Effectiveness of Physical Therapy for Patients with Adhesive Capsulitis: a Randomized Controlled Trial

Kingkaew Pajareya MD*, Navaporn Chadchavalpanichaya MD*,
Somluck Painmanakit PT*, Chanjira Kaidwan PT*,
Patcharin Puttaruksa PT*, Yananee Wongsaranuchit RN*

** Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University*

Objective : *To compare the effectiveness of a combined technique of physical and ibuprofen for the treatment of adhesive capsulitis with ibuprofen alone.*
Material and Method : *122 subjects were randomly allocated to have 3 weeks treatment either with ibuprofen (n=61) or ibuprofen and a combined technique of physical therapy (n=61). Outcome measures were carried out 3 weeks and 12 weeks after randomization. Primary outcome measures were the success of treatment measured by improvement in the Shoulder Pain and Disability Index, and global rating.*
Results : *At 3 weeks, 21 (35.0%) of 60 patients in the study group were considered to have had successful treatment compared with 11 (18.6%) of 59 in the control group (difference between groups 16.4%, 95% CI: 4.0-31.3, p=0.044). There was no significant difference in the success rate between the two groups at the 12th week follow-up.*
Conclusion : *The results of this study support the use of physical therapy for patients with adhesive capsulitis.*

Keywords : *Randomised controlled trial, Physical Therapy, Non-steroidal anti-inflammatory drugs, Adhesive capsulitis*

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Adhesive capsulitis (so-called "frozen shoulder") is a common problem in general practice, rheumatologic, orthopaedic and rehabilitation clinics. It is characterised by shoulder pain that is aggravated by movement and limitation of the range of shoulder motion and daily activities. Several different therapeutic regimens have been used for the purpose of increasing the extent and speed of recovery. Conventional management includes patient advice, analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), steroid injection and a wide variety of physical therapy methods. Manipulation while anaesthetised can be effective, but significant complications have been documented and publication reports protracted recovery[1]. Arthroscopic release done under general anaesthesia is invasive and few patients' outcomes have been reported[2-3].

Correspondence to : Pajareya K, Department of Rehabilitation Medicine, 9th floor Srisungwan Building, Siriraj Hospital, Bangkok 10700, Thailand. Phone: 0-2419-7508, Fax: 0-2411-4813

Various physical therapy regimens are used conventionally. Systematic reviews have shown that there is insufficient data to draw a conclusion about the effectiveness of physical therapy[4-5]. However, previous studies usually compared the efficacy of one component of physical therapy which were unlike routine use. For example, comparing the effect of ultrasound alone[6-7] or mobilisation alone[8]. Winter et al studied the effects of "classic" physical therapy, manipulation and corticosteroid injection. Their survival analysis showed that the duration of shoulder complaint in patients with a synovial problem was shortest in the corticosteroid injection group. However, the "classic" physical therapy in this study comprised exercise therapy, massage and physical application but no mobilisation techniques were allowed[9] . Van de Windt et al tried to enhance the external validity of this study by adding passive mobilisation in their PT protocol[10] but they used a superficial modality instead of the deep heat modality

that is usually recommended in a chronic condition like adhesive capsulitis[11].

The primary objective of this prospective, randomised, controlled trial was to study the effectiveness of a combined technique of PT, which is similar to the usual clinical practice in patients with primary adhesive capsulitis in terms of success rate. The secondary objectives were to compare the mean quantity of analgesic used, the mean change in The Shoulder Pain and Disability Index (The SPADI)[12], the mean change in the range of motion, and patients' satisfaction between the two groups including any adverse effects of PT.

Material and Method

Subjects

All patients who had shoulder pain and limitation of a passive range of shoulder motion in all directions that interfered with their activities of daily living and attended the orthopaedic and rehabilitation clinic at Siriraj Hospital were eligible for the study. Exclusion criteria included patients with secondary adhesive capsulitis; with intrinsic causes of shoulder problems such as a history of fracture, or dislocation or extrinsic causes such as neuromuscular disorders (stroke, parkinsonism), generalised arthritis, bilateral involvement, contraindication for NSAIDs, or who had bleeding tendencies.

Randomization

The patients who gave informed written consent were randomly allocated to a 3-week treatment protocol by simple randomisation using a random numbers table and allocation concealed within an opaque envelope.

Assessments

The outcomes of the intervention were assessed at 3 weeks. The patients were asked to rate one global rating on pain and disability on a five point Likert scale; disappearance of shoulder complaints, some pain or limitation but which does not interfere with everyday life, minimal inconvenience to everyday life, moderate inconvenience, and marked inconvenience. For measuring the primary outcome, patients were counted as a success if they rated themselves as having disappearance of shoulder complaints or some pain/ limitation which does not interfere with everyday life. The following secondary outcome measures were included:

1. The Shoulder Pain and Disability Index (the SPADI) score change. The SPADI is a 13 item, self-administered instrument developed by Roach KE et al in 1991[12]. It consists of two separate scales: one for pain and the other for functional activities. The score varies from 0 to 100. A higher score indicates worse problems. The change in score for each patient was calculated for each patient by subtracting the result at baseline from the follow-up at the end of the 3rd week.

2. Range of shoulder motion measured with a goniometer according to the method advocated by Clarke by a investigator blinded to the type of treatment[13]. The goniometer was attached by a Velcro® strap to the upper arm with the patient sitting upright for total abduction. External rotation of the shoulder was assessed while lying supine with the shoulder in 90 degrees of abduction and the goniometer attached to the dorsal aspect of the forearm. Internal rotation range was quantified by measuring the distance between the spine of C7 and the tip of the thumb with the arm fully internal rotated. An independent study demonstrated that the inter-ratter reliability for abduction, external rotation and internal rotation was 0.98, 0.92, and 0.99 respectively.

3. Patients' satisfaction was rated concerning the treatment regimens on a four point Likert scale "very satisfied, moderately satisfied, unsatisfied, very unsatisfied".

4. The quantity of analgesic used was calculated from the number prescribed minus the number of pills left.

5. Adverse reactions recorded by the patients who received the PT program for the questions "Do you have pain that persisted more than 2 hours after treatment or more disability the next morning or not?" Moreover, at each follow-up, an investigator, blinded to treatment modality asked all patients "Have the trial drugs and/or treatment program upset you in any way?" and examined the patient for any signs of echymosis or burn during range of motion evaluation.

Additional follow-up assessments were scheduled to evaluate the primary outcome only at 6, 12, and 24 weeks. The assessments at 12 and 24 weeks were by telephone or postal questionnaire.

Intervention

The patients in the control group had ibuprofen 400 mg three times daily for 3 weeks and they also received an information sheet containing advice on protection of the shoulder from vigorous

activities such as pushing and pulling. They were encouraged to use their arms in a normal fashion for reaching and other activities of daily life. All the subjects were asked to have no other adjuvant therapy during the study except for oral acetaminophen (up to 6 g/day). All of them were asked to record if they received any additional treatment.

The patients in the study group had ibuprofen and general advice, which was same as the control group in addition to the combined technique of PT. A hospital-based PT program was carried out 3 times a week by each of the three research physical therapists whose performance had been standardised. Each session comprised short wave diathermy (20 minutes), mobilisation and passive glenohumeral joint stretching exercises up to the patient's tolerance. On the days they did not receive the hospital-based PT program, they were advised to perform pulley exercises (actively assisted exercises for 5 minutes). Active non-assisted exercises using a towel and wall (5 minutes after applying a hot pack for 20 minutes). The exercise guideline was based on Cyriax[14]. If, during the passive movements the patients felt pain before the therapist reached the end of the range, exercise was contraindicated. If pain was experienced at the end of the range then exercise was attempted. Subjects were asked to complete a diary documenting the number of hospital-based PT they actually received and the number of home exercise programs they performed. The number of patients needing additional treatment after three weeks and the types of treatment received are shown in Table 3.

Statistical analysis

Intention to treat analysis was used to evaluate a statistical difference between the two groups. Chi-square was used in comparing the proportions of patients. Using Student - t test, compared the difference in the mean improvements in The SPADI score and range of motion between the two groups. The Man-Whitney U test was used to compare the median of patients' satisfaction between the two groups. Multiple logistic regression was used to detect any effects of the difference in baseline.

Sample size calculation was based on the ability to detect a clinically important difference in success rate of 25 % between two groups. The authors assumed a success rate of 40% in the group having the least successful treatment and, thus, estimated a target sample size of 60 patients in each group. (two-tailed, a = 0.05, b = 0.02).

Results

From January 2001 to September, 2001, 255 patients with adhesive capsulitis attended the orthopaedic clinic and rehabilitation at Siriraj Hospital. There was a total of 122 patients with adhesive capsulitis who fulfilled the eligible criteria and were willing to join the present study. Of the 133 subjects not recruited, it was inconvenient for 83 cases because they lived far away from Bangkok, so they were instructed to receive treatment and to be followed up at the hospital in their hometown instead of the coming to Bangkok, 28 had secondary adhesive capsulitis, 16 had contra-indications for NSAIDs, and 6 had bilateral involvement. At the end of the 3rd week, 2 subjects dropped out from the study; 1 from the control group and 1 from the study group. The total number of cases included in the analysis was 59 in the control and 60 in the study group. By the end of the 24th week, a total of 12 cases (10.1%) had withdrawn from the study (Fig. 1). All of them lost to follow-up for unknown reasons and the investigators could not contact them.

Details of the baseline characteristics of the patients are shown in Table 1. The study group tended to have a greater male/ female ratio, more subjects who had a history of minor trauma before onset, less association with neck pain and less personal preference as to randomisation. However, these differences were not statistically significant.

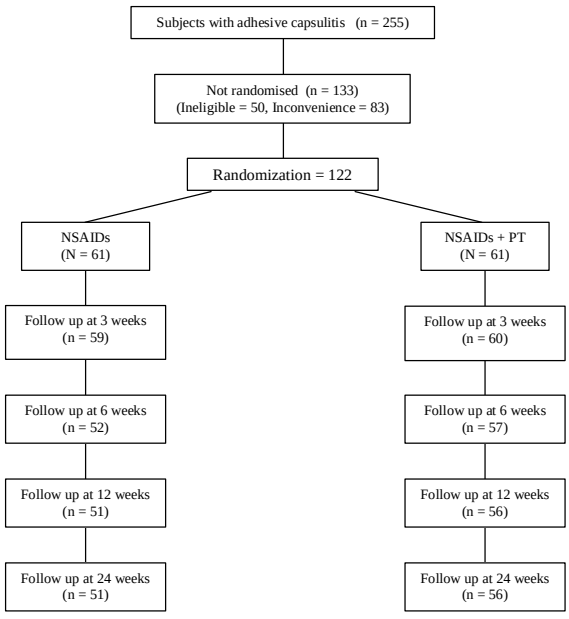

Fig. 1 Summary data for study recruitment and completion.

Table 1. Baseline characteristics of patients with adhesive capsulitis by group. Values are numbers (percentages) unless indicated otherwise

Baseline variables	The control group (n = 59)	The study group (n = 60)
Mean (SD) of age (years)	57.7 (10.0)	56.3(10.6)
Gender (male, female)	14 (23.7%), 45 (73.3%)	24 (40.0%), 36 (60.0%)
Duration of disability;		
- < 6 weeks	6 (10.2%)	13 (21.7%)
- 6 weeks but < 12 weeks	20 (33.9%)	20 (33.3%)
- ≥12 weeks	33 (55.9%)	27 (45.0%)
Dominant shoulder involvement	31 (52.5%)	28 (46.7%)
History of minor trauma before onset	11 (18.6%)	17 (28.3%)
Associated with DM	10 (16.9%)	10 (16.7%)
Concomitant neck pain	12 (20.3%)	8 (13.0%)
Patient's preference as randomisation	50 (89.8%)	45 (76.7%)
Global rating of pain and disability		
- No shoulder complaint	0	0
- Some pain or limitation but does not interfere with everyday life	0	0
- Minimal inconvenience	12 (20.3%)	9 (15.0%)
- Moderate inconvenience	34 (57.6%)	35 (58.3%)
- marked inconvenience	13 (22.3%)	16 (26.7%)
Mean (SD) of the SPADI score*	50.6 (16.6)	54.93 (21.3)
Range of motion		
- Mean (SD) glenohumeral abduction (degree)	121.3 (27.8)	121.9 (27.8)
- Mean (SD) glenohumeral external rotation (degree)	75.3 (16.0)	74.8 (22.1)
- Mean (SD) of distance between tip of thumb and C7 spine (cm)**	41.1 (10.3)	41.2 (10.6)

* Pain and disability as rated on the SPADI score in which scores range from 0-100; the higher scores indicate more severe pain and disability

** Internal rotation was quantified by measuring distance between thumb and tip of C7 spine in hand behind back position

At the end of the 3rd week, 21 cases (35.0%) in the study group (n = 60) had successful treatment, whereas, 11 cases (18.6%) in the control group (n = 59) were successful. The difference between groups was 16.4% (95% CI: 4.0-31.3, p = 0.040).

For secondary outcome variables, the number of analgesics used, changes of the SPADI scores, and range of motion improvement (glenohumeral abduction, external rotation and internal rotation) were continuous data. All of these variables were tested for normality of distribution. It was found that improvements in the SPADI scores, and ranges of motion were normally distributed. These changes were tested for differences between the 2 groups by Student's t-test. The quantity of analgesics used in both groups was tested by Mann-Whitney U test due to the fact that this parameter was not normally distributed.

The mean (standard deviation) changes of the SPADI scores of the study group and the control group were 11.9 (14.2) points and 20.4 (15.4) points, respectively. The subjects in the study group showed a mean improvement in the score of 8.6 points more than the control group (95% CI: 3.1-13.9 points, p = 0.002).

Regarding range of motion, the study group showed a mean improvement in glenohumeral abduction 7.2 degrees more than the control group (95% CI: 1.2-14.2 degrees, p = 0.005) (Table 2). For glenohumeral external rotation, the mean improvement in the study group was 3.0 degrees more than the control group but the difference was not statistically significant (95% CI: - 2.0 to 8.6, p = 0.085). The distance between the thumb to the tip of C7 spine (cm) was used to quantify glenohumeral internal rotation. The analysis showed that the study group showed a significantly greater improvement than the control group (p = 0.015). The magnitude of the difference was 3.3 centimetres (95% CI was 0.7 cm to 6.0 cm).

Table 2. Outcome variables of patients with adhesive capsulitis by group of treatment at the end of the 3rd week with additional follow- up of primary outcome. Values are numbers (percentages) unless indicated otherwise

Outcome variables	The control group (n = 59)	The study group (n = 60)	Difference (95% CI)	P value
Had successful treatment				
- 3 weeks	11/59 (18.6%)	21/60 (35.0%)	16.4% (4.0%–31.3%)	0.044
- 6 weeks	22/52 (42.3%)	35/57 (61.4%)	19.1% (4.0%-36.1%)	0.046
- 12 weeks	31/51 (60.8%)	43/56 (76.8%)	16.0% (-1.50%-32.5%)	0.073
- 24 weeks	42/51 (82.4%)	45/56 (80.4%)	-2.0% (-16.6%-13.1)	0.791
Mean (SD) 0f the SPADI score improvement	11.9 (14.2)	20.5 (15.4)	8.6 (3.1 to 13.9)	0.002
Mean (SD) of improve in abduction (degree)	14.7 (18.1)	21.9 (21.0)	7.2 (1.2 to 14.2)	0.005
Mean (SD) of improvement in external rotation (degree)	18.3 (15.4)	21.3 (15.3)	3.0 (-2.6 to 8.6)	0085
Mean (SD) of improvement in internal rotation (cm)	3.0 (7.0)	6.3 (7.7)	3.3 (0.7 to 6.0)	0.040
Mean rank of number of analgesic use (tab)	58.59	61.38		0.652*
Satisfaction;				
- Very satisfied	1		5	
- Moderately satisfied	1	7		< 0.001
- Unsatisfied	13		24	
- Very unsatisfied	45		23	

Mann-Whitney U test found that the median quantity of analgesics used did not differ significantly between the two groups (p = 0.652).

For ordinal secondary outcomes, Man-Whitney U test was used to compare the results between the two groups. It was found that the subjects in the study group rated their satisfaction better than the subjects in the control group, which was significant (P < 0.001) (Table 2).

During the 3-week period, the patients in the study group reported a total of 10 episodes of pain that persisted more than 2 hours after treatment from 4 subjects. There were no other complications recorded. Regarding NSAIDs, 15 subjects (12.6 %) had gastrointestinal side effects; the number of those who had severe dyspepsia and had to stop NSAIDs was 6 (4.2%). There were 2 report of severe oedema and 1 case with a severe headache, which rapidly subsided after the drug was discontinued.

Compliance, Contamination and Co-intervention

About three-quarters of the subjects of both groups received NSAIDs as prescribed. The reasons why some patients received fewer NSAIDs than the others was due to gastrointestinal discomfort, forgetting to take them or a misunderstanding about the schedule. In the study group, 7 cases (11.7%) received fewer than 6 sessions of hospital-based PT, 5 cases (8.3%) performed the home programme exercises fewer than 6 sessions. Two cases from the control group reported that they had additional treatment; 1 had Chinese herbal medicine and 1 received analgesics from a private clinic. No patient in the control group had hospital-based PT or home exercise therapy for their shoulder. The number of patients needing additional treatment after three weeks and the types of treatment received are shown in Table 3.

Table 3. Number (percentage) of patients with adhesive capsulitis needing treatment for residual pain and disability at the fourth week follow-up (treatment no longer restricted to interventions as described in protocol)

Additional treatment	The control group (n = 52)	The study group (n = 57)
Non-steroidal anti-inflammatory drugs	18 (34.6%)	13 (22.8%)
Non-steroidal anti-inflammatory drugs and physical therapy	12 (23.1%)	17 (29.8%)
Physical therapy	3 (5.4%)	5 (8.8%)
Corticosteroid injections	3 (5.4%)	3 (5.3%)
Home exercise	13 (25.0%)	21 (36.8%)

At the 6th week, 35 cases (61.4%) in the study group (n=57) were counted as successful, whereas 22 (18.6%) cases in the control group (n=52) were successful. The study group had a greater success rate than the control group by 19.1% (95% confidence interval: 4.0-36.1, p=0.044). There was no significant difference between the two groups at the 12th and 24th week follow-up (Table 2).

Discussion

This randomised, controlled trial demonstrated that the 3-week treatment regimen comprising a combined technique of PT and ibuprofen produced more beneficial effects than the use of ibuprofen alone for the treatment of (primary) adhesive capsulitis in terms of success rate, improvement in the SPADI score, patients' satisfaction and improvement in the range of motion. At the end of the 6th week, the success rate of patients who received physical therapy was more than the success rate of the control group. After that, the differences were not statistically significant. The results were analysed by intention to treat analysis even though the treatments actually received were modified from the protocol, because it was found that the reasons for modifying the treatment were strongly related to the results of allocated interventions[15] .

The results of the present study are different from previous studies in which systematic reviews concluded that there was insufficient data to draw conclusions about the effectiveness of PT[4-5]. The reasons might be due to the fact that the PT regimen in the present study comprised important components. Deep heat modality was introduced in order to increase the tissue temperature and its extensibility, making a passive range of motion more effective[11] . To use this combined technique of PT in addition to NSAIDs can make the patients more comfortable.

One important limitation in the present study was the lack of the blinding process. It was not possible to keep the subjects blinded as to the experimental conditions for each subject and as the primary outcome was a subjective measurement, it was probably directly influenced by the subjects preconceived idea regarding the effectiveness of intervention. Patients' preferences can be an important determinant of the outcomes[16-17] . Participants who were randomised to their treatment of choice may have a better outcome irrespective of the physiological effects of the intervention. The placebo treatment, which theoretically would have alleviated this threat to internal validity, was not convenient in the present study. Therefore, the differences of primary outcome between the two groups in the present study could be due to a placebo effect. However, this problem might have been partly ameliorated because the patients' treatment preferences were elicited after randomisation and it was found that the patients in the control group had a tendency to prefer their allocated treatment compared with the patients in the study group. This would make it unlikely that the difference in primary outcome at the end of the study was due to the patients' preference.

The deviation from the protocol in the present study might not reverse the results. On the contrary, the differences of the outcomes at the end of the study should be elicited more easily if there was no protocol deviation. Because the patients in the study group received fewer treatments than the schedule determined (six cases had fewer than 6 sessions of hospital-based PT and 6 cases performed home exercise fewer than 6 sessions), while the subjects in the control group received more treatment than the schedule (one case had Chinese herbal medicine and 1 case had analgesics from a private clinic).

In conclusion, the results of the present study give us evidence to support the use of physical therapy for patients with adhesive capsulitis from the beginning of the treatment.

However, because a combined technique of physical therapy needs a wide variety of resources such as people, time, facilities and equipment, it is necessary to carry out a further study to evaluate the economic aspect of this study to provide a balance sheet of the benefits, harms and costs for making the choice for a combined treatment regimen. If the combined technique of physical therapy is not cost-effective, a home-programme of physical therapy should be an alternative intervention to be studied in a further trial.

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ศึกษาเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบกับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ

กิ่งแก้ว ปาจรีย์, นวพร ชัชวาลพาณิชย์, สมลักษณ์ เพียรมานะกิจ, จันทร์จิรา เกิดวัน, พัชรินทร์ พุทธรักษา, ญาณณี วงศรานุชิต

วัตถุประสงค์ *: เพื่อเปรียบเทียบประสิทธิผลระหว่างการทำกายภาพบำบัดร่วมกับการใช้ยาต้านการอักเสบกับการใช้ยาต้านการอักเสบอย่างเดียวในผู้ป่วยเอ็นข้อไหล่อักเสบ*

วิธีการ *: คัดเลือกผู้ป่วยที่มีปัญหาข้อไหล่อักเสบตามเกณฑ์ที่กำหนด แล้วสุ่มให้เข้ากลุ่มรับการรักษานาน 3 สัปดาห์ กลุ่มควบคุมรับประทานยา Ibuprofen กลุ่มที่ศึกษาได้รับยา ibuprofen ร่วมกับการทำกายภาพบำบัดที่โรงพยาบาล สัปดาห์ละ 3 ครั้ง ประเมินผลเมื่อสิ้นสุดสัปดาห์ที่ 3, 6, 12 และ 24 ความสำเร็จในการรักษาประเมินจากแบบสอบถาม The Numeric Shoulder Pain and Disability Index (ภาคภาษาไทย) และ global rating of improvement นำตัวแปรทั้งสองกลุ่มมาเปรียบเทียบกันด้วยวิธี intention to treat analysis*

ผลการศึกษา *: เมื่อครบ 3 สัปดาห์ พบว่าร้อยละ 35.0 (21 รายจากจำนวน 60 ราย) ของผู้ป่วยกลุ่มศึกษาประสบความสำเร็จในการรักษา มากกว่ากลุ่มควบคุม ซึ่งประสบความสำเร็จร้อยละ 18.6 (11 รายจากจำนวน 59 ราย) คิดเป็นร้อยละ 16.4 (ค่าร้อยละ 95 ของความเชื่อมั่น = ร้อยละ 4.0 - 31.3, ค่า p = 0.044) เมื่อติดตามครบ 6 สัปดาห์ อัตราความสำเร็จของกลุ่มศึกษามากกว่ากลุ่มควบคุมร้อยละ 19.1 (ค่าร้อยละ 95 ของความเชื่อมั่น = ร้อยละ 4.0 – 36.1, ค่า p = 0.046)*

สรุป *: การศึกษานี้สนับสนุนการทำกายภาพบำบัดในผู้ป่วยเอ็นข้อไหล่อักเสบ*