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Recent History

DO PHYSICAL THERAPY AND O... GO

DO PHYSICAL THERAPY AND OCCUPATIONAL THERAPY REDUCE THE IMPAIRMENT PERCENTAGE IN REFLEX SYMPATHETIC DYSTROPHY?[1]

[Research Articles]

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Approved by the Independent Ethics Committees of the University Hospital Nijmegen and the University Hospital Amsterdam, Nijmegen, The Netherlands.

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ABSTRACT

Reflex sympathetic dystrophy (RSD) is a disorder that can potentially result in permanent impairment. Because there are no adequate comparative studies regarding the additional value of physical therapy (PT) or occupational therapy (OT) for reducing the severity of permanent impairment in RSD, we prospectively investigated their effectiveness. At two university hospitals, we randomly assigned 135 patients with RSD of one upper limb, existing for <1 yr, to PT, OT, or control therapy (CT). One year after inclusion, impairment percentages were calculated according to the general method of the American Medical Association's *Guides to the Evaluation of Permanent Impairment.* For statistical evaluation, the Wilcoxon's signed-rank test (two-sided; [alpha] = 0.05) was used. The mean whole body impairments were as follows: PT, 21.6% and 19.1%; OT, 22.8% and 22.1%; CT, 22.0% and 22.1% (intention-to-treat and per protocol analysis, respectively). There were no significant differences between the groups. We conclude that impairment percentages in RSD patients treated with PT or OT did not differ significantly from those treated with CT at 12 months after inclusion.

Reflex sympathetic dystrophy (RSD), also called complex regional pain syndrome I,[1] is a syndrome characterized by a triad of sensory, motor, and autonomic disturbances.[2,3] Early signs and symptoms, which include diffuse pain, edema, temperature changes, and reduced range of motion, occur in an area much larger than the area of primary injury or operation, including the area distal to the primary injury.[4] Furthermore, they are aggravated by use of the affected limb.[4] RSD can occur after (sometimes minor) injury to a limb [5] or even spontaneously. Only one of five RSD patients is fully capable of resuming previous activities.[6] Signs and symptoms may persist in patients [4,7,8] and, therefore, may result in permanent impairment.

A variety of medical treatments have been described for RSD, although none is uniformly successful. Furthermore, adjuvant treatment with physical therapy and, to a minor extent, occupational therapy have often been recommended.[9-17]

Unfortunately, there are no adequate comparative studies regarding physical therapy or occupational therapy in RSD.[12] Studies concluding that physical therapy is effective as a treatment for RSD lack control groups.[10,14,17] To fill this gap, we conducted a randomized, controlled clinical study on the additional value-adjuvant to the medical treatment-of physical therapy *v* occupational therapy in patients with RSD of one upper limb. This study addresses the research question: What is the influence of various treatments on the severity of permanent impairment, as calculated according to the guidelines of the American Medical Association?[18]

METHODS

Patients

Patients with RSD of one upper limb, existing for <1 yr, who visited the outpatient clinic of the University Hospitals in Nijmegen or Amsterdam were approached to participate in the study. Complete treatment had to be given at the University Hospitals in Nijmegen or Amsterdam, and the patients had to be >=18 yr old. Criteria for exclusion consisted of the following: impairment in the contralateral limb (for example, because of rheumatoid arthritis), relapse of RSD, pregnancy, lactation, and previous sympathectomy of the affected limb. According to the criteria formulated by Veldman et al.,[4] the diagnosis of RSD was made if the following conditions were met: (1) four of the five following signs and symptoms were present: pain, altered skin color, altered skin temperature, edema, and/or reduced range of motion; (2) the symptoms were present in an area much larger than and also distal to the primary injury; or (3) the symptoms were aggravated by activity of the limb.

Patients were given written and verbal information concerning the study. Written informed consent was obtained from all the participants. The protocol was approved by the Independent Ethics Committees of the University Hospital Nijmegen and the University Hospital Amsterdam. Each patient was seen by one tester. Three testers participated in the evaluations, all of whom were experienced in measuring and evaluating impairments and well informed about the RSD syndrome.

Design

The study was designed as a prospective, randomized, controlled, single-blinded clinical trial. All participating patients received medical treatment according to a fixed pre-established protocol, consisting of

free-radical scavengers, peripheral vasodilators in the case of primarily cold RSD, and treatment of trigger points. The effectiveness of this medical treatment has been demonstrated previously.[19-21] The patients received general information with rules of life related to RSD.

After inclusion in the study, patients were randomly assigned to one of three groups: group I, physical therapy (PT); group II, occupational therapy (OT); or group III, control therapy (social work; CT). Assignment to groups was performed according to allocation lists established by the Department of Medical Statistics of the University of Nijmegen, with stratification to the duration of illness (two categories, 0-6 months and 7-12 months) and to the temperature of the skin of the affected limb at intake (two categories, warm and cold). The rationale for this stratification was the greater chance for recovery in patients with warm RSD and RSD of short duration, compared with those with cold RSD and RSD of long duration. Randomization was restricted to blocks of six patients. To control equal distribution of impairments for the three groups, signs and symptoms of RSD were measured and the Impairment level SumScore was computed.[22] The nature of PT, OT, and CT is described in general terms in the appendix. If, during the period of the trial, the patient explicitly indicated that he or she wanted to change to another adjuvant therapy, this was allowed. A coin toss determined which adjuvant treatment was next. For PT and OT, the duration of each treatment session was 30 min; the number of treatment sessions could vary among patients and depended on the severity of the RSD and the reaction of the patient toward the treatment. Eleven therapists participated in the study, six PT and five OT. For CT, the number of treatment sessions could vary among patients and was based on each patient's personal wish. Four social workers participated in the research project. Impairment rating was performed 12 months after inclusion in the study.

Outcome Measure

The impairment rating was performed according to the American Medical Association's *Guides to the Evaluation of Permanent Impairment*[18] (GEPI). In the GEPI, impairment is defined as a deviation from normal in a body part or organ system and its functioning.[18] The GEPI provides a standard framework and method of analysis for making impairment ratings in general, with some further specifications for a limited number of disorders. A subsection is dedicated to impairment evaluation of RSD of the upper limb, which describes a specific evaluation method. At our hospital, this specific

method was found to be difficult to interpret and perform, and to have imperfections. Therefore, the general method for impairment evaluation from the GEPI was used.

For this rating method, the active range of motion (AROM) of all joints of both upper limbs was obtained using goniometers. AROM was scored in an alternative manner. Because inter-rater reliability of range of motion measurements is not very high,[23-25] we used intra-rater outcomes, measuring each joint on both the unimpaired and the impaired sides before continuing with the next joint. The AROM of the impaired limb was compared with the AROM of the contralateral limb to determine the individual restriction in active motion.[22] Both the difference in AROMs and the AROM of the impaired limb were related to the rating scale of the GEPI to derive the appropriate impairment percentages for loss of range of motion.

Sensory loss in the fingers and thumb was assessed using the two-point discrimination test. To avoid duplication of impairments in the same pathological process, the section "vascular disorders of the upper limb" and the parts "bone and joint deformities" and "musculotendinous impairments" in the section "other disorders of the upper limb" were skipped. Because RSD/complex regional pain syndrome I is defined as a syndrome without a definable nerve lesion, the section concerning impairment resulting from peripheral nerve disorders also was skipped.

As signs and symptoms in RSD increase during or after effort,[4] activities are often avoided or cannot be performed. Also, these patients suffer from weakness of the skeletal muscles in the affected limb.[4] Therefore, grip strength, which measures activity in many arm and hand muscles, was judged to be an important indicator of impairment and was, therefore, included in the evaluation. Grip strength was measured with a Jamar Dynamometer (Asimov Engineering Co., Los Angeles, CA), using the second handle-spacing position, when both the intrinsic and extrinsic muscles of the hand contributed to the voluntary effort.[26] As described in the GEPI, first, regional impairments were rated, with multiple regional impairments combined using the Combined Values Chart. After the values for regional upper limb impairment and grip strength were obtained, they were combined with an upper limb impairment rating, which was converted into the whole-person impairment (Table 1). The maximum whole-person impairment percentage for upper limb impairment is 60%.

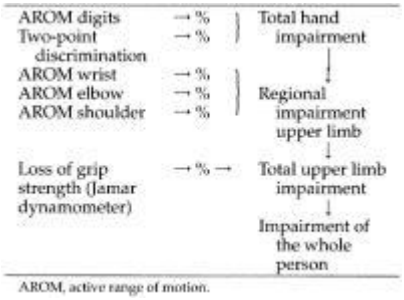

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TABLE 1 Diagram of impairment evaluation, constructed according to the general method for evaluating impairment of the upper limb as described in the *Guides to the Evaluation of Permanent Impairment*

Statistics

Data are expressed descriptively. Because we did not expect the outcomes to have a normal distribution, the Wilcoxon's signed-rank test (two-sided; [alpha] = 0.05) was used to determine whether the median impairment percentages and their distribution, 12 months after inclusion, differed significantly between the three groups. Two analyses were done: an intention-to-treat analysis and a per protocol analysis. In the intention-to-treat analysis, outcomes of all participating patients were used for the group to which they were originally assigned. In the per protocol analysis, outcomes of dropouts or protocol violators (for example, patients who had switched adjuvant therapy) were ignored.

RESULTS

Patients

From June 1, 1994, to February 28, 1998, 145 consecutive patients who fulfilled the inclusion and exclusion criteria were approached to participate in the study. Of these, 10 refused to take part; thus, 135 patients were included, 95 women and 40 men. Mean age of the participants was 53 yr (SD, 17). None of them had a peripheral nerve lesion, so all were complex regional pain syndrome I. RSD was located in the right upper limb in 45% of the patients and in the left upper limb in the remaining 55%. At inclusion, the mean duration of complaints was 3.6 months (SD, 3.4). The characteristics of the patient sample are described in Table 2. No relevant differences were present between the two participating hospitals regarding the

characteristics of the patients included. The patients in the three research groups had similar characteristics at enrollment. The Impairment level SumScore did not vary significantly among groups.

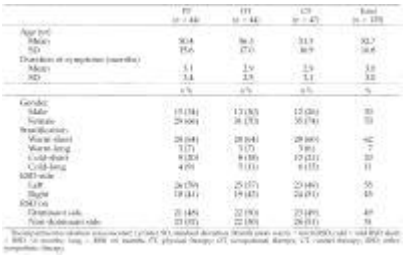

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TABLE 2 Characteristics of the patient sample when entering the study

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After inclusion in the study, 44 patients were referred to PT, 44 to OT, and 47 to CT (Fig. 1). In the course of the 1-yr study period, seven PT, four OT, and four CT patients abandoned the trial. Three patients from the PT group could not complete the treatment protocol (protocol violators) but had test continuity. Furthermore, three patients (one from each group) did not attend the impairment rating. Fourteen patients changed therapy: 12 from CT to PT (nine patients) or OT (three patients) and two from OT to PT.

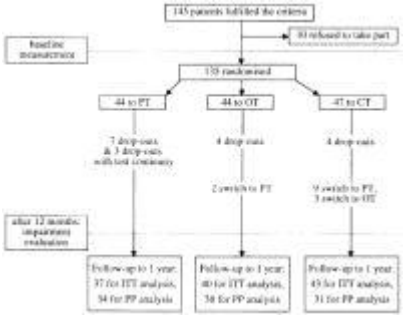

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Figure 1. Trial profile; *CT,* control therapy; *PT,* physical therapy; *OT,* occupational therapy; *ITT analysis,* intention-to-treat analysis; *PP analysis,* per protocol analysis.

Impairment Rating

Concerning the intention-to-treat analysis, the mean outcome was 21.6% whole-body impairment (WBI) (SD, 15.3) in the PT group, 22.8% WBI (SD, 13.6) in the OT group, and 22.0% WBI (SD, 13.3) in the control group (Table 3). There were no significant differences between the groups; all *p* values were >0.10.

	Mean	SD	Median	q1–q3
Total hand impairment				
PT	19.0	19.5	11.0	6–24
OT	16.7	14.1	15.5	5.5–22
CT	17.9	20.4	12.0	6–18
Regional impairment of the upper limb				
PT	25.0	22.5	17.0	7–30
OT	24.4	18.5	19.0	10–33
CT	25.0	20.4	18.0	13–30
Total upper limb impairment				
PT	35.9	25.7	33.0	15–51
OT	36.7	20.6	35.5	22–51
CT	35.5	21.4	31.0	23–44
Impairment of the whole person				
PT	21.6	15.3	20.0	9–31
OT	22.8	13.6	21.5	13–31
CT	22.0	13.3	20.0	14–26

q1–q3, interquartile range.

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TABLE 3 (Regional) impairment percentages after 1 yr of physical therapy (PT; n = 37), occupational therapy (OT; n = 40), or control therapy (CT; n = 43): intention-to-treat analysis

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Concerning the per protocol analysis, the mean outcome was 19.1% WBI (SD, 13.1) in the PT group, 22.1% WBI (SD, 13.6) in the OT group, and 22.1% WBI (SD, 13.8) in the control group (Table 4). Again, there were no significant differences between the three groups.

	Mean	SD	Median	q1–q3
Total hand impairment				
PT	16.0	16.8	10.5	5–23
OT	16.1	14.0	15.0	5–21
CT	18.4	20.9	13.0	6–18
Regional impairment of the upper limb				
PT	22.7	17.6	17.0	7–30
OT	23.5	18.4	19.0	9–32
CT	25.1	20.2	18.0	13–31
Total upper limb impairment				
PT	31.6	22.0	30.0	12–51
OT	35.6	20.5	35.0	22–49
CT	35.1	21.9	30.0	22–45
Impairment of the whole person				
PT	19.1	13.1	18.5	7–31
OT	22.1	13.6	21.0	13–31
CT	22.1	13.8	20.0	13–27

q1–q3, interquartile range.

TABLE 4 (Regional) impairment percentages after 1 yr of physical therapy (PT; n = 34), occupational therapy (OT; n = 38), or control therapy (CT; n = 31): per protocol analysis

DISCUSSION

In this study, no significant differences were detected between the treatment groups and the control group regarding permanent impairment, 12 months after inclusion. The impairment rating based on the American Medical Association's GEPI yielded similar outcomes. There are several explanations for this finding. First, the effectiveness of PT and OT might not be represented in the impairments measured. With PT and OT, much attention is given to reducing pain and raising pain control. Although pain is the most prominent symptom in RSD,[1,3] it is not incorporated into this impairment rating. Also, other diagnostic signs and symptoms, such as the difference in skin temperature and edema, are not represented in the impairment rating. In the PT and OT protocols used in this study, a great deal of attention was paid to reducing pain and raising pain control and to reducing edema and normalizing the circulation. These therapeutic points of interest have been confirmed by others.[9,13,15,27,28]

A second explanation for the lack of significant differences between the groups might be the length of time since the onset of RSD. In patients with long-standing RSD, Geertzen et al.[29] found that differences in AROM between limbs was never more than 7°. Although the mean duration of RSD in their patient population was longer than that in our population, this improvement of ROM in time might also have contributed to the lack of differences between our groups.

Probably the additional value of PT and OT is more pronounced when the signs and symptoms are most prominent, leading to quicker improvement. Therefore, attention should be paid to these aspects of patient recovery.

In patients with RSD, differences exist between measurement outcomes and the subjective experience of the patients concerning their impairments.[29,30] Perceived impairments were not incorporated into the impairment rating. Therefore, no statements can be made about the opinions of the patients regarding their degree of impairment.

The impairment rating according to the GEPI implies the actual rating of impairments. Disabilities were not rated. In the GEPI, it is stated that with an impairment percentage, an informed estimate can be made of the degree to which an individual's capacity to perform daily activities has been decreased.[18] This statement is supported by Gloss and Wardle,[31] who indicated that the GEPI's ratings show both substantial reliability and accuracy with various tests of hand function. Others stated that outcomes on the level of impairment and disability are not necessarily correlated.[32-34] We agree that an estimation of the disability level should not be made on the basis of the impairment rating alone. It is advisable to measure and rate disabilities apart from impairment.

Other points of discussion concern the study design. In our study, Veldman's criteria were used to set the diagnosis of RSD. We found bedside evaluation of RSD using Veldman's criteria to be in good accord with psychometric or laboratory testing of these criteria.[30] Therefore, we did not consider using other sets of criteria, although they are mentioned in literature.[1,35-38]

Although the study was single-blinded, blinding was violated partially by the patients during the year of treatment. For example, patients were seen on their way to the treatment departments or they asked to switch to another adjuvant therapy, and this was executed by the researcher. Therefore, the internal validity of the study might be slightly compromised. However, because impairment evaluation was performed using an objective method in which the influence of the tester was negligible, the results can be considered valid.

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APPENDIX

Physical therapy, occupational therapy, and social work treatment protocols for patients with RSD of the upper limb.

Physical Therapy and Occupational Therapy

After a structured assessment and according to pre-fixed criteria, the patient was assigned to a specific treatment condition within the protocol for which the main treatment objectives were specified and adapted for intensity and method. Then, the intensity and form of treatment were adjusted to the individual patient. Measurements were taken monthly to evaluate and adjust the treatment condition. The treatment modalities and their use are described in the protocols.

Physical Therapy

Main treatment objectives were as follows: (1) to increase pain control and to optimize coping with RSD by talking (directed toward helping the patient to gain control of the pain complaints by offering

insight, practical advice, and support) or by relaxation exercises (to increase the selectivity of the patients); (2) to extinguish the source of the ongoing pain by rest (local), connective tissue massage, trancutaneous electric nerve stimulation, or exercises for reducing the pain (directed at stimulating kinetic receptors type I and II); and (3) to improve skills by practicing compensatory activities, giving instructions about the position of the body, and training skills.

Occupational Therapy

Main treatment objectives were as follows: (1) to reduce symptoms of inflammation and/or to protect and support the hand/wrist/forearm in the most functional and comfortable position (for example, by means of splint treatment); (2) to normalize sensibility by means of different tactile materials, game activities, and/or techniques with a great deal of tactile and proprioceptive input; (3) to improve functional abilities of the arm/hand by having the patient execute various activities while moving as normally as possible; and (4) to improve independence in activities of daily living. This was done by training, by teaching the patient how to perform activities differently, and/or by advising the patient regarding devices.

Social Work

In the control group, social work mostly comprised providing attention to the patient. Attention was given in a passive form, by listening to the patients and helping them in a limited way to gain insight into the social problems accompanying RSD. General information regarding RSD was also offered to the patients, concerning how not to evoke pain, and they were encouraged to take enough rest and to ask for help with executing activities that were too demanding for them.

Further information concerning the protocols can be obtained from J. Oosterhof, 355 Department of Physical Therapy, or E. H. C. Cup, 300 Department of Occupational Therapy, University Hospital Nijmegen, PO Box 9101, 6500 HB Nijmegen, The Netherlands. [Context Link]

Key Words: Randomized Controlled Trial; Reflex Sympathetic Dystrophy; Physical Therapy; Occupational Therapy; Impairment Rating

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