RESEARCH REPORT

Treatment of the symptoms of Psoriasis in Patients, using bio-energiser quaver phase applied to the feet.

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SUMMARY

Psoriasis is a recurrent skin condition that affects around 2% of the population in the UK. In simple terms, it is only an acceleration of the usual replacement processes of the skin. Normally a skin cell matures in 21 to 28 days during its passage to the surface where a constant invisible shedding of dead cells, as scales, takes place. Psoriatic cells, however, are believed to turn over in two to three days and in such profusion that even live cells reach the surface and accumulate with the dead cells in visible layers. Psoriasis affects both sexes equally. It may appear for the first time at any age, although it is more likely to appear between the ages of 11 and 45. It appears as raised red patches of skin covered with silvery scales. It can occur on any part of the body although elbows, knees and the scalp are usual sites. There is often accompanying irritation. Some parts of the body do not have this typical scale. These are areas where two skin surfaces come together as in the natural skin creases and folds e.g. the groin and genital area and underneath women's breasts. Psoriasis, in these areas can look bright red and shiny rather than scaly.**

Key words: bio energiser, quaver, disability, quality of life questionnaire,

INTRODUCTION

The impact of psoriasis on health-related QOL has been shown to be similar to that of other major diseases such as diabetes, congestive heart failure and chronic lung disease.[1]

Dermatologists usually select treatments based upon their assessment of the physical extent of the psoriasis and the degree of inflammation manifested. The Psoriasis Area and Severity Index is a widely used measure of physical severity, but it does not correlate well with the patient's global rating of overall health.[2,3] Studies have shown that the manifest physical disability does not always correlate with the degree of psychosocial disability.[4] Patients with psoriasis often avoid common social activities. This avoidance is not restricted to patients with moderate or extensive disease but include many with mild disease.[5] The change in a patient's perception of his/her ability to live a useful and functional life as a result of a therapeutic intervention is an important assessment of that treatment's efficacy.

The bio-energiser has been shown to be effective in reducing the extent of psoriasis and producing a remission of variable duration. Studies support the administration of quaver therapy based upon establishment of the therapeutic modality of the bio-energiser. It has been demonstrated that the most effective regime is to administer treatment three times a week with a 30 minute program.

The aim of our study was to investigate whether we could demonstrate that patients attending a busy private practice clinic experienced an improvement in QOL after treatment with the non-invasive bio-energiser system, using the protocol described above.

METHODS

Subjects

A total of 21 consecutive patients were referred for bio-energiser therapy to the feet and hands and The Wessex Nuffield Hospital, Hampshire, between October 2003 and February 2004. The use of the bio-energiser as a therapy was considered when the patient's psoriasis was inadequately controlled by topical therapies alone and there are contraindications to the use of the BE.

**National Psoriasis Association (UK).

Abbreviations

QV	quaver (mJ)
BE	bio energiser
PDI	psoriasis disability index
QOL	quality of life

After the expected benefits and risks of the treatment were explained, the patient signed an informed consent.

Questionnaire

Patients completed questionnaires at the beginning and again at the completion of the course of the therapy. The questionnaire (Table 1) used 15 questions based upon those devised by Finlay and co-workers in developing their PDI.[2,11,12]

We omitted some of the questions and rephrased others to make them more appropriate for our population.
We used a four-point Likert scale to rate the questions. We did not use the scoring system of the PDI. However, as with the PDI, we asked the patients to rate the impact of the psoriasis on their functioning and interactions over the preceding 4 weeks. Our final question requested the patient to rate his/her psoriasis at that point in time. In addition, in the post-therapy questionnaire, the patients were asked to rate the improvement of their psoriasis on a scale of 1 to 10 on a visual analogue scale. One represented no improvement while 18 represented considerable improvement (Fig. 1).

In order to analyse the change in QOL, questions were divided into three groups including activities of daily living, physical parameters and impact on interpersonal relationships (Table 1).

Table 1 Quality of life questionnaire

Over the past four weeks:

Activities of daily living

1. How much has your psoriasis interfered with you carrying out work around the house or garden?
2. How often have you worn different types or colours of clothes because of your psoriasis?
3. How much do you have to change or wash your clothes?
4. Has your psoriasis been much of a problem at the hairdressers?
5. Has your psoriasis resulted in your having to take more baths or showers than usual?
6. Has your career been affected by your psoriasis?

Physical

7. Is your psoriasis making it difficult for you to do sport?
8. Have you been criticised or stopped from using communal pools or changing facilities?
9. Have you avoided swimming or going to the beach because of your psoriasis?
10. Has your psoriasis resulted in you smoking or drinking alcohol more than you would do normally?
11. To what extent has your psoriasis or treatment made your home messy or untidy?

Interpersonal relationships

12. As a result of having psoriasis, have you felt aggressive, frustrated or embarrassed?
13. Has your psoriasis interfered with your daily social life, social events or relationships?
14. How have you felt about your skin over the last month?
15. How bad do you think your psoriasis is now?

Bio-Energiser Therapy

The therapy was administered in a standardised fashion as per protocol (Appendix I). Parameters recorded included measured water and low sodium salt, the starting time, polarity intervals, colour changes and quaver cumulative pulses (all measured as millijoules per square centimeter in the water).

Statistical analysis

In order to explore the validity of the three groups, we employed clinical decision, factor analysis and use of Cronbach's alpha coefficient. Exploratory factor analysis was carried out using the varimax rotation method with Kaiser normalization. Computation of Cronbach's alpha coefficient was utilized to measure internal consistency reliability.[14] The Cronbach's alpha coefficient of group 1, 2 and 3 were 0.7, 0.5 and 0.7, respectively. The mathematical analysis confirmed the validity of these groupings. We therefore analysed the data using these three groups.

The pre- and post-therapy responses were compared using the paired sample *t*-test. Results were expressed as a mean and standard deviation. A *P*-value of <0.05 was considered significant. Statistical analysis was performed using SPSS 11.0 for Windows.

RESULTS

Results from 20/21 subjects were analysed; 9 were men. one patient left the clinic without completing the questionnaire and were thus excluded from the study. The mean and standard deviation of the three paired groups are shown in Table 2. The improvement in QOL was statistically significant. Specifically, the improvement in activities of daily living was significant (t=2.9, d.f.=89,P=0.005), as was the improvement in physical parameters (t=6.0, d.f.=89,P<0.001) and interpersonal parameters (t=16.4, d.f. =89,P<0.001).

The visual analogue scale rating revealed that patients thought this method of therapy significantly improved their psoriasis (P<0.001; Fig. 2). Eighteen patients (80%) thought their psoriasis was completely improved by the bio-energiser system , while only two patient (20%) thought the psoriasis showed no improvement with the therapy.

There were no reported adverse events recorded from the treatments.

DISCUSSION

When measuring the effect of a treatment (in our case the improvement in the patient's QOL) it is important to administer the treatment in a standardised fashion. While aware that there are many unidentified environmental stimuli that may modulate the severity of each exacerbation of psoriasis and that there is a therapeutic effect from being in a supportive environment of clinic interested in treating psoriasis.

There are a number of different protocols used for the administration of this type of therapy on psoriasis. We chose to use the patient as his/her own control to determine the dosing regimen rather than using a categorical scale such as a fixed frequency in which according to other systems, a set dose of milliamps is used to commence treatment with standardised alternating increments given at subsequent treatment.

Table 2 Efficacy measures before and after bio-energiser

Groups	Mean, before bio energiser	Mean, after bio energiser	Change in (Mean ± SD)	*P*-value
ADL	1.67	1.51	0.16 ± 0.52	<0.005
Physical	1.82	1.52	0.30 ± 0.47	<0.001
Interpersonal	2.95	1.80	1.13 ± 0.66	<0.001

ADL, activities of daily living; SD, standard deviation

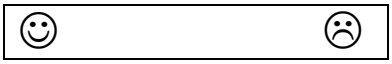

Figure 1
Visual analogue scale. The patient is shown a ruler and asked to state where he/she felt his/her psoriasis was currently. The sad face represents no improvement (corresponding to a score of 1) and the happy face considerable improvement (corresponding to a score of 10).

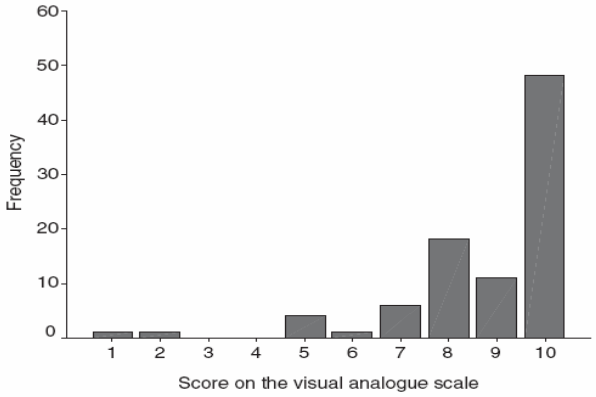

Figure 2 Results of the visual analogue scale at completion of therapy.

Discussions cont.

The concern with the protocol using the categorical scale is that two subjects with the same condition may demonstrate different responses to the same dose of quaver thus affecting their therapeutic response to the therapy. In the interest of achieving the optimal response to a course of the treatment, we adopted a protocol requiring that the patient's to stand up for 30 seconds and drink small to medium size glass of water.

There is some indirect evidence from long-term follow up of patients treated with PUVA photochemotherapy that when dosimetry is individualised there is a reduced risk of longterm development of cutaneous neoplasia and melanomas than when phototype-based therapy is employed.[16] At this time, there are no such long-term data for nbUVB phototherapy. However, in the UK where there is a high incidence of skin cancers, it behoves us to minimize therapeutic UV exposure.

One prospective study evaluated 100 patients attending an outpatient clinic using the Psoriasis Area and Severity Index and the Dermatologists Global Assessment as well as physical measures of disease severity.[17] The PDI was used to measure the patient's QOL at the beginning of treatment and at their 3-month review. Our treatment protocol differed from theirs in that our focus was on how the QOL changed from the beginning to the completion of the BE quaver therapy treatment.

The impact of psoriasis on QOL is frequently profound and often underestimated by the dermatologist. The dermatologist tends to focus on the physical aspects of the disorder, but from the patient's perspective it is often the interactional and functional difficulties that loom largest. In the absence of a permanent cure, the goal of treatment is to minimize the extent and severity of psoriasis to the point at which it no longer substantially disrupts the patient's QOL.[18] It is important to evaluate not just the change in appearance or extent of the patient's disease but also whether at the completion of the treatment course the patient is better able to fully participate in his/her life. Evaluation of the impact of a disease on a patient's QOL measures directly how a disease affects a patient's day-today functioning and sense of satisfaction with his/her life. It is conceptualized functionally by the patient's perceptions of performance in four areas, namely physical, occupational, psychological and social interaction.[19] Good QOL is present when 'the hopes of an individual are matched by experience'.[20] In addition, QOL is not a static measurement, but continually changes over time.[3] For instance, those patients with chronic illnesses at the time of their initial diagnosis may demonstrate a greater impact on QOL compared with later when some degree of mental adaptation has occurred.[3] Will the degree of improvement in QOL be maintained with subsequent courses of treatment? Any dermatologist or medical practitioner who looks after patients with psoriasis knows that the severity of the disease may vary from one clinical episode to another, so response to and duration of effect from treatment may vary from one episode to another. Even if the patient starts from a worse situation than on previous occasions or does not clear as well as on other occasions, an improvement in life quality is a desirable outcome.

Our data demonstrate that there is a significant change in patient-perceived QOL from the commencement of our standardised course of quaver therapy to the completion of the course. There are many questions that still need to be answered. Psoriasis demonstrates a relapsing clinical course. Our study did not measure the length of remission either in terms of continuing reports of good QOL or lack of objective evidence of disease activity. This is information we need to obtain. The long-term squeal of repeated courses of this kind of therapy are also unknown. To obtain this information will require further long-term study.

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APPENDIX I

The BE system was built by Xecare Limited. It contained quaver technology from Q Science. Prior to each course of treatment the patient's condition was established by exposing non-sun-exposed skin of the feet or arms for pre-preparation doses of quaver energy. Starting doses for treatment were estimated on basis of skin colour and the severity of psoriasis. Dosage increments for determining the correct quaver mJ and mAps were 0.5 times the preceding dose. For example, in this system to establish the quaver and amperage for fair skin we would start with 0.5amps. The second square would be exposed to 1×0.5=0.5amps with 1mJ, then 2×0.5=1amp with 2.0mJ, then 3×0.5=1.5amps with 3 mJ. It should be noted that the numerical number of amps or millijoules delivered does not represent a figure transferable to other or similar systems. We have previously presented data demonstrating that under current calibration methodology the dose measured in amps or millijoules in one machine is not equivalent to that measured in millijoules in another machine.[13]

Treatment was given three times a week. The starting therapeutic dose was applied. At each subsequent treatment, the dose was increased by 10% unless there was improvement when the dose was adjusted as per the protocol. Arms and legs were given a full 30 minute treatment. A maximum of 30 treatments were given in any one course. All patients were asked to drink one litre of water a day and prior to receiving the BE therapy. Patients were permitted to continue concomitant topical therapies. Treatment was terminated when the psoriasis had resolved sufficiently to no longer be of concern to the patient, or a maximum of 30 treatments had been given. Missed treatments were handled as per protocol.