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COOLING SUIT FOR MULTIPLE SCLEROSIS: FUNCTIONAL IMPROVEMENT IN DAILY LIVING?

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Eight cryopositive patients with multiple sclerosis used cooling suits for 40 minutes regularly one or more times daily for a six-week period. The patients were given repeated motor and mental tests by a physiotherapist in order to determine whether they had a continuous beneficial effect of cooling during this period. Additionally, selected activities of daily living performed in the patient's homes were evaluated and registered according to Assessment of Motor and Process Skills (AMPS). Six out of eight patients improved in at least one motor test and all patients improved according to AMPS. For one of the patients, who was profoundly handicapped, the effect of cooling was evaluated differently.

Key words: multiple sclerosis, cooling suit, activity of daily living.

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INTRODUCTION

Local application of cold packs to spastic muscles is often used to decrease spasticity in patients with multiple sclerosis (MS) (1, 14). Lowering of the body temperature by exposure to cold water or cold air could improve other signs and symptoms of this disease (25). This treatment was previously, however, both too impractical and uncomfortable for patients to be of common use.

A new convenient way to provide generalized cooling is the use of a cooling garment for 40–45 minutes. Cooling in this way leads to improvement in different aspects of motor performance, as has been shown previously (4, 5, 26).

In an earlier study, performed in a day-rehabilitation centre, we verified a positive response to cooling in a majority of the investigated patients with MS. This was especially seen in ambulatory tests (12).

The aim of the present study was to determine whether regular cooling could give symptomatic relief and improved function in tests measuring activities of daily living. Of major importance was that the tests were performed in the patient's homes over a sufficiently long period. The effect of cooling on motor and mental functions were investigated repeatedly, following a test protocol used in a previous study.

PATIENTS AND METHODS

Patients with MS

Four men and four women aged 34–62 years (median 48 years), with duration of disease varying from 11 to 31 years participated in this study. Two walked with unilateral support, five with bilateral support and one used a wheelchair. Their Extended Disability Status Score (EDSS) (15) varied from 6.0 to 8.0. All patients fulfilled the criteria for clinically definitive or laboratory supported clinically definitive MS proposed by Poser et al. (21).

The cooling system

The cooling garment (Fig. 1) comprises a vest and head-cap with channels for circulating cooling fluid (Mark VII Microclimate Cooling Suit, Life Support Systems Inc., Mountain View, CA, USA). A pump system driven by chargeable batteries is connected to a cooling box where the circulating fluid, a water-glycol mixture, passes ice water of 10°C. The patient wears the cooling garment for 40 minutes. A timekeeper registered the usage of the equipment.

Procedures

During the six-week study period, the patients were recommended to use the cooling garment 2–3 times daily, except for 24 h before testing. A physiotherapist (LW) tested the patients every second week, before, immediately after and 1.5 h after, using the cooling garment. Once a week, an occupational therapist (UA) observed each patient in his/her home, when performing ADL tasks before and 1.5 h after using the cooling garment.

A physician (YK) was responsible for the fulfilment of the inclusion and exclusion criteria and registered possible subjective beneficial effects on MS symptoms as well as possible unwanted effects associated with cooling. The duration of the cooling effect was also noted.

Motor and mental tests: evaluation by a physiotherapist (LW). Mobility was measured in climbing a staircase and walking 7.5 metres on level ground, turning around and walking the same distance back again. Time in seconds was measured with a hand-held stopwatch. Tandem gait was expressed as the number of steps heel to toe along a white straight line on the floor without loosing balance. The patients were allowed to have a walking aid if necessary.

For the wheelchair dependent patients, these tests were replaced by a test measuring the distance in metres the patients were able to walk within bars during 30 seconds.

Spasticity was evaluated and classified according to the Ashworth scale (16).

Muscle power was evaluated in the right iliopsoas muscle. The results were registered according to the scheme supported by the Medical Research Council (3).

Dexterity in the right hand was measured using a peg board device. Time was measured in seconds. Grip strength of the right hand was evaluated by a dynamometer (kPa).

Response speed was measured using a computer system. The time, in milliseconds, between the appearance of a visual stimulus on a monitor

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Fig. 1. The cooling suit comprises a vest and a head cap, with channels for circulating cooling fluid, attached to a cooling box (Mark VII Microclimate Cooling suit, Life Support Systems Inc., Mountain View, CA, USA).

screen and the patient touching a key on the keyboard, was calculated by the computer program and the mean result of three tests was recorded.

Serial subtraction of 7 from 100, was recorded as the number of correct subtractions in one minute.

A subjective assessment, i.e. the patient's own evaluation of the overall effect of cooling as marked, moderate or slightly better or worse, or unchanged, was transformed into figures +3, +2, +1, 0, −1, −2 and −3.

Temperature recordings. Rectal temperature was used as a measure of core temperature. The thermometer (in Celsius) was validated against a reference thermometer in a water-bath. The deviation expressed as the standard error of the mean was 0.003°C. Temperature recordings were made immediately before and after cooling and before the motor and mental tests.

AMPS evaluation by an occupational therapist (UA). Assessment of Motor and Process Skills, the AMPS, (11) measures the quality of performance of ADL activities, e.g. meal preparation, household management tasks. Many-faceted Rasch analysis program (18) and FACETS Rasch analysis software (17) have been used when developing the AMPS (9, 11). This observational instrument evaluates both motor skills and process skills in the context of performing a familiar and relevant ADL task. The AMPS makes it possible to account for personal biases of the rater and the relative challenge of the different skill items (10). Different tasks can be used when a person is observed more than once and the problems of learning tasks do not occur. Motor skills are defined as the operations or actions that a person use to move the body and/or subjects during the performance of all activities in daily life, relating to underlying postural control, mobility, coordination and strength. Process skills pertain to underlying attentional, conceptual, organizational and adaptive capabilities that a person uses logically to organize and adapt the behaviour to fulfil an activity (11).

The AMPS includes 63 standardized tasks, e.g. making an open sandwich, setting a table, preparing canned soup, vacuuming. Each observation must include at least two tasks that are relevant for the patient regarding habits, volition and performance skills. The observed performance of the skill items (Table I) is rated on a four-point rating scale (4 = competent, 3 = questionable, 2 = ineffective, 1 = deficient) by a trained and calibrated AMPS rater who has a manual with scoring criteria for support. The rater then uses a personal copy of the AMPS software in which the raw scores are entered and converted into linear personal ability measures which are adjusted for skill item difficulty, task challenge and rater severity. The results are expressed in equal-interval units and placed on linear motor and process continua.

Table I. *Motor and process skill items in Assessment of Motor and Process Skills (AMPS) 7.0*

Motor skills	Process skills
Stabilizes	Attends
Aligns	Paces
Positions	Chooses
Walks	Uses
Reaches	Handles
Bends	Heeds
Coordinates	Inquires
Manipulates	Notices
Flows	Initiates
Moves	Continues
Transports	Sequences
Lifts	Terminates
Calibrates	Searches
Grips	Gathers
Endures	Organizes
Paces	Restores
	Accommodates
	Adjusts
	Navigates
	Benefits

ADL activity in which dexterity is important. The time taken to button a cardigan, blouse or shirt with at least four buttons was measured in seconds with a handheld stopwatch before and 1–1.5 h after using the cooling suit.

Single case study. One of the patients with advanced disease (EDSS = 8.0) could not perform any of the 63 tasks in the AMPS or the dexterity test. In this case three other relevant ADL activities were chosen.

1. Wheeling a manual chair indoors 8 metres, time measured in seconds.
2. Eating a meal, with the same dish, amount, spoon, plate and sitting position every time. Performance was measured as time to complete the meal, or if this was impossible, the volume of remaining food.
3. Handwriting test, with the same pencil and sitting position every time.

Questionnaire

Before the study, the patients were asked about their specific MS symptoms according to a standardized protocol. At the end of the study the patients were asked about the effect of the cooling on these symptoms. In a written questionnaire, three closed and two open questions were given. The patients were asked if they felt improved and, if so, could they accomplish tasks they could not do before? Was the magnitude of improvement of such significance that they felt motivated to continue to use the cooling suit?

Statistics

In the motor and mental tests Mann–Whitney test was used because of uncertainty about normal distribution.

Wilcoxon signed rank test was used in the AMPS part of the study. This method was used because of the AMPS design using comparisons in pairs. All p-values were tested against improvement as well as

deterioration. A p-value < 0.05 was registered as a non-random deviation.

RESULTS

Motor and mental tests

In the motor and mental tests for each patient the results before cooling (three registrations) were compared with the results after (three registrations immediately and 3 intervals of 1.5-hours after cooling).

Six out of eight patients improved statistically in at least one motor test. Five out of these six increased their ambulatory ability in walking on level ground and climbing stairs or in walking in parallel bars for the wheelchair-dependent patients. One patient increased the speed on the pegboard and showed a clear tendency towards improvement in walking.

Two out of eight did not improve statistically, but both increased their capacity ($p = 0.095$), one in walking and the other in grip strength.

Three patients had consistent marked spasticity (4 on the Ashworth scale), all improved and in two the improvement reached statistical significance.

One patient, who improved in motor tests also improved his speed in serial subtraction, otherwise there were no significant effects of cooling on mental tests.

There was an almost total agreement between functional improvement and the patients' subjective judgement.

AMPS

Six observations (each including two different ADL tasks) were made before, and six after, cooling. Significant improved quality in performing motor skills in ADL activities according to the AMPS was found in all seven cases studied, with p-values of 0.028 or less (Fig. 2). The improvement was stable when comparing the results from the first half with the second half. Two patients also showed significant improvement in process skills (Fig. 3).

ADL activity in which dexterity is important. Time to button a cardigan, blouse or shirt did not change after cooling. Median values were 58.5 and 56 seconds, respectively.

Single case report. Significant improvement ($p = 0.043$) was registered in time wheeling the ambulant chair. Median value before cooling was 31.5 seconds (range 17–43 seconds) and 19 seconds (range 15–21 seconds) after cooling. Before cooling, the patient was able to eat a standardized meal in one out of five attempts. After cooling, improved motor control (less ataxia) allowed the patient to complete his meal four times out of five. Three handwriting results are shown in Fig. 4. Technical problems with the cooling suit excluded one of the test days of ADL functions. Thus the number of observations were five before and five after cooling.

Utilization of cooling suit. When the usage time, as registered by the timekeeper, was compared with the patients' own estimations of usage, there was a tendency among the patients to overestimate the time spent in the cooling suit. During six weeks' home-treatment, the average use measured with the timekeeper was 30 h, with a variation from 10 to 50 h. The average use of the cooling suit was 45 minutes, once a day.

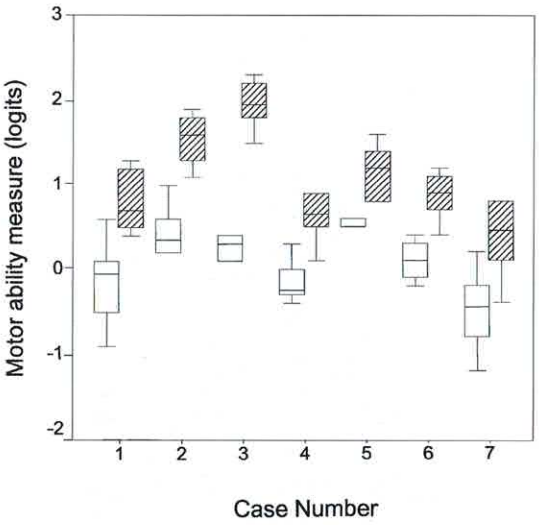

Fig. 2. Box plot of AMPS motor ability measures before (unshaded) and after (shaded) cooling suit treatment. The boxes represent 50% of the values ($n = 6$), median and range are indicated.

Mean temperature reduction. The mean rectal temperature reduction was 0.18°C, median 0.21°C.

Questionnaire. All patients experienced less tiredness. All patients with muscle stiffness and six out of seven with micturation disturbances reported improvement after cooling. Two patients noted improved speech, two improved visual acuity, one diminished pain and one improved sensibility. The

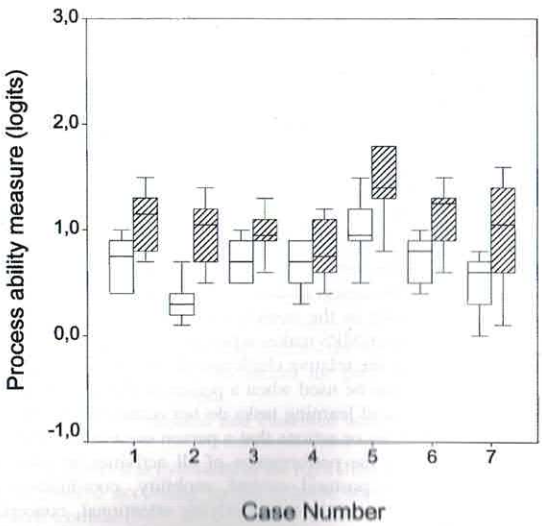

Fig. 3. Box plot of AMPS process ability measures before (unshaded) and after (shaded) cooling suit treatment. The boxes represent 50% of the values ($n = 6$), median and range are indicated.

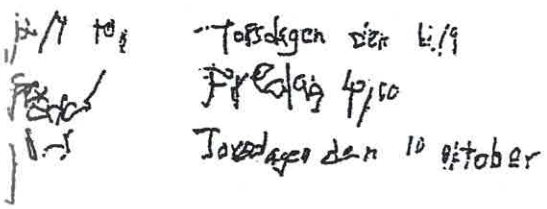

Fig. 4. Examples of handwriting by a patient with multiple sclerosis with severe spastic-ataxic motor dysfunction performed before and after cooling.

estimated duration of positive effects varied between 1 and 24 h, with a median of 5 h.

In the written questionnaire four patients described abilities that they had gained after cooling, e.g. working in a standing position, using a pencil, buttering a sandwich, improved eating procedure, sleeping through the night without the urge to micturate.

DISCUSSION

All the patients in this study had a moderate to severe functional handicap (EDSS 6.0 or more) and needed some form of daily assistance. They were all cryopositive, and in earlier investigations had responded with improved motor performance after cooling. To ascertain that there was a continuous positive effect of cooling, the patients were investigated repeatedly by a physiotherapist with the same tests throughout the study. In six out of eight patients a positive motor response to cooling was registered. In the remaining two patients, the results showed a positive tendency which, however, did not reach statistical significance. This was probably due to the low number of observations: three registrations before and six after cooling.

The results are in agreement with a previous study, in which we found a positive response to cooling in 16 out of 20 ambulatory patients with MS and in all 6 wheelchair-dependent patients (12). However, improvement in motor tests does not necessarily mean reduced disability. The AMPS is a valid and reliable instrument to measure disability (2, 6, 8, 11, 20). It is sensitive to changes in the quality of performance of ADL tasks and also gives the observer information about underlying impairments that influence the efficiency, effectiveness and safety of ADL task performance. It is also well suited for studies of patients with MS (7). All tasks in the AMPS were well known to the patients and were performed in their homes. This fact diminished the problem of learning.

The AMPS results showed significant improvement for all seven investigated patients in motor skills and in two patients in process skills. These results are in agreement with reduced disability, probably due to an improved motor ability after cooling. The improvement in process skills in our two patients can be explained by improved physical conditions leading to fewer problems needing adjustments during the course of task performance.

One patient was too handicapped to be applicable for AMPS. In this patient improvement in other test items were obvious. For all patients the improvements revealed in tests were further substantiated by the results of a questionnaire.

All patients had a median motor and process score of less than 1.0 in the AMPS before cooling. Through descriptive analysis, Fisher has found that the vast majority of persons that have a score of <2.0 on the motor scale and/or <1.0 on the process scale have limitations that make them require assistance (11). After cooling all patients reached higher median motor ability scores and one reached 2.0. This last patient also reached a median process score close to 1.0. Despite the recorded improvements after cooling, problems remained that made all patients need some form of assistance from another person in their daily life.

The possible vitalizing and positive effect of an occupational therapist intervening in the patient's own home must of course be taken into account. This factor could *per se* encourage the patient towards a more independent performance. According to the timekeepers attached to the cooling boxes, the patients overestimated the time spent in the suit. This could be a sign of good behaviour to please the investigators and thus represent a possible placebo effect. On the other hand, the patients' endurance in using the suits and the persistent positive response during six weeks argue against a placebo effect.

The possible mechanism behind the beneficial effect of cooling in some patients with MS is not known. Several hypotheses have been proposed. Perhaps the most attractive theoretical explanation is a direct effect on nerve-impulse propagation through demyelinated nerve segments (23). However, studies with motor and sensory evoked potentials do not substantiate this explanation (13, 22).

The temperature recordings were made rectally. The mean temperature reduction was 0.18°C and median 0.21°C, well in accordance with our results in an earlier study (12). In most other studies with cooling garments, the recordings have been made either from the oral cavity or the tympanic membrane. The use of a head cap close to these areas may influence the recordings (19) and therefore we chose a rectal recording. Ideally, the temperature should be recorded in the target organ, e.g. the myelin or its closest substitute, i.e. the oesophagus (24). This, however, is impractical and inconvenient.

The results from this study support our earlier study and confirm that, for some patients with MS, the cooling suit treatment may bring about a useful reduction of symptoms and increase their ability to perform complex motor skills, which is of importance for independence and thus for their quality of life.

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