQI, children's dermatology life quality index; IDQOL, infants' dermatitis quality of life index; QLPCAD, quality of life of parents of children with atopic dermatitis.

^aWith help if needed.

- (4) All my attention has to go to him.
- (5) I worry about the way he looks.
- (6) It is difficult to find time for shopping.
- (7) There is a lot of tension in the family.

The PIQoL-AD was used in two trials comparing the impact of emollients, pimecrolimus and topical corticosteroids with 'usual care'; emollients, topical corticosteroids and a vehicle cream to maintain study blinding [17]. Both trials were randomized and double-blinded. The first trial involved patients aged between 3 months and 2 years and the second children aged two to 17 years. QoL assessments were conducted at baseline, 6 weeks, 6 months and 12 months. PIQoL-AD scores at each postbaseline visit showed a greater improvement in parent's QoL for pimecrolimus compared with usual care at all time points in both trials. The ability of the PIQoL-AD to show improvements in the QoL of parents resulting from effective treatment of their children testifies to the sensitivity of the questionnaire.

The original item pool for the PIQoL-AD included items that commented on the impact of atopic dermatitis on the children themselves. While these were rejected from the main scale, they were used to create another outcome measure – the childhood impact of atopic dermatitis (CIAD) [18*]. Example items from the CIAD are as follows:

- (1) He is very moody.
- (2) He cannot be comforted.
- (3) He is very demanding.
- (4) He misses out on a lot of childhood activities.
- (5) Other children don't like holding his hand.

The measure was used in clinical trials based in Europe and the US comparing pimecrolimus with placebo in patients aged three months to 18 years. Only the parents of patients up to the age of 8 years completed the CIAD. Despite this, in the European trial, CIAD scores improved significantly more for those patients receiving pimecrolimus than those on placebo. A similar (nonsignificant) trend was found in the US trial.

Items from the CIAD have also been used to generate a disease-specific preference-based measure for use in children with atopic dermatitis [19]. Such measures are required in order to calculate quality adjusted life years accurately and allow economic evaluations of new products. The study showed the importance of atopic dermatitis in children as the value of the health state valuations ranged markedly from 0.36 to 0.84 (on a scale from 0 = death to 1 = perfect health).

Recent publications reporting on patient and carer-related outcomes in paediatric atopic dermatitis

Surprisingly, little work has been conducted in this area during the review period. Ganåmo and colleagues [20] report scores obtained on the IDQOL and CDLQI in a sample of Swedish children with atopic dermatitis. No attempt is made to interpret the meaning of these scores. Ricci *et al.* [21] published a similar paper, reporting IDQOL and DFI data from Italy. Again, no attempt was made to determine how meaningful the scores are. It appears from the article that the authors used an Italian version of the questionnaire that had not been adequately adapted and validated for use in Italy. They also employed a control group consisting of healthy children. This is not a valid procedure without first establishing that the measure is valid for use with such children and that they interpret the items in the same way as children with atopic dermatitis.

Beattie and Lewis-Jones [22] also used the IDQOL and DFI in an audit of the impact of a consultation with a paediatric dermatology team. They were able to show statistically significant improvements in score on these measures over a mean of 10.9 weeks following an initial consultation with a dermatologist. However, again no evidence was presented on how meaningful these improvements were. The authors also make the mistake of presenting findings for individual items in the scale. Individual items that make up scales are not validated to be used outside the scale and will be unreliable by definition. Scores on a true scale will represent the relation between the individual items as well as the impact of the intervention on the patient.

Grimalt *et al.* [23] employed the IDQOL and DFI in a study of the steroid-sparing effect of emollient therapy in children with atopic dermatitis. Although changes were found in the scores on these measures, they were not able to show differences between the study groups. The authors again selected out the sleep item in the DFI to suggest that the group using emollients had greater benefit.

Fölster-Holst and colleagues [24] used the QLPCAD to evaluate the effect of *Lactobacillus rhamnosus* in infants with moderate to severe atopic dermatitis. Unfortunately, the treatment was ineffective and no changes were found on the QLPCAD.

Finally, a Thai study attempted to show the effect of tacrolimus on the QoL of patients aged two to 12 years (in addition to safety and efficacy) [25]. However, it is not clear how they measured QoL, as it appears

that a standardized and validated measure was not employed.

Conclusion

Surprisingly, little attention has been paid to the impact of atopic dermatitis on the QoL of children and their parents. Although a number of measures are available for assessing the impact of paediatric atopic dermatitis on infants, children and their parents only one—the PIQoL-AD—is a measure of QoL. The other available questionnaires assess HRQL and fall short of providing information on the impact of atopic dermatitis from the patient's or parent's perspective. As proxies cannot provide information on the QoL of patients, only a measure designed for older children could address their QoL.

Where standardized measures have been used in clinical studies and trials, they are poorly applied, analysed and interpreted. In particular, the reader needs to know what changes in scores on the measure mean and if they are clinically important.

There is a clear need for more careful selection of outcome measures for clinical trials. Only then will it be possible to learn more about the impact of paediatric atopic dermatitis on patients and their parents and to judge whether interventions are acceptable to the patient as well as safe and effective.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 277).

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