THE ROLE OF COMPLEX PHYSICAL- KINETIC REHABILITATION TREATMENT IN PATIENTS WITH SERONEGATIVE SPONDILARTHROPATHIES

-ABSTRACT-

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KEY WORDS: ankylosing spondylitis, psoriatic arthritis, rehabilitation treatment, assessment, quality of life.

INTRODUCTION

The appearance of the concept of seronegative spondylarthropathies represented an outstanding contribution of brilliant researchers: Brewerton and all (1973), Aho and all (1973), Moll, Wright and all (1974). Actually, the certitude of the existence of the spondylarthropathies group, which includes diseases that „gravitate” around patients immunogenetically stigmatised and bound to the presence of the antigen HLA-B27 is generally accepted.

Ankylosing spondylitis, without any doubt the leader of the spondylarthropathies group, and most of the other diseases related to it (the Reiter-Fiessinger Leroy syndrome and reactive arthritis, psoriatic arthritis, arthritis from the inflammatory bowel diseases and undifferentiated spondylarthropathies) are chronic inflammatory diseases with the evolution of the pathogen inflammatory process inside characteristic tisular structures, especially the locomotors ones.

Ankylosing spondylitis is not rare; its prevalence is similar to rheumatoid arthritis (around 1%) at least at the populations of temperate and Nordic areas; in some situations ankylosing spondylitis is not diagnosed because the patients are considered to have mechanical lumbar pain and are incorrectly treated. Regarding psoriatic arthritis, if psoriasis affects 1-2% of general population and the peripheral joint involvement appears at 5-7% of the patients with psoriasis, the result is that this rheumatic disease is relative frequently met (0.1% of the population).

The causes and the pathogenic mechanism of seronegative spondylarthropathies are not completely elucidated yet. Most probably there are involved environmental factors acting on a predisposing genetic field, causing inflammatory reactions leading in time to disabilities secondary to joint destruction and generating important invalidities even from the first years of evolution.

The social and economic costs generated by the late diagnose of these diseases are a lot bigger than the ones imposed by early diagnose and the initiation of an aggressive treatment for the cases at onset of the disease. With few exceptions, for the spondylarthropathies doesn’t exist an etiological treatment, so that the means of action will be mainly pathogenic, aiming the inflammatory process and supportive meant to preserve the structure and function of the involved tissues and organs.
Therapeutic means are the following: igieno-dietetic treatment, medication, kinotherapy, physiotherapy, balneology, orthopaedic and surgical treatment.

The complete evaluation of patients with seronegative spondylarthopathies is essential for assessing different means of treatment. For this purpose were elaborated a great number of variables due to measure different aspects of the disease, some anatomical, other functional, biological or imagistic.

The present study had as a general objective the increase of quality of life for patients with seronegative spondylarthopathies, due to the importance as a medical and social problem of this group of diseases.

The study is structured in two parts: the general part, that includes theoretical notions about the spondylarthopathies and a special part, which includes: material and methods, the results obtained after the complex evaluation of the patients, discussions and the final conclusions. The studied lot included patients with ankylosing spondylitis and psoriatic arthritis and emphasises the influence of different kinetic and physiotherapy treatments on their functional capacity and quality of life.

AIMS

The aims of the study are the following:

1. The elaboration of an individualised rehabilitation program meant to allow a significant change in the management of the SASN and to determine an increase of the quality of life by familial, social and even professional integration of patients, diminishing the social and economical costs.
2. To evaluate the influence of the kinetotherapy program on the quality of life and the compliance to treatment of the patient.
3. To appreciate if the results of the complex physical-kinetic treatment are maintained after one year of therapy.
4. To elaborate a complex rehabilitation program that will include except kinetotherapy other methods of physical treatment (electrotherapy, hydrotherapy, massage) and to compare the results of this treatment with those obtained at the patients that followed only the physical exercise program.
5. To analyze the correlations between the initial and final values of some indicators (the questionnaire for the disease activity BASDAI, the questionnaire for functional status BASFI, the questionnaire for the quality of life HAQ) depending on the rehabilitation program.
6. To determinate the influence of the physical-kinetic treatment on the functional status of the patients by measuring the spinal and peripheral joints mobility and the muscular force.
7. To establish the correct indications and contraindications of the physical-kinetic treatment in the seronegative spondylarthopathies in function of the disease stage and of the co morbidities.
8. To evaluate the contribution of the physical-kinetic treatment to the decrease of the doses of the medication.
9. To integrate the specific methods of treatment of rehabilitation medicine, function of the results of the analyze of the studied parameters, in the multidisciplinary approach of the management of these patients, with the elaboration of a medical team that will include together with the rehabilitation medicine physician, other specialists: the general medicine physician, the rheumatologist, the orthopedist, the radiologist, the physiotherapist, the psychologist etc.
10. To elaborate the profile of the patient with the best response to the physical-kinetic rehabilitation treatment.

**MATERIAL AND METHODS**

We elaborated a longitudinal, controlled, randomised trial that included 232 patients, 138 with ankylosing spondylitis (59,48%) and 94 with psoriatic arthritis (40,51%) for a 6 years period, between 2003-2009, in the Physical Medicine and Rehabilitation Clinic of Craiova Emergency Hospital; the patients were assessed following an unique researching protocol and evaluated at regular intervals.

The main purpose of the study was to emphasise the efficacy of different therapeutic schemes materialized in the improvement of the quality of life and to identify the profile of the patient with a possible sustained therapeutic response.

The efficacy of the complex physical-kinetic rehabilitation treatment evaluated in this clinical study regarded the medical benefit of the treatment, result that I have tried to quantify in terms of health benefit, of decreasing the suffering of the patient, of reducing the symptoms and increasing the quality of life of the patients.

**The evaluation protocol**

**Patients selection criteria**

*Criteria of inclusion in the study:*
- patient’s agreement for participation;
- inclusion of the disease in the group of seronegative spondylarthropathies based on the ESSG criteria (European Spondylitis Study Group);
- patients with ankylosing spondylitis according to the modified New York criteria(1984);
- patients with psoriatic arthritis according to Moll and Wright criteria;
- patients with spinal involvement;
- regardless of the application of previous remissive therapies (including patients with therapies interrupted because of adverse reactions/ lack of therapeutic response);
- regardless of the previous steroidian or nesteroidian anti-inflammatory drugs.

*Exclusion criteria*

The following categories of patients were not included in the study:
- patients with intense disease inflammatory activity;
- patients without axial involvement;
- cardiac failure or severe angor pectoris;
- patients with silent coronaries ischemia;
- miocardic infarction or coronaries bypass 3 months before the inclusion in the study;
- high uncontrolled blood pressure (values › 149/90 mmHg);
- uncontrolled diabetes;
- severe obstructive bronchitis;
- blood coagulation problems;
- tumours in all stages of evolution;
- active tuberculosis;
- fever;
- tromboflebitis;
- severe psychical diseases;
- pregnancy and lactation;
- alcohol dependence;
- patients not willing to cooperate;
- patients involved in other clinical trials.

The parameters of the study
The diagnose of ankylosing spondylitis and psoriatic arthritis was suggerated by the clinical examination and confirmed by the laboratory tests, so that all the patients accomplished the New York modified criteria (1984) and respectively Moll and Wright criteria.

The anamnesis data were the following:
- demographic and anthropometric parameters: age, sex, origin, occupation;
- significant familial antecedents: ankylosing spondylitis, psoriasis, sacroiliitis, and uveitis;
- personal physiological antecedents (for women);
- work and life conditions: alimentation, smoking habits, alcohol, education, profession;
- symptoms: inflammatory spinal/ peripheral joints pain, the duration of morning stiffness, physical asthenia;
- other anamnesis data: the age of the patient at the onset of the disease, disease duration, other diseases, extraarticular manifestations, previous medication or rehabilitation and balneal treatment.

The clinical examination showed: general status, the thermic and ponderal curves, spinal and peripheral joints mobility, muscular strength, functional status, anxiety and depression.

The laboratory tests effectuated for the patients included in the study were the following:
- biological tests: inflammatory tests (erythrocyte sedimentation rate- ESR and C reactive protein- CRP), HLA-B27 antigen, rheumatoid factor;
- imagistic examination: sacroiliac joints, cervical, thoracic and lumbar spine and peripheral joints X-rays, MRI (magnetic resonance imaging), musculoskeletal ultrasound;
- functional respiratory tests.

The assessment of disease activity was effectuated using BASDAI (Bath Ankylosing Spondylitis Disease Activity Index).
The evaluation of functional disabilities was realised using BASFI (Bath Ankylosing Spondylitis Functional Index).

We assessed the quality of life using HAQ (Health Assessment Questionnaire).

The assessment of therapeutic response included:
- the dynamic assessment of BASDAI, BASFI and HAQ;
- the levels of lumbosacral pain both nocturnal and during the last week appreciated by the patient on a visual analogue scale (VAS1, respectively VAS2);
- the changes of the values of ESR and CRP;
- the evolution of the mobility index for cervical, thoracic and lumbar spine;
- the values for the peripheral joints mobility;
- the dynamic assessment of muscular strength for the flexors and extensor of the cervical spine, for the hip stabilisation muscles, quadriceps and the ischiogambiers muscles.

The statistical analyse
Clinical studies involve the application of a therapeutic intervention on a group of subjects and the assessment of the effect by comparison with other interventions.
The variables of the study are described in the table below (table no. 1).

**Table no.1 The variables of the study and their mode of description**

<table>
<thead>
<tr>
<th>Qualitative variables</th>
<th>Quantitative variables</th>
</tr>
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<tbody>
<tr>
<td>1. sex (female/male)</td>
<td>1. patient’s age</td>
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<td>2. profession (professionally active/ without work or at pension)</td>
<td>2. patient’s age at the onset of the disease</td>
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<td>3. smoking habits (non-smoker/previous smoker/actual smoker)</td>
<td>3. disease duration</td>
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<td>4. environment (rural/urban)</td>
<td>4. the number of diagnose criteria</td>
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<td>5. HLA-B 27 antigen(present/absent)</td>
<td>5. the stage of the disease</td>
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<td>6. systemic involvement (uveitis, cardiac involvement)</td>
<td>6. erythrocyte sedimentation rate (ESR)</td>
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<td>7. comorbidities (present/absent)</td>
<td>7. VAS1 (nocturnal lumbosacral pain)</td>
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<td>8. concomitant medication at the inclusion in the study (with/without nesteroidian anti-inflammatory drugs, medication for the associated diseases)</td>
<td>8. VAS2 (global lumbosacral pain during the previous week)</td>
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<td>9. the adverse reactions (absent/present)</td>
<td>9. BASDAI</td>
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<td>10. education (level of education &lt; 10 classes/&gt; 10 classes)</td>
<td>10. BASFI</td>
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<td>11. HAQ</td>
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<td>12. the menton-stern index</td>
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<td>13. the tragus-acromion index</td>
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<td>14. the menton-acromion index</td>
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<td>15. thoracic perimeter</td>
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<td>16. Ott index</td>
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<td>17. Schöber index</td>
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<td>18. hip flexion</td>
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<td>19. hip extension</td>
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<td>20. hip abduction</td>
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<td>21. hip adduction</td>
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<td>22. external hip rotation</td>
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<tr>
<td></td>
<td>23. internal hip rotation</td>
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<td>24. knee flexion</td>
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<td>25. deficit of knee extension</td>
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<td>26. muscular strength for spinal flexors</td>
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<td></td>
<td>27. muscular strength for spinal extensors</td>
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<td></td>
<td>28. muscular strength for hip flexors</td>
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<td></td>
<td>29. muscular strength for hip extensor</td>
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</table>
After establishing the ankylosing spondylitis and psoriatic arthritis diagnose, the patients were included in the studied lot after obtaining their agreement and after analysing the inclusion and the exclusion criteria. The randomising was in 6 lots; both the patients with ankylosing spondylitis and psoriatic arthritis were subdivided in three lots:

- **the control lot with medication**, which had only medication and igieno-dietetic treatment (56 patients with ankylosing spondylitis- 40,57%, respectively 32 patients with psoriatic arthritis- 34,04%);

- **the control lot with kinotherapy**, which followed a well established and supervised kinotherapy program during hospitalisation period and then continued at home the exercise program for one year (41 patients with ankylosing spondylitis- 29,71%, respectively 32 patients with psoriatic arthritis- 30,04%);

- **the studied lot with kinotherapy and physiotherapy**, which followed a complex rehabilitation program that included the kinotherapy program together with electrotherapy, hydrotherapy, thermotherapy and massage (41 patients with ankylosing spondylitis- 29,71%, respectively 36 patients with psoriatic arthritis- 38,29%).

The patients were evaluated periodically, beginning from the moment of the inclusion in the study (the T1 moment) and after 3 months, 6 months and one year (T2, T3, T4). The periodic assessment included the use of all the clinical, biological and functional parameters that could bring information about the disease evolution and the therapeutic response.

The patients that abandoned the study (because of the inefficacy of the treatment, of the adverse reactions or abandon) were comprised in the acceptable limit (under 20%).

**RESULTS AND DISCUSSIONS FOR ANKYLOSING SPONDYLITIS**

Quality of life studies in patients with ankylosing spondylitis attest to its significant impact on day to day activities and social interactions. The aim of this study was to assess the efficacy of complex rehabilitation treatment and its influence on the clinical and functional status of these patients.

The study included 138 patients with ankylosing spondylitis, mean age 41,52±11,63 years, randomized function of the treatment in 3 lots: medication lot (56 patients), exercise lot (41 patients) and the studied lot with complex rehabilitation treatment (41 patients). The patients were clinical, biological and functional evaluated at the beginning of the study, after 3 months, 6 months and 12 months.

The efficacy of physical-kinetic treatment is reflected by statistically significant improvements (p<0.05) of scores for BASFI (Bath Ankylosing Spondylitis Functional Index), HAQ (Health Assessment Questionnaire), spinal and peripheral joints mobility, muscular force and decrease of lumbosacral pain on a visual analogue scale.
The minimal number of patients we need to treat for 52 weeks (number needed to treat-NNT) to prevent the quality of life decrease for one of them was 4 in the studied lot with complex rehabilitation treatment and 6 for the control lot with kinotherapy.

We also established the profile of the patient with ankylosing spondylitis with a maximal response at the physical-kinetic therapy.

The improvement of the clinical and functional parameters has a significant impact on their quality of life.

RESULTS AND DISCUSSIONS FOR PSORIATIC ARTHRITIS

Approaching the patient with psoriatic arthritis (AP) depends on the clinical form and the associated dermatoses. The main purpose of the management of these patients is to ensure a normal and independent living and an appropriated quality of life. In this context we considered it appropriate to evaluate the effectiveness of evolution of the score for Health Assessment Questionnaire (HAQ).

The study included 94 patients, 54% men, divided in three groups comparable in gender, residence, duration of psoriatic arthritis and of psoriasis, age, disease characteristics, smoking: two control lot with drug therapy (32 patients), respectively with kinotherapy (26 subjects) and a test lot with procedures and exercises (36 patients).

Average age of the patients was 45.3±6.21 years, mean duration of AP 15.5±8.75 years and of psoriasis 20.11±9.7 years. All patients were evaluated clinical and functional at the initiation of the study, after 3 months, 6 months and one year.

HAQ dynamics during the 12 months reveals a positive change especially in the physical-kinetic therapy group.

Based on HAQ indicator we calculated the minimum number of patients to be treated for 52 weeks to prevent decreasing the quality of life in at least one of them: 2 in the lot with physical-kinetic therapy and 3 in the lot with kinotherapy. Bath Ankylosing Spondylitis Functional Index (BASFI) influence on HAQ improvement is well above 50%; there is a correlation between indicators estimated as moderately high (0.8).

The results show the contribution of complex physical kinetic therapy to increasing the quality of life for patients with psoriatic arthritis.

CONCLUSIONS

1. For evaluating the efficacy of the complex rehabilitation treatment in patients with ankylosing spondylitis and psoriatic arthritis, a complex initial evaluation is necessary, using parameters with impact on the quality of life. The efficacy of the rehabilitation treatment was evaluated in function of the improvement of the spinal and peripheral joints mobility, muscular strength, disease activity, functional status and spinal pain. We considered opportune for the assessment of the therapeutic response an instrument that reflects the patient’s point of view about what he considers to influence its quality of life: HAQ (Health Assessment Questionnaire).

2. For the ankylosing spondylitis studied lot, the patients structure in function of the stage of the disease was dominated by the stages III (46%) and IV (31%), suggesting the difficulties concerning the early diagnose of the disease.

3. For the medication lot, the most important improvement was observed for lumbosacral pain (the scales VAS1, VAS2) and for the disease activity (BASDAI).
4. Observing the evolution of the inflammatory tests, we demonstrated that the influence of the therapy on ESR was not statistically significant for the lot with ankylosing spondylitis, but the decrease of CRP is certainly the result of the applied therapy both for the patients with ankylosing spondylitis and psoriatic arthritis (p<0.05). Given the role of CRP as a sensible marker for disease activity, these results confirmed the researches according to which the rehabilitation treatment influences the mediators of the immune response.

5. The superiority of the physical-kinetic therapy is reflected by the model of significant improvements (p<0.05) obtained for functional status, quality of life (the scores BASFI, respectively HAQ), for the spine and peripheral joints mobility (hip, joints), muscular strength. For the patients from the control lot with kinotherapy was demonstrated the favourable evolution of the same parameters, but the results were inferior to those obtained at the patients of the studied lot.

6. The restrictive respiratory dysfunction was objectivised at over 60% of the patients. Related to it we analysed the variation of the cirtometric index; the values were differentiated (p<0.05) in function of the smoking habits (p=0.010660), the respiratory restrictive dysfunction (p=0.045689), the stage of the disease (p= 0.009105).

7. The application of the regression analyse for the cirtometric index emphasises that, in the conditions of the physical-kinetic therapy, after only 3 months of treatment, the expansion of the thoracic cage can reach the normal value of 4.419 cm, the result being influenced by the patient’s age, the duration of the disease, the stage of the disease, the severity of the inflammation, the smoking habits, and the restrictive respiratory dysfunction; the results are superior after 6 months.

8. Based on HAQ we calculated NNT – number needed to treat. For the studied lots with complex rehabilitation treatment, this is of 4 patients for the ankylosing spondylitis lot and respectively 2 patients for the psoriatic arthritis lot, inferior to the other compared therapies (the lots with medication and kinotherapy).

9. One of the aims of the study was that, in function of the biological and clinical parameters, to realise the specific profile of the patient of which the physical-kinetic therapy could have a success. It is a male patient, in the fourth decade of life, non-smoker, with a disease duration of approximatively 15 years, with moderate initial values of the disease activity, of the scores of evaluation of disease activity (BASDAI), of the score for quality of life (HAQ) and of the functional status (BASFI), without extraarticular manifestations like uveitis or cardiac involvement, without peripheral joints involvement and respiratory restrictive dysfunction.

10. The improvement we obtained for the evaluated parameters has a significant impact on the patient’s quality of life. Between the studied lots the difference between the mean values initial and final of HAQ had a high statistic significance (p<0.001). Both for the patients with ankylosing spondylitis and psoriatic arthritis we demonstrated a correlation between the improvement of the functional status (BASFI) and the increase of the quality of life (HAQ).
CURRICULUM VITAE

1. Name: Marcu
2. Forename: Iulia-Rahela
3. Date and place of birth: 24.09.1976, Craiova
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5. Marital status: married.

6. Education:

<table>
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<tr>
<th>Institution</th>
<th>General School number 31, Craiova</th>
<th>High School „Nicolae Balcescu”</th>
<th>Faculty of Medicine, University of Medicine and Pharmacy, Craiova</th>
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<td>Physician Diploma</td>
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7. Scientific title: preparing for a doctor’s degree in Medical Sciences.

8. Professional experience:

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<td>Physical Medicine and Rehabilitation Department</td>
<td>Physical Medicine and Rehabilitation Department</td>
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<tr>
<td>Institution</td>
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<tr>
<td>Function</td>
<td>Resident physician</td>
<td>University Preparator</td>
<td>University Assistant</td>
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