Multi-Center Randomized Controlled Trial of Acupuncture and Moxibustion for Rheumatoid Arthritis

Daichi KASUYA[1], Tetsuji SAWADA[2], Hideyuki ISOBE[2], Seigou AKAO[3], Makoto KIKKAWA[4], Kumiko TAKATA[4], Satoru YAMAGUCHI[5], Hiroshi OMATA[5], Kazuhiko YAMAMOTO[2]

1) Physical Therapy Section, Central Rehabilitation Service, the University of Tokyo Hospital.

2) Department of Allergy and Rheumatology, Graduate School of Medicine, the University of Tokyo Hospital.

3) Department of Oriental Medicine, Gifu Medical School.

4) Tokyo Women`s Medical University, Institute of Oriental Medicine.

5) Department of Oriental Medicine, Saitama Medical School.

関節リウマチに対する鍼灸治療の多施設ランダム化比較試験

粕谷大智[1]、沢田哲治[2]、 磯部秀之[2]、 赤尾清剛[3]、
吉川 信[4]、 髙田久実子[4]、 山口 智[5]、小俣 浩[5]、山本一彦[2]

1）東京大学医学部附属病院 リハビリテーション部物理療法部門

2）東京大学医学部附属病院 アレルギー・リウマチ内科

3）岐阜大学医学部附属病院 東洋医学講座

4）東京女子医科大学 東洋医学研究所

5）埼玉医科大学 東洋医学科

抄 録

（はじめに）我々は関節リウマチに対する鍼灸治療の有効性と有用性および安全性を、外来にて薬物療法を行っている群を対照とした多施設ランダム化比較試験により検討した。

（方法）鍼灸臨床研究において重要なendpoint（評価項目）は、1. ACRコアセット（アメリカリウマチ学会提唱の活動性指標）による改善基準と、2. RAのQOL評価法であるAIMS-2日本語版を用い、介入（治療法）については、関節リウマチの病期別に患者の活動性や機能障害を考慮しながら局所と全身の治療を行えるように病期別治療法チャートを作成し、患者の病態に応じて統一した治療法にした。

（結果）1. 症例の収集についてはA群（薬物療法群）80例（女性80例、男性2例、うち2例脱落）、B群（鍼灸治療併用群）90例（女性90例、男性6例、うち6例脱落）の計170例が解析の対象となった。2. ACRコアセット改善基準を満たしている症例（改善例）は、A群80例中8例、B群90例中20例で、2×2カイ二乗検定よりP＝0.04で両群間において有意差を認め、鍼灸併用群の方が有意に改善を示した。3. AIMS-2質問紙によるQOL変化：12ヶ月時点で両群間でP＝0.001と有意差を認め、鍼灸併用群の方が有意に改善を認めた。4. AIMS-2質問紙の各項目の変化：両群間で有意に鍼灸併用群に改善を認めた項目は歩行能、手指機能、家事、社交、痛み、気分、自覚改善度であった。

（結語）今回、多施設ランダム化比較試験において鍼灸併用群で上述の項目において有意に改善を認めたことは、従来の治療に鍼灸治療を

併用することで身体機能低下を予防し、血行改善や精神的安定も得られ、関節リウマチ患者のQOL向上に寄与することが示唆された。

Key words : acupuncture and moxibustion treatment, rheumatoid arthritis, randomized controlled trial, quality of life

I INTRODUCTION

Rheumatoid arthritis (RA) is a systemic chronic inflammatory disease with joint complaints as chief symptoms. Majority of patients with RA exhibit gradual progression through repeated remissions and exacerbations, and, destruction and deformity of joints with severe limitation of activities of daily living. Afflictions of RA patients are not limited to the physical aspect, but involve their entire life including the mental, social and economic aspects. Recently, attempts have been made to understand these multifaceted afflictions of RA patients comprehensively from the viewpoint of quality of life (QOL) using a quantitative approach, and utilize the results of the measurements to evaluate the health status of individual patients and follow up the clinical course as well as for treatment.

According to a survey by the Ministry of Health and Welfare in 1998, osteoarthritic and rheumatic diseases, along with cerebrovascular accidents, account for the majority of physical disability cases, and rank fourth as the cause of patients becoming bedridden, after cerebral apoplexy, senility and fracture caused by falls. The national health survey conducted annually by the Ministry of Health and Welfare revealed that 3-10% of RA patients receive, in addition to therapy provided by hospitals, acupuncture / moxibustion and massage, which clinically relieved pain, extended the range of motion and contributed to the improvement of QOL. However, as compared with drug therapy and therapeutic exercise, acupuncture and moxibustion has not been established as a therapy for RA, and literature reports are still rare in Japan. With the current trend toward evidence based medicine (EBM), there is a strong demand that therapy should be supported by scientific rationale, which also applies to acupuncture and moxibustion. For acupuncture and moxibustion to be recognized as valid and effective therapeutic procedures in RA treatment, it is necessary that the efficacy should be verified by a controlled clinical trial. However, reports of controlled clinical studies of acupuncture and moxibustion are few, and such studies for RA have not been conducted in Japan.

We conducted a randomized multicenter parallel-group comparative study on the effect of acupuncture and moxibustion on the QOL of ambulatory RA patients at 4 centers, to evaluate the efficacy, usefulness and safety of acupuncture and moxibustion for RA with ambulatory patients receiving only drug therapy as control.

II SUBJECTS AND METHODS

1. Subjects

Ambulatory RA patients in 2001 to 2003 participated in the study. These patients were randomized into two groups, a drug therapy group and a drug therapy plus acupuncture and moxibustion

group, and these groups were compared. Randomization was accomplished by allocating patients with even-numbered ID to the drug therapy group and those with odd-numbered ID to the drug therapy plus acupuncture and moxibustion group. Physicians performed evaluation with masking of group allocation of patients. To minimize scatter in patient characteristics, the following criteria were specified. Patients must be1) able to visit the outpatient clinic,2) aged 20-75 years and,3) with at least 2 years elapsed after onset. Patients treated with steroid at $\geq$10mg/day were excluded.
Prior to the study, which was based on the Japanese version of the GCP, it was approved by the institutional review board at each center, and patients submitted written informed consent of their own free will.

2. Endpoints

The endpoints used were1) improvement criteria in the ACR core set variables (ACR 20)[1),2)], and 2) the Japanese version of the Arthritis Impact Measurement Scales version 2 (AIMS-2)[3)~5)]

3. Acupuncture and moxibustion treatment

Acupuncture and moxibustion treatment was adapted to the severity of joint damage and the general condition of each RA patient. As Table 1 shows, the local condition of the joint was determined from the degree of irreversible change and activity, and treatment was adapted to the disease stage in each joint, while the general condition was evaluated from the presence or absence of fever and the degree of fatigue. The intensity of stimulation was adjusted, and treatment was given once every week or every 2 weeks for non-specific complaints, gastrointestinal disorders likely to be due to drugs or low back pain due to osteoporosis. The course of the illness was observed for about 1 year. In the therapy chart for joints by disease stage, RA was divided into 4 stages, and the relevant therapy is shown. Although therapy is programmed for each joint by morbidity period, not all programs can be shown here due to space limitation, and the knee joint, which is frequently treated clinically, is described. For other joints, readers should refer to our reports and to textbooks[6)].

Table 1 Acupuncture and moxibustion therapy

(1) Joint: Foot/ankle

	Morbidity period	Initial Stage	Early stage	Advanced stage	Late stage
Clinical profile	Irreversible changes	Stage I	Stage II	Stage III	Stage IV
	Activity	(+)	(+)-(++)	(++)	(±)-(-)
	General condition	(-)-(±)	(+)	(+)-(++)	(+)-(++)
Purpose of treatment		[1] Removal of excessive pain around the knees [2] Improvement of restrictions of knee dorsal flexion [3] Maintenance and enhancement of the function of the forefoot and toes, and prevention of toe deformity [4] Strengthening of toe flexor muscles			
Treatment method		[1] To improve the muscular tension of the tricepts surae and Achilles tendon, and ensure their flexibility, place needles in other areas of tenderness and induration. Later, perform passive exercises such as separating the talocrural joint. [2] Perform passive exercises to separate the MP joint [3] Place needles in shallow areas of the toe extensor group where tenderness is present [4] Perform toe flexion resistance exercises			

(2) Total body: weak-stimulation treatment for

[1] Unidentified complaints syndrome (feeling of fatigue, stiffness and cold) and
[2] Gastrointestinal disorders

For each patient, determine the treatment site and amount of stimulation to be provided while monitoring the severity of joint disorders and overall body condition, and establish a therapeutic policy/strategy.

III RESULTS

1. Collection of cases

After submission of written informed consent and randomization, 178 patients in total participated in the clinical study, with 82 patients in Group A (drug therapy group) and 96 patients in Group B (drug therapy plus acupuncture and moxibustion group). In the course of the study, therapy had to be discontinued in 2 patients in Group A (one because of difficulty in visiting the hospital and one because of a steroid dose exceeding 10mg/day), and 6 patients in Group B (two because of surgery, one because of difficulty in visiting the hospital and three because of steroid doses exceeding 10mg/day). At 12 months after initiation of intervention, Group A (drug therapy group) contained 80 patients, and Group B (drug therapy plus acupuncture and moxibustion group) 90 patients, with a total of 170 patients participating in the analysis (Fig. 1).

2. Patient characteristics

In patient characteristics, no significant difference was detected between the groups ($P>0.15$) with respect to age, sex, ACR core set variables such as number of tender joints, number of swollen joints, erythrocyte sedimentation rate (ESR), stage, class, patient pain visual analog scale (VAS), patient global assessment VAS, physician's VAS, duration of illness and AIMS-2. A difference between the groups ($P<0.15$) was detected with respect to activities of daily living (ADL) ($P=0.15$) (Table 2).

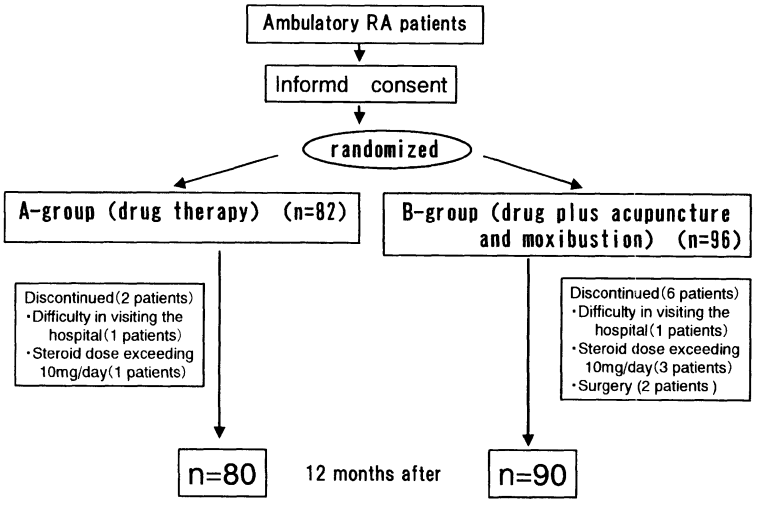

Fig. 1 **Flow Diagram (collection of cases)**
After submission of written informed consent and randomization, 178 patients in total participated in the clinical study, with 82 patients in Group A (drug therapy group) and 96 patients in Group B (drug therapy plus acupuncture and moxibustion group). At 12 months after initiation of intervention, Group A (drug therapy group) contained 80 patients, and Group B (drug therapy plus acupuncture and moxibustion group) 90 patients, with a total of 170 patients participating in the analysis.

3. Evaluation by improvement criteria in ACR core set variables (Table 3)

1) The improvement criteria were satisfied in 8 out of 80 patients in Group A and 20 out of 90 patients in Group B (improved patients). In the 2×2 table chi squared test, a significant difference was detected between the groups (P=0.04), with Group B showing a significantly higher rate of improvement.

2) Items with 20% or higher improvement in ACR core set were the patient global assessment alone in Group A, and the number of tender joints, patient pain assessment, patient global assessment and physician's assessment in Group B.

Table 2 Patient characteristics

	A-group (MEAN±SD)	B-group (MEAN±SD)	(P)
age	58.5±11.1	57.9±12.1	0.7630
sex	F 80/M 2	F 90/M 6	0.2903
Tender joint	17.3±7.35	18.6±10.8	0.5477
Swollen joint	9.32±4.56	10.6±7.49	0.8498
ESR	34.5±21.5	33.1±16.4	0.6325
stage	2.45±0.85	2.46±0.89	0.9378
class	2.44±0.25	2.33±0.57	0.2166
Patient's assessment pain VAS	6.31±1.58	6.05±2.28	0.4935
Patient's global assessment VAS	5.65±1.41	5.83±1.98	0.1892
Physician's global assessment VAS	5.76±1.68	6.10±1.87	0.2496
duration of illness	17.8±9.85	17.2±9.83	0.6855
ADL	34.8±6.19	36.6±8.31	0.1475 *
AIMS-2	145.5±27.2	143.4±29.2	0.4698

Table 3 ACR disease activity measures for rheumatoid arthrtis clinical trials : core set (ACR 20) Diesease activity measure

	A group	B group	P
ACR(20)	8/80	20/90	0.04
1. Tender joint count	17.5 → 16.4 (93%)	18.1 → 14.5 (80%)	0.42
2. Swollen joint count	9.5 → 8.4 (89%)	10.5 → 8.5 (81%)	0.34
3. Patient's assessment of pain (VAS)	6.3 → 5.4 (85%)	6 → 4.8 (79%)	0.005
4. Patient's global assessment of disease activity (VAS)	5.7 → 4.5 (79%)	5.8 → 3.5 (61%)	0.003
5. Physician's global assessment of disease activity (VAS)	5.8 → 5.2 (85%)	6.2 → 4.8 (78%)	0.55
6. Patient's assessment of physical function (AIMS)	34.8 → 29.6 (85%)	36.5 → 30.3 (82%)	0.79
7. Acute-phase reactant value	34.4 → 34.5 (102%)	32.9 → 29.6 (90%)	0.29

A group : drug therapy group

B group : drug plus acupuncture and moxibustion treatment group

The improvement criteria in ACR core set variables were satisfied in 8 out of 80 patients in Group A and 20 out of 90 patients in Group B (improved patients). In the 2×2 table chi squared test, a significant difference was detected between the groups (P=0.04), with the drug therapy plus acupuncture and moxibustion group showing a significantly higher rate of improvement.

4. Changes in AIMS-2

1) Global assessment

QOL change investigated by the AIMS-2 instrument was 145.2→135.3 (93%) in Group A, and 143.6 →117.4 (81%) in Group B. In assessment at 12 months after initiation of treatment, a significant difference was detected between the groups (P = 0.01), with Group B showing significantly better improvement (Fig.2).

2) Assessment of each item

Table 4 shows changes in each item in the AIMS-2 questionnaire. The items showing statistically significant improvement in Group B were "walking and bending", "hand and finger function", "household tasks", " social activity", "pain", "mood" and "subjective level of health". The AIMS-2 questionnaire form includes a question about prioritizing the items for improvement asking "for which item would you most like to see improvement?" Items most frequently desired to be improved were "pain", "locomotion ability", "ability to walk" and "hand and finger function". In the present study, these items tended to show significant improvement as compared with other items in Group B.

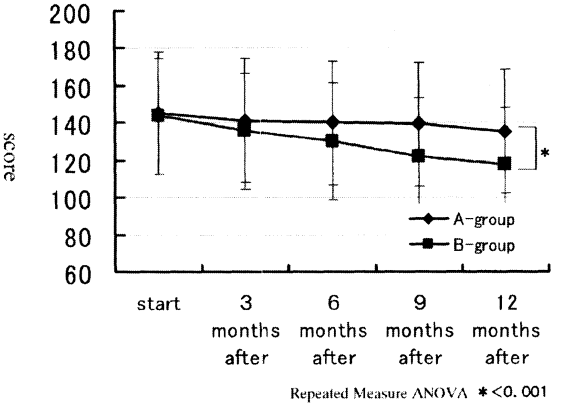

Fig.2 **Changes in AIMS-2**
QOL change investigated by the AIMS-2 questionnaire: At 12 months after initiation of the treatment, a significant difference (P=0.001) was detected between the groups, with the drug therapy plus acupuncture and moxibustion group showing a significantly better improvement.

Table 4 Change in the AIMS-2 questionnaire

	A-group		B-group	
	start	1 years after	start	1 years after
Mobility level	12.6±2.8	11.8±2.3	11.3±3.7	9.4±2
Walking and bending	11.7±2.8	11.3±2.8	11.4±2.8	9.2±1.9 *
Hand and finger function	12±3.1	11.1±3.2	11.1±3.2	8.6±2
Arm function	11.7±3	10.7±3	11.9±2.3	9.7±2.2
Self-care	9.7±2.5	9.1±2.7	9.7±2.6	8.2±2.1
Household tasks	10.1±2.9	9.4±2.7	9.7±2.5	8.7±1.7 *
Support from family and friends	10.7±2.3	10.2±2.2	11.2±2.1	9.2±2.4
Arthritis pain	14.6±3	13.7±3.1	14.9±3	10.4±3.8 *
Social activities	10.7±2.8	10.2±2.6	10.5±2.8	9.5±2.6 *
Work	9.8±2.3	9.6±2	10.6±2.4	8.5±2
Level of tension	11±2.4	9.9±2.4	10±2.9	8.5±2
Mood	9.7±2.3	9.3±1.7	9.1±2.4	8.7±1.7 *

Repeated Measure ANOVA * P<0.01

shows changes in each item in the AIMS-2 questionnaire. The items showing statistically significant improvement in Group B were "walking and bending", "hand and finger function", "household tasks", "social activity", "pain", "mood" and "subjective level of health".

Ⅳ DISCUSSION

1. Background of the clinical study of acupuncture and moxibustion

According to the idea of evidence based medicine, scientific rationale is essential for the clinical application of therapy. The art of acupuncture and moxibustion must also have a scientific explanation of efficacy. For acupuncture and moxibustion to be accepted as a reasonable and efficacious system of treatment, its efficacy must be demonstrated by controlled clinical trials[7]. However, reports of controlled clinical studies of acupuncture and moxibustion in Japan are rare, and randomized, multicenter, parallel-group clinical studies have not been conducted. To incorporate acupuncture and moxibustion in medical care in Japan, high-quality clinical studies are indispensable.

The present study was aimed at evaluating the usefulness of acupuncture and moxibustion in the treatment of rheumatoid arthritis, which is frequently encountered in the practice of acupuncture and moxibustion, by a randomized multicenter parallel-group study. What characterizes the present study is that it is a cooperative study in 4 institutions with a special RA outpatient clinic that provides Oriental Medicine services (acupuncture and moxibustion) and frequently uses acupuncture and moxibustion to treat RA. This multicenter study allowed us to obtain a large number of cases, reduce bias specific to certain institutions, ensure the quality of acupuncture and moxibustion, and evaluate acupuncture and moxibustion treatment using the standards of Western medicine at the same time. This is the first attempt in Japan at a randomized controlled trial of acupuncture and moxibustion at multiple hospitals. Organization of a clinical study team on this subject designed to serve as a source of EBM for acupuncture and moxibustion has never been attempted. The population size as of 12 months after initiation of the intervention was relatively large, with 82 patients in Group A and 96 patients in Group B, for a total of 178 patients. This solves the problem of small population size common in previous comparative clinical studies on acupuncture and moxibustion. This seemed largely attributable to the fact that 4 institutions with a special RA outpatient clinic that provides Oriental Medicine services (acupuncture and moxibustion) joined forces. Results at 12 months after initiation of the intervention suggested that the use of acupuncture and moxibustion in combination with conventional treatment reduced deterioration of physical functions and contributed to the improvement of QOL in RA patients.

2. Clinical efficacy of acupuncture and moxibustion treatment

Literature on the efficacy of acupuncture and moxibustion for RA is limited, and is also largely of unsatisfactory quality, so that presentation of data for evidence based medicine is needed. We conducted a randomized parallel-group trial using drug therapy and drug therapy plus acupuncture and moxibustion groups for assessment of the efficacy of acupuncture and moxibustion for RA, and analyzed the results from the viewpoint of QOL. The improvement criteria in the ACR core set were satisfied in 8 out of 80 patients in Group A and 20 of 90 patients in Group B, which indicated that improvement occurred significantly more frequently in Group B ($P=0.04$). In the ACR core set variables, improvement of $\geq 20\%$ only in Group B was obtained for patient pain VAS, patient global assessment, etc.

Comparison of changes in the AIMS-2 questionnaire for QOL assessment showed significantly

higher improvements in Group B. The AIMS-2 questionnaire items with significant differences between groups were ability to walk, hand and finger function, household tasks, social activity, pain, mood and subjective level of health.

According to the "2000 Survey of Actual Conditions of RA patients"[8] published by the Japan RA Patients Association, three major hardships for rheumatoid arthritis patients are "Violent pain that does not go away" in 49.7% of respondents, "Asking others for help in trivial matters" in 40.5% and "Unable to attend ceremonial events, or to socialize with neighbors" in 26.3% (multiple responses permitted). About half of the patients complained of "agonizing pain". Pain markedly reduces QOL of RA patients. RA patients usually receive drug therapy and joint injections for the control of pain and inflammation at the outpatient clinic. Their pain is controlled to a certain extent, but they still have such complaints as "weariness", "dull pain", "numbness", "shooting pain" and "stiffness". In the present comparison between the drug therapy and drug therapy plus acupuncture and moxibustion groups, patient assessment of pain in the ACR core set and pain in AIMS-2 items significantly improved more frequently in the drug therapy plus acupuncture and moxibustion group. These results show that alleviation or improvement of symptoms particularly concerned with pain can be expected from acupuncture and moxibustion, which suggests the possibility that these effects would maintain a favorable overall condition of RA patients and contribute to the improvement of QOL. However, improvement to the point where the inflammatory reaction diminished or drug dose was reduced was extremely rare, and statistically not significant. In consideration of the fact that RA is a chronic inflammatory auto-immune disease, it is important to reduce the severity of clinical symptoms of patients, and acupuncture and moxibustion should be highly useful as adjunctive treatment in modern medical treatment.

Our policy in the application of acupuncture and moxibustion is to understand the pathophysiology of RA patients from the viewpoint of modern medicine, and adapt acupuncture and moxibustion treatment to the disease stage of each RA patient. In concrete terms, acupuncture and moxibustion treatment is aimed at reducing pain and stiffness of RA to maintain and strengthen joint functions, with relief of inflammation and prevention of deformities, contracture and rigidity as the chief therapeutic goal. In the present study, a significant improvement was shown in the AIMS-2 questionnaire in mood, pain, hand and finger function and ability to walk in the drug therapy plus acupuncture and moxibustion group, which suggested that acupuncture and moxibustion not only prevented deterioration of the physical functions of RA patients, but also improved hemodynamics and stabilized the mental state, contributing to the improvement of QOL of RA patients.

In the treatment of RA, a medical team composed of physicians, nurses, physiotherapists (PT), occupational therapists (OP) and medical social workers (MSW) should make efforts to improve the QOL of RA patients. To establish a rationale for acupuncture and moxibustion in the team care of RA, it is necessary to show clearly the part that can be played by acupuncture and moxibustion, and for acupuncture and moxibustion experts to be able to cooperate smoothly with physicians and medical staff, and to have sufficient knowledge to interpret and evaluate laboratory data and pathophysiology accurately.

V CONCLUSION

A randomized trial on RA patients was conducted to compare changes in RA activity indicators (ACR core set) and QOL (AIMS-2) between a drug therapy group (Group A) and drug therapy plus acupuncture and moxibustion group (Group B).

1. The improvement criteria in ACR core set variables were satisfied in 8 out of 80 patients in Group A and 20 out of 90 patients in Group B (improved patients). In the 2×2 table chi squared test, a significant difference was detected between the groups ($P=0.04$), with the drug therapy plus acupuncture and moxibustion group showing a significantly higher rate of improvement.
2. QOL change investigated by the AIMS-2 questionnaire: At 12 months after initiation of the treatment, a significant difference ($P=0.001$) was detected between the groups, with the drug therapy plus acupuncture and moxibustion group showing a significantly better improvement.
3. To evaluate the effect of acupuncture and moxibustion treatment on RA, it was considered appropriate at present to use a QOL assessment instrument such as the ACR core set and AIMS-2.

The above findings suggested that acupuncture and moxibustion treatment contributed to improvement of QOL, and that this treatment should be useful in the treatment of RA as a part of team therapy in future.

This study was funded by the Ministry of Health and Welfare Comprehensive Research Project on Longevity Science (2000-2002).

References

1) Felson DT, et al : The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum. 1993 ; 36 : 729-40.

2) Felson DT, et al : The American College of Rheumatology preliminary definition of improvemwnt in rheumatoid. Arthritis Rheum. 1995 ; 38 : 727-35.

3) Meenan RF et al : AIMS-2 : The content and properties of a revised and expanded Arthritis Impact Measurement Scales Health Status Questionnaire. Arthritis Rheum. 1992 ; 35 : 1-10.

4) Meenan RF, Gertman PM, Mason JH : Measuring health status in arthritis : the arthritis Impact Measurement Scales. Arthritis Rheum. 1980 ; 23 : 146-52.

5) Hajime S et al : The Validity and Reliability of a Japanese Version of Arthritis Impact Measurement Scales in Patients with Rheumatoid Arthritis. Rheumatol. 1995 ; 35 (3) : 566-74.

6) Acupuncture and Moxibustion treatment for rheumatoid arthritis. — Multi-Center Randomized Controlled Trial of Acupuncture and Moxibustion for Rheumatoid arthritis — The Ministry of Health and Welfare Comprehensive Research Project on Longevity Science 2003.

7) Daichi K, Fujio T, Kazuhiko Y : Acupuncture treatment for Rheumatoid Arthritis. Clin Rheumatol. 2003 ; 15 : 277-81.

8) Published by the Japan RA Patients Association, 2000 Survey of Actual Conditions of RA Patients. Ragare. 211 : 2000.

Summary

We evaluated the efficacy, usefulness and safety of acupuncture and moxibustion treatment in rheumatoid arthritis, by the randomized, parallel-group, multi-center study with the drug-treated outpatient group as the control. The endpoints, important in the clinical assessment of acupuncture treatment, included the improvement criteria in ACR core set variables and the Japanese version of the Arthritis Impact Measurement Scales Version 2 (AIMS-2), a system of evaluation of the QOL of patients with RA.

Regarding intervention (therapy), a therapy chart for each stage of disease was drawn up to give local and systemic treatment in consideration of the patient's activity and disability in each stage of rheumatoid arthritis, so that generally consistent therapy adapted to the patient's condition would be provided. Result 1. Patients eligible for analysis were 80 patients of A-group (drug therapy group) (80 females, 2 males, 2dropped) and 90 patients of B-group (drug plus acupuncture and moxibustion group), total 170 patients. 2. Patients who satisfied the improvement criteria in ACR core set variables (improved patients) were 8 of 80 patients in A-group and 20 of 90 patients in B-group. The improvement rate was significantly higher for B-group treated by drug plus acupuncture and moxibustion versus A-group, with $P= 0.04$ in 2×2 table chi square test. 3. In QOL change investigated by AIMS-2 questionnaire, the improvement occurred significantly more frequently in the drug plus acupuncture and moxibustion group, with difference between groups at 12 months after the initiation of clinical study at $P= 0.001$. 4. Changes in the subjects included in AIMS-2 questionnaire: Improvement was significantly more frequent in the drug plus acupuncture and moxibustion group versus drug therapy group in respect to the ability to walk, finger function, housework, sociableness, pain, mood, and the degree of subjective improvement. In the present randomized, parallel-group, multicenter study, a significant improvement was detected in the drug plus acupuncture and moxibustion group versus the drug therapy group in the aforesaid respect, which suggested that the use of acupuncture and moxibustion combined with the conventional therapy would prevent deterioration of physical functions, improve blood circulation, stabilize mental status, and thereby contribute to the improvement of QOL in patients with rheumatoid arthritis.

連絡先：〒113-8655 文京区本郷7-3-1 (Tel 03-3815-5411 内線 33185 Fax 03-5684-2094)
東京大学医学部附属病院 リハビリテーション部 物理療法部門 粕谷 大智
E-mail: