The Effects of Comprehensive Home Physiotherapy and Supervision on Patients with Ankylosing Spondylitis — A Randomized Controlled Trial

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Abstract. **Fifty-three patients with ankylosing spondylitis (AS) were randomly allocated; 26 experimental patients received physiotherapy and disease education, 27 control patients received neither. The primary treatment outcome was change in spinal mobility measured at 4 months by fingertip-to-floor distance. Experimental patients had more improvement in fingertip-to-floor distance ($p2 < 0.004$) and in function ($p2 < 0.001$) than control patients. Physiotherapy with disease education is effective in the treatment of patients with AS.** (*J Rheumatol 1990;*17:228–33)

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RCT PHYSIOTHERAPY ANKYLOSING SPONDYLITIS

Ankylosing spondylitis (AS) is a chronic systemic inflammatory disorder of unknown etiology that primarily affects the axial skeleton with sacroiliitis as its most conspicuous feature. AS is much more common than is generally appreciated with a prevalence about 1%. It predominantly affects young adults who typically experience an insidious onset of morning stiffness and low back pain which is unrelieved by rest but which improves with exercise. The course of AS is unpredictable in an individual patient but is generally favorable. Earlier studies suggesting an unremitting course with immobility, poor posture, and severe functional impairment involved patients studied at tertiary care centers.

There is no definitive treatment for AS but excellent control of the disease can be achieved. Although drug therapy with nonsteroidal antiinflammatory agents can be effective, the cornerstone of medical management is therapeutic exercise with the prime objective of maintaining normal posture and activity. This is highlighted in any reference on the management of AS including a recent text devoted to the spondyloarthropathies[1].

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A Medline search of the English literature dating back to 1963 was conducted to review the effect of therapeutic exercise in the management of AS. The key indexing terms used were treatment, management, therapy, physiotherapy (PT), hydrotherapy, postural correction "associated with AS." Of 63 articles reviewed, only 2 dealt meaningfully with the value of physiotherapy in AS and neither of these was a randomized controlled trial. One was a single group cohort study of intensive group PT where 25 of 35 patients showed substantial improvement in neck movement as a reflection of spinal mobility[2]. In the second, 178 of 236 patients were controlling their major symptoms by exercise alone[3].

Appropriately, physiotherapy resources are extensively utilized to provide education and treatment for these patients; but since there were no randomized controlled trials that examined the value of therapeutic exercise in AS, the merit of exercise in these patients remained unproven.

We conducted a randomized controlled trial to determine whether a home program of therapeutic exercise with disease education is effective in patients with AS with reduced spinal mobility and function. It was hypothesized that an increase in spinal mobility would enhance the postural alignment of the spine and associated structures, thereby improving physical function and well-being for these patients.

MATERIALS AND METHODS

Consenting patients referred to the Ottawa Arthritis Society's home physiotherapy service, with a presumed diagnosis of AS, were screened for eligibility by a rheumatologist (GRK) based on the following criteria: confirmed AS as defined by the New York criteria[4]; stable clinical status and drug therapy; ARA functional class 1, 2, or 3[5]; English comprehension; absence of corticosteroid therapy for at least 3 months and immunosuppressive therapy for at least 6 months prestudy; no surgery anticipated in the next 4 months; and if female, practising reliable contraception and not pregnant. Patients with more than 10% loss of flexion in either hip joint and those receiving any contravening treatment were excluded.

Two independent assessors (IA) were trained in interview, and specific

measurement techniques preceding the commencement of the study, including a pretest on 4 patients with AS each. The use of IA in rheumatological clinical trials was validated in 1977[6]. The IA administered a prestructured questionnaire at baseline and at 4 months with both interviews scheduled as close to the same time of day as possible. The questionnaire sought sociodemographic information, history of disease duration, information on drugs, pain, sleep patterns and function. At these times, the IA also performed and recorded spinal mobility measurements. To reduce interobserver variation, the same IA assessed a patient at baseline and at 4 months[7]. The IA also obtained the patients' written consent.

Following the initial IA interview, 53 patients met all criteria and were admitted to the study. They were stratified according to age: 18 to 35 years, and 36 years and over. Stratification was considered appropriate because patients under the age of 35 tend to have better treatment outcomes[8]. Within each stratum, the patients were allocated equally to the experimental and control groups at random in blocks of 4. Following randomization, an IA was assigned to each patient and was responsible for interviewing that patient at baseline and at the end of 4 months.

All patients admitted to the study were instructed to remain taking stable medical therapy and not to seek medical attention for AS during the 4-month experimental period unless there was a medical emergency. Both experimental and control patients were instructed to complete diaries reporting medication intake. These diaries were filled in on a daily basis and submitted weekly.

The experimental maneuvre consisted of home physiotherapy. It was administered by Arthritis Society PT who were specially trained in the total assessment of inflammatory polyarthritis[9]. In preparation for the study, an intense review of AS, its assessment and management, was undertaken by the PT. Standardized assessment and therapeutic exercise protocols were then developed. A problem list common to patients with AS included (1) lack of knowledge about the disease and its management; (2) inflammatory activity causing joint damage and ankylosis; (3) acute pain causing muscle spasm resulting in loss of sleep, spinal mobility, endurance and function; (4) chronic pain leading to continuing stiffness, contractures and decreased muscle strength; (5) postural alterations including loss of cervical curve with protrusion of the jaw, increased dorsal kyphosis and loss of lumbar curve; (6) decreased rib cage mobility with resultant reduced pulmonary vital capacity; (7) decreased function including difficulties in body transfer, dressing activities, ambulation, and work activities; (8) poor compliance; and (9) psychosocial problems.

Based on this problem list, treatment objectives were to educate patients about the disease and its physical management; decrease local as well as generalized pain; increase mobility of spinal, costovertebral and peripheral joints; improve posture; increase pulmonary vital capacity; increase muscle strength and endurance and improve physical function; improve exercise compliance; and enhance psychosocial adjustment.

Patient management focused on a one-to-one educational strategy designed to inform a patient about the disease and methods of self-management. The "hands-on" approach used by the PT included the administration of heat or cold modalities; the demonstration of correct posture in lying, sitting and standing; application of therapeutic exercise designed to increase mobility of the spine, rib cage and peripheral joints, as well as to increase muscle strength and endurance. These exercises were based on normal movement patterns and proprioceptive neuromuscular facilitation techniques used worldwide by PT[10]. This manually applied treatment was augmented by a self-administered daily exercise program specific to the individual patient. The intensity of the manual techniques was decreased between the 6th and 16th week and the self-administered exercise program correspondingly increased. Patients in the experimental group were treated, in their homes or at their places of business, not fewer than 8 times and not more than 16 times during the 4-month period.

Patients in the control group received no treatment during the 4-month study period, however, the therapy program was offered to them at the end of 4 months.

An 8-month crossover followup was conducted on patients to determine if control patients who elected to receive the treatment maneuvre achieved similar success to the experimental patients, and if the effect on the experimental patients was sustained. The results of this followup will be reported later.

Outcome measures were based on prespecified and valid quantitative measures of change obtained by the IA between baseline and 4 months. The chief outcome measure was spinal mobility as measured by the fingertip-to-floor distance. This technique was chosen due to its simplicity, speed and reproducibility as demonstrated in a validation study comparing it with 3 other measures of spinal mobility[11]. In order to control for diurnal variation, the IA were instructed to schedule final interview measurements to coincide with baseline interview measurements within a 1 h window.

For fingertip-to-floor measurement, the patient stood on a 30 × 30 × 10 cm styrofoam block to allow for the fact that some patients might be able to reach beyond their toes in forward flexion. The patient was instructed to stand with feet together, toes at the edge of the styrofoam block, and knees straight. The patient bent forward to touch fingertips to floor and the vertical distance between the floor and the patient's longest finger was recorded. Patients were instructed not to exercise prior to the interview and only the initial forward-bending movement was measured and recorded.

We further refined this technique by developing a portable spinal mobility measuring device using a modified foot measure. Based on a validation study, we were able to show that the technique was reproducible, valid and simpler to use than a flexible dressmaker's tape[7].

A study to validate 4 measures of spinal mobility[11] showed the within patient standard deviation for fingertip-to-floor distance was estimated as 3.39 cm based on 12° of freedom. Using a clinically important difference of 3 cm between the experimental group and the control group, a one-tailed Student's t test with $\alpha = 0.05$ and $\beta = 0.10$, there was a sample size requirement of $n = 23$ patients for each of the 2 groups. Using a 10% dropout rate, this inflated to 26 patients/group for a total of 52 patients[12].

Secondary outcomes were also evaluated. The Toronto Activities of Daily Living Questionnaire[13,14] was slightly modified for patients with AS. Patients were asked about changes over the preceding 4 months with regard to ability to (1) get in and out of and drive a car; (2) use public transportation; (3) move out of bed, out of a chair and get up from the floor; (4) dress and undress; (5) wash and groom; (6) do light physical work; (7) do heavy physical work; and (8) participate in recreation. Possible responses were a lot better (+2), somewhat better (+1), no change (0), somewhat worse (−1), a lot worse (−2). A function score, ranging from −16 to +16, was comprised of the responses. Postural alignment was monitored by measuring occiput-to-wall distance and the Schöber test was used to measure lumbar flexion. Pain level was indicated by the patients on a horizontal 100 mm visual analogue scale, anchored at 0 with "no pain" and at 100 with "most pain" and marked at 25, 50 and 75 mm. Information regarding morning stiffness and sleep patterns was provided by the patients when responding to the questionnaire. All outcome measures were assessed by the same IA on admission to the trial and at 4 months. Following the 4-month interview, the IA were asked to indicate to which treatment group, experimental or control, each patient was assigned, as a test of their blindness. At the end of 4 months, experimental patients commented on their degree of satisfaction with the program in a self-administered questionnaire.

Summary statistics include sample size, mean, standard deviation, frequency and percentage. The comparability of the experimental and control groups was monitored with χ^2 statistics for categorical variables and unpaired Student's t tests for measurement variables. The number 2 after the p indicates that it is a 2-tailed probability. The percentages in the tables correspond to column totals unless otherwise specified.

RESULTS

Fifty-three patients were admitted to the study 27 (50.9%) were in Stratum 1 (age 18 to 35 years) and 26 (49.1%) were in Stratum 2 (age 36 years or more). The experimental group consisted of 13 patients from each stratum; the control group

had 14 patients from Stratum 1 and 13 patients from Stratum 2. Forty-two (79.2%) patients were men, 11 (20.8%) were women. The patients varied in age from 19 to 73 with a mean of 37.8 years.

All patients satisfied the New York criteria for AS as shown in Table 1. Neither the control group nor the experimental group had mild disease confined to the sacroiliac joints as shown by the incidence of radiographic syndesmophytes and thoracic involvement. Iritis occurred in an incidence expected for AS, and the groups were comparable except that the control group reported significantly more rib cage pain and stiffness than the experimental group.

Five (9.4%) of the 53 patients were declared dropouts; 3 experienced a disease flare requiring medical intervention; 1 was in a leg cast at the time of the 4-month interview prohibiting the IA from taking spinal mobility measurements; and 1 had a prescribed medication change due to drug side effects experienced after entering the study. Four of these patients were assigned to the experimental group and 1 was assigned to the control group. Three of the patients withdrawn were women, 2 were men; 3 patients were in Stratum 1 and 2 were in Stratum 2. Only 1 of the dropout patients was not interviewed at the end of 4 months; this patient's rheumatologist requested that she not be interviewed.

The study protocol called for measurement of a variety of patient characteristics and allocation features to check on the effectiveness of the randomization procedure. Characteristics of the baseline interview (Table 2) indicate homogeneous groups of patients on 19 variables.

Only 1 patient in the experimental group was not available for the final interview by the IA at 4 months. Consequently, the effectiveness or "intent-to-treat" analysis was based on 25 patients in the experimental group and 27 in the control group for a total of 52 patients. The intent-to-treat change outcomes are displayed in Table 3.

The primary outcome measure, fingertip-to-floor distance, showed a highly significant improvement in the experimental group (−8.3 cm) when compared to the worsening in the control group (2.0 cm); $p2 < 0.001$. In the secondary outcome measures, there was no significant difference between the 2 groups in change in pain, change in spinal alignment or change in the Schöber test. However, there was a highly significant improvement in functional ability in the experimental group (3.92) when compared to almost no change in the control group (−0.19); $p2 < 0.001$. The spinal alignment did not improve in the experimental group (0.95 cm) more than the control group (0.65 cm); $p2 = 0.727$, when patients who were zero at baseline were excluded from the analysis.

The 4 dropouts and 1 refusal to submit to the final interview constitute a group that was removed for the efficacy analysis. The efficacy analysis (Table 4) showed essentially the same results as the intent-to-treat analysis.

Eighteen (72.0%) of the 25 experimental patients interviewed at 4 months responded to a satisfaction survey and expressed a high level of satisfaction with the program.

A check on blindness indicated that the IA did not know the group allocation. (Estimated kappa = 0.17, p2 = 0.123).

There were no changes in variables that could have contributed to differences in outcomes such as medical intervention, other illness, or drug changes. Two independent rheumatologists, blinded to patient allocation, reviewed the

Table 1. *Disease characteristics in patients referred to the home physiotherapy service with a presumed diagnosis of AS**

Inclusion Criteria (Score Value)		Group: Experimental (n=26)	Control (n=27)	χ^{2}** df=1	P2
1. Low back pain 3 months unrelieved by rest (1)		24 (92.3)	26 (96.3)	c 0.001	0.97
2. Rib cage pain & stiffness (1)		16 (61.5)	24 (88.9)	c 3.977	0.05
3. Limited chest expansion (1)		20 (76.9)	24 (88.9)	c 0.630	0.43
4. Limited motion in lumbar spine (1)		23 (88.5)	27 (100.0)	c 1.495	0.22
5. Past or present evidence of iritis (1)		8 (30.8)	7 (25.9)	c 0.007	0.93
6. Bilateral radiology sacroiliitis (3)		26 (100.0)	27 (100.0)	—	—
7. Radiographic syndesmophytosis (1)		19 (73.1)	16 (59.3)	c 0.596	0.44
Total inclusion score =	4	1 (3.8)	0 (0.0)		
	5	4 (15.4)	1 (3.7)		
	6	0 (0.0)	3 (11.1)		
	7	8 (30.8)	3 (11.1)		
	8	9 (34.6)	19 (70.4)		
	9	4 (15.4)	1 (3.7)		
Mean (SD)		7.2 (1.4)	7.6 (0.9)	t (51)=−1.31	0.26

* Entries are frequency (%).

** Yates' corrected χ^{2} denoted by "c"; dash indicates no value computed.

Table 2. *Baseline characteristics of 53 patients with AS in experimental and control groups*

a) Categorical Variables [f(%)]		Group			
Variable	Name	Experimental (n=26)	Control (n=27)	χ^2 df=1	P2
Male		20 (76.9)	22 (81.5)	c 0.005	0.94
Single		5 (19.2)	10 (37.0)	1.285	0.26
Patient education**:	High school	11 (42.3)	11 (40.7)	0.025	0.99
	College	4 (15.4)	4 (14.8)		
Job classification**:	Unskilled	(30.8)	5 (18.5)	1.084	0.59
	Skilled	6 (23.1)	7 (25.9)		
Patient income < $25K		8 (30.8)	‡26:13 (50.0)	1.997	0.15
Family income < $25K		25:3 (12.0)	23:5 (21.7)	0.818	0.63
Seen specialist in last 6 months		13 (50.0)	9 (33.3)	0.907	0.34
Morning stiffness in last week		17 (65.4)	23 (85.2)	2.805	0.09
Sleep quality**:	Very well	16 (61.5)	13 (48.1)	1.292	0.52
	Average	6 (23.1)	10 (37.0)		
b) Continuous Variables [n:m,s]†				t (51)	P2
Continuous pain (yr)		15.8, 27.6	16.9, 28.0	−0.15	0.88
Pain scale (mm)		32.2, 21.1	38.7, 28.8	−0.94	0.35
Today's morning stiffness (min)		12: 49.2, 44.2	18: 94.7, 89.4	−1.85	0.08
Last week's morning stiffness (min)		5: 81.8, 100.1	5:77.0, 93.0	0.08	0.94
Height (cm)		175.0, 8.1	171.9, 8.1	1.40	0.17
Weight (kg)		73.0, 12.1	67.5, 11.4	1.71	0.09
Function score		0.50, 3.51	0.33, 3.60	0.17	0.86
Fingertip-to-floor distance (cm)		23.6, 11.5	27.5, 15.2	−1.04	0.30
Occiput-to-wall distance (cm)		3.3, 3.1	3.4, 4.8	−0.09	0.93
Schöber (cm)		13.7, 1.5	13.3, 1.6	0.91	0.37

‡ Entry shows sample size if less than n at head of column.

* Yates' corrected χ^2 denoted by "c".

** 3 categories and 2 df.

† Entries are sample size:mean, standard deviation.

Table 3. *Intent-to-treat analysis* for the experimental and control groups for patients with AS*

	Group			
Variable Name	Experimental (n=25)	Control (n=27)	t	P2
Fingertip-to-floor (cm)	24:−8.3, 5.4**	2.0, 9.1	−4.97	<0.001
Pain scale (mm)	5.2, 26.3	−5.2, 26.7	1.41	0.162
Spinal alignment (cm)	24:−1.0, 2.4	−0.2, 2.0	−1.32	0.192
(Removing 0 at baseline)	15: 0.95, 2.31	15: 0.65, 2.45	0.35	0.727
Schöber (cm)	24:−2.4, 6.7	−2.7, 9.9	0.14	0.892
Function score	3.92, 2.94	−0.19, 1.86	5.96	<0.001

* Includes all patients admitted to the study and who started the therapy but did not fully comply.

** Entries are sample size:mean, standard deviation. Entry shows sample size only if less than n at head of column.

Table 4. *Efficacy analysis* for the experimental and control groups for patients with AS*

	Group			
Variable Name	Experimental (n=22)	Control (n=26)	t	P2
Fingertip-to-floor (cm)	−8.0, 5.0**	2.0, 9.3	−4.75	<0.001
Pain scale (mm)	7.2, 25.9	−3.4, 25.4	1.42	0.161
Spinal alignment (cm)	−0.6, 1.9	−0.2, 2.0	−0.78	0.439
Schöber (cm)	−2.1, 6.5	−2.6, 10.1	0.22	0.829
Function score	4.14, 2.92	0.08, 1.39	6.05	<0.001

* Includes patients who completed the study and complied with the therapy.

** Entries are mean, standard deviation.

data collected from patient diaries on medication intake. Both rheumatologists judged the control and experimental patients to be comparable in terms of compliance.

DISCUSSION

Physiotherapy remains an important intervention for patients with rheumatic diseases. Costly resources are utilized to provide such care without strong evidence that it is effective in terms of randomized clinical trials. We live in a climate of ever-spiralling medical costs and limited growth potential which requires constant prioritization in the allocation of resources. Intelligent decisions can only be made with strong evidence of effectiveness through randomized clinical trials.

Our study examines the role of physiotherapy in patients with AS using a randomized trial. The required sample size was achieved and only 1 patient was unavailable for final outcome assessment.

Although the experimental and control groups were similar at the beginning of the study on 19 different variables, there were 2 areas to be considered as possible sources of bias, "rib cage pain and stiffness" and "today's morning stiffness." Although significantly more control patients had rib cage pain and stiffness than experimental patients, it is improbable that this would create a bias, as the primary outcome measure, fingertip-to-floor distance, would probably not be affected by thoracic pain and stiffness. Patients were similar on all other features of the New York criteria for AS. For morning stiffness today, the difference was not statistically significant, however at 45 min, it could be clinically important. It is difficult for us to assess the extent of such bias, however, we suspect that it was small as most of these patients were seen mid-morning or late afternoon, well beyond the mean of 95 min seen in the control group. It is our belief that the lateness of the assessment cancelled out any effect morning stiffness may have had on the results.

An improvement of at least 3 cm in the primary outcome measure, fingertip-to-floor distance, was felt to be clinically important when comparing experimental and control groups and the study was designed to detect this degree of change. In fact, in the intent-to-treat analysis, the experimental group demonstrated an improvement of 10.3 cm compared with the control group which was highly statistically significant and clinically important. There was a statistically significant improvement of 4.11 in functional ability for the experimental patients compared with the control patients. Any improvement (i.e., $\geq$ 1 on the Toronto Activities of Daily Living Questionnaire) was declared clinically important.

Improvements in pain and sleep were also noted with larger than predetermined clinically important effect sizes. However, power analysis indicates a much larger study would be required to declare them statistically significant. A stringent reduction of at least 50% in the duration of morning stiffness was determined to be clinically important and, although morning stiffness improved, this effect was not achieved.

An improvement of at least 10% was deemed a clinically important change for the Schöber test but this was not achieved. Since the Schöber test is important diagnostically and reflects limitation of the lower lumbar spine affected by the inflammatory process characteristic of AS, one could argue that no effect on the disease process was achieved. Such an effect was beyond the scope of this study. In fact, there is no form of treatment currently available that "cures" AS or clearly has an effect on the natural history of the disease. The aim of treatment is to control inflammation, improve function, and minimize deformity. It may well be that unaffected or mildly affected segments of the spine responded to exercise and compensated for the area of restricted movement. Factors such as a training effect, stretching of hamstrings or muscles about the shoulder girdle and increased hip flexion all may have played some role in the improved fingertip-to-floor distance. For whatever reason, the important clinical point is that the total range of movement can be improved and, as a result, functional ability improved. Although secondary outcome measures such as pain, sleep patterns and morning stiffness did not show statistical improvement, the strong tendency toward improvement was very encouraging. A different design with a larger sample size may be able to detect significant improvement in these outcomes as well. The satisfaction survey was also most encouraging. Experimental subjects were generally very satisfied with the therapy, satisfied with their knowledge about AS and felt that they were better able to cope with their disease.

In summary, physiotherapy is effective in patients with AS. Physiotherapy improved spinal mobility as measured by fingertip-to-floor distance. The patients' ability to function improved and patients were highly satisfied with the program. Favorable indications were evident in secondary outcome measures such as reduction of pain and improvement in sleep but a larger study will be needed to determine if this improvement is real. The Schöber test, which likely reflects permanent change in the lower lumbar spine, did not improve.

Our study is one of few randomized controlled trials in physiotherapy. Such trials will determine where restricted services have the greatest effect and will be crucial in prioritizing the allocation of such resources. Physiotherapy in AS should remain a priority for health professionals dealing with rheumatic disorders.

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