RESEARCH STUDY

Treatment for hyperhydrosis, using bio-energiser quaver phase applied to the hands and feet.

Dr Mark Draper[1] Dr Paul Choham[1] Dr Anthony Dunstan-Fox[2]
[1] Malvern Integrated Health Centre
[2]The Wessex Nuffield Hospital, Hampshire

INTRODUCTION

Hyperhydrosis, or excessive sweating beyond physiological needs, may be either focal (localized) or generalised. Generalised hyperhydrosis, affecting the entire skin surface area, is most likely to appear secondary to other medical conditions, and is outside the scope of this guideline. Focal hyperhydrosis is most commonly primary, and defined as "a chronic idiopathic disorder of excessive sweating that many affects the axillas, the palms, the soles of the feet and the face" (Naumann & Low 2001). More rarely, focal hyperhydrosis may occur secondary to other medical conditions, e.g. compensatory hyperhydrosis, gustatory hyperhydrosis in Frey's syndrome, diabetes mellitus, spinal cord injuries, post-zoster syndrome and Ross syndrome.

The incidence of focal hyperhydrosis is estimated to be between 0.6 and 1% of the population for all severities and all locations (Alder et al 1977). The palms and soles of the feet are the most commonly affected sites.

The underlying cause of primary focal hyperhydrosis is unknown, through a positive family history in 30-50% of cases suggests that there is a genetic predisposition, even for the age of onset (Mosek & Korczyn 1995). Age of onset is typically in the teenage years, though the condition may present in childhood or adulthood. In the majority of patients, the disease follows a chronic course.

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

Abbreviations: QV = quaver (mJ), BE = bio energiser, HDI = Hyperhydrosis disability index, QOL = quality of life

THE METHOD

The bio-energiser has been effective in reducing the extent of Hyperhydrosis and producing a remission of variable duration. Studies support the administration of QV therapy based upon establishment of the therapeutic modalities of the BE. It has been demonstrated that the most effective regime is to administer treatment two 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 BE system.

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

Subjects

A total of 8 consecutive patients were referred for bio-energiser therapy to the feet and hands at The Wessex Nuffield Hospital, Hampshire, 2 consecutive patients at the Malvern Integrated Health Centre between August 2004 and July 2005. The use of the bio-energiser as a therapy was considered when the patient's hyperhydrosis was inadequately controlled by topical therapies alone and there are contraindications to the use of the bio-energiser.

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[8,9,10]

We omitted some of the questions and rephrased others to make them more appropriate for our hyperhydrosis sufferers population.

We used a four-point Likert scale to rate the questions. We did not use the scoring system of the HDI. However, as with the HDI, we asked the patients to rate the impact of the hyperhydrosis on their functioning and interactions over the preceding 4 weeks. Our final question requested the patient to rate his/her hyperhydrosis at that point in time. In addition, in the post-therapy questionnaire, the patients were asked to rate the improvement of their hyperhydrosis on a scale of 1 to 10 on a visual analogue scale. one represented no improvement while 9 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 sixteen weeks:

Activities of daily living

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

Physical

7. Is your hyperhydrosis making it difficult for you to do Sport or any other activity?

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 hyperhydrosis?

10. Has your hyperhydrosis resulted in you smoking or drinking alcohol more than you would do normally?

11. To what extent has your hyperhydrosis or treatment made your home messy or untidy?

Interpersonal relationships

12. As a result of having hyperhydrosis, have you felt aggressive, frustrated or embarrassed?

13. Has your hyperhydrosis interfered with your daily social life, social events or relationships?

13. How have you felt about your condition over the last four months?

15. How bad do you think your hyperhydrosis is now?

The 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 and quaver cumulative pulses (all measured as millijoules per square centimeter in the water).

Statistical analysis

In order to explore the validity of the two 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.[2]

The Cronbach's alpha coefficient of group 1, and 2 were 0.7 and 0.5, respectively. The mathematical analysis confirmed the validity of these groupings. We therefore analysed the data using these two 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 9/10 subjects were analysed; 7 were men. One patient left the clinic without completing the questionnaire and was excluded from the study.

The mean and standard deviation of the two 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.=88, P=0.005), as was the improvement in physical parameters (t=6.0, d.f.=88, P<0.001) and interpersonal parameters (t=16.4, d.f. =88,P<0.001).

The visual analogue scale rating revealed that patients thought this method of therapy significantly improved their hyperhydrosis (P<0.001; Fig. 2). Nine patients (90%) thought their hyperhydosis was improved by the bio-energiser system , while only one patient (10%) thought the hyperhydrosis showed no improvement with the therapy.

There were no reported adverse events recorded from the treatments.

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	1.61	1.51	0.15 ± 0.51	<0.005
Physical	1.85	1.51	0.29 ± 0.46	<0.001
Interpersonal	2.02	1.79	1.12 ± 0.66	<0.001

ADL, activities of daily living; SD, standard deviation

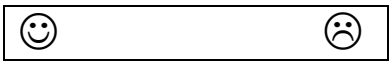

Figure 1

Visual analogue scale. The patient is shown a ruler and asked to state where he/she felt his/her hyperhydrosis 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).

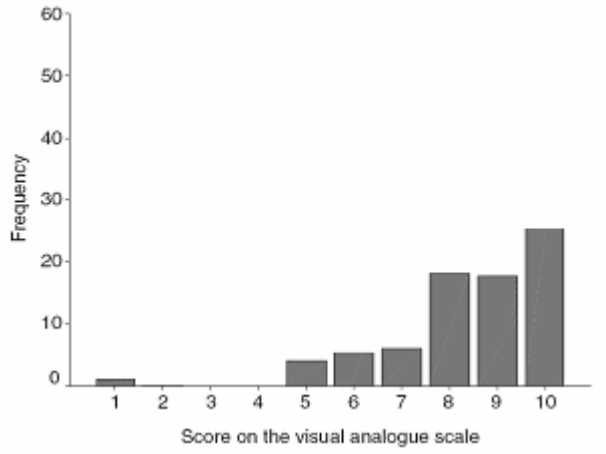

Figure 2

Results of the visual analogue scale at completion of therapy.

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 do not take any other form of hyperhydrosis iontophoresis treatment.

The impact of hyperhydrosis on QOL is frequently profound and often underestimated by the clinician. The clinician 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 hyperhydrosis to the point at which it no longer substantially disrupts the patient's QOL.

It is important to evaluate not just the change in the appearance or extent of the patient's prognosis 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 hyperhydrosis on a patient's QOL measures directly how this condition affects a patient's day-to-day functioning and sense of satisfaction with his/her life. It is conceptualised functionally by the patient's perceptions of performance in four areas, namely physical, occupational, psychological and social interaction.[1]

Good QOL is present when 'the hopes of an individual are matched by experience'[3].

In addition, QOL is not a static measurement, but continually changes over time.[2] 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. Will the degree of improvement in QOL be maintained with subsequent courses of treatment? Any clinical practitioner who looks after patients with hyperhydrosis knows that the severity of the condition 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 good change in patient-perceived QOL from the commencement of our standardised course of BE quaver therapy to the completion of the course. There are many questions that still need to be answered.

Hyperhydrosis 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 the condition activity. This is information we need to obtain. The long-term sequel of repeated courses of this kind of therapy are also unknown. To obtain this information will require further long-term clinical study evaluation.

APPENDIX I

The BE system was developed and built by Xecare Ltd. It contained quaver technology from Q Science. Prior to each course of treatment the patient's condition was established by exposing the hands or feet for pre-preparation doses of quaver electrolysis energy. Starting doses for treatment were estimated on basis of perspiration area and the severity of hyperhydrosis. Dosage increments for determining the correct quaver mJ and milliamps were 0.5 times the preceding dose. For example, in this system to establish the quaver and amperage for perspiration cm^2 area of 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.[4]

Treatment was given two 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. Hands and Feet 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 hyperhydrosis no longer be of concern to the patient, or a maximum of 30 treatments had been given. Missed treatments were handled as per protocol.

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