Manipulation under anesthesia with home exercises versus home exercises alone in the treatment of frozen shoulder: A randomized, controlled trial with 125 patients

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We aimed to determine the effect of manipulation under anesthesia in frozen shoulder patients. A blinded randomized trial with a 1-year follow-up was performed at 3 referral hospitals in Southern Finland. We randomly assigned 125 patients with clinically verified frozen shoulder to the manipulation group (n = 65) or control group (n = 60). Both the intervention group and the control group were instructed in specific therapeutic exercises by physiotherapists. Clinical data were gathered at baseline and at 6 weeks and 3, 6, and 12 months after randomization. The 2 groups did not differ at any time of the follow-up in terms of shoulder pain or working ability. Small differences in the range of movement were detected in favor of the manipulation group. Perceived shoulder pain decreased during follow-up equally in the 2 groups, and at 1 year after randomization, only slight pain remained. Manipulation under anesthesia does not add effectiveness to an exercise program carried out by the patient after instruction. (J Shoulder Elbow Surg 2007;16:722-726.)

Codman[7] introduced frozen shoulder as a distinct clinical entity in 1934. It has characterized by fibrous adhesion in the joint capsule. In the advanced phase of the disease, a biopsy reveals chronic inflammation and fibrosis in the rotator cuff tendons and joint capsule.[15] The etiology and pathogenesis of frozen shoulder are not known, but individuals with diabetes[2] and hemiplegia[12] are predisposed. In southern Sweden, it is estimated that about 2% of the population will have frozen shoulder during their lifetime.[15]

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Frozen shoulder causes pain, tenderness, and gradually increasing stiffness in the affected shoulder.[18] The range of movement decreases in a capsular pattern, in which internal rotation and external rotation decrease more than flexion and abduction. Radiography and ultrasonography yield normal results, but typical diminution of joint folds and shrinkage of the joint cavity are seen on arthrography.[16]

If untreated, frozen shoulder has been noted to last up to 3 years and does tend to appear in the same shoulder again.[15] Physiotherapy,[4] cortisone injections,[1,20] oral cortisone,[3] manipulation under anesthesia,[11,13] release of adhesions arthroscopically,[6] and manipulation under anesthesia followed by arthroscopy[5] have all been used in attempts to shorten the duration of shoulder symptoms. There is little evidence to support or refute the efficiency of these procedures.[10] Although manipulation under anesthesia is widely used, there are no randomized trials on its effectiveness.[9]

The aim of our trial was to evaluate the effect of home exercises and manipulation under anesthesia on frozen shoulder by comparing this intervention with home exercises only.

MATERIALS AND METHODS

Three regional hospitals in Southern Finland recruited patients who had a stiff and painful shoulder between June 1999 and September 2002. All underwent radiography of the shoulder joint. Specialists in physical medicine and rehabilitation ensured that the history and physical findings fit the diagnosis of frozen shoulder, and they also controlled the list of exclusion and inclusion criteria and executed the manipulations.

Adult patients with gradually increasing shoulder pain and stiffness were included in the study. The physician measured the range of movement with a tape measure and goniometry. Passive flexion, abduction, and internal rotation were measured with the patient standing, and external rotation was determined with the patient lying supine. In flexion and abduction, the angle between the arm and body was measured. In internal rotation, the arm was raised behind the back as high as possible,[13] and the distance from the caudal edge of the contralateral scapula

was measured. In the evaluation of the range of external rotation, the arm was kept close to the patient's side with the elbow flexed to 90°, and at the end point of the movement, the angle between the vertical line and forearm line was measured.

Shoulder mobility of no more than 140° in elevation and 30° in external rotation was allowed.

Exclusion criteria included arthritis, osteoarthritis, or traumatic bone or tendon changes in the affected shoulder. A rotator cuff rupture was suspected in patients with weak external rotation or abduction. Ultrasound examination was performed in these patients, with a verified rotator cuff rupture leading to exclusion.

A structured questionnaire was used to determine the health status and shoulder problems of the patients. The questionnaire inquired about medications, previous operations, chronic disorders, various joint problems, intensity of shoulder pain, and disability due to shoulder pain. Actual shoulder pain and working ability were rated on a scale from 0 to 10. Data on shoulder symptoms during various activities in a 24-hour period were obtained with a slightly modified version of the Shoulder Disability Questionnaire (SDQ).[9] From the original SDQ with 16 questions, 2 questions were left out because we believed that they did not give essential information.

Five patients refused to participate in the study. The physician then randomized the 125 consecutive patients who were willing to participate and were eligible for the study into 1 of 2 study groups by opening a sealed, opaque envelope. A biostatistician had prepared the order from a number table. A secretary, unconnected with the patients, had numbered the envelopes sequentially to prevent their rearrangement.

The manipulations under short general anesthesia were performed less than 2 weeks after the randomization. During the procedure, the patient was supine. After confirming the capsular contracture, the physician lifted the affected extremity and pushed the upper arm in flexion and abduction while supporting the patient's scapula against the thoracic cage. After the shoulder was stretched into flexion, the elbow was flexed to a right angle, and the upper arm was gently rotated into internal and external rotation. Any cracking sound in the shoulder joint during the manipulation was recorded. Normal or nearly normal mobility was achieved during the procedure.

Physiotherapists were trained to give similar instructions to all patients in both treatment groups. The patients received physiotherapy advice in 2 sessions and written instructions for a daily training program. It included pendulum exercises for the arm and stretching techniques for the shoulder joint.

A physiotherapist who was unaware of the treatment group performed follow-up examinations at 6 weeks, 3 months, 6 months, and 1 year after the randomization. The range of movement was measured in the same manner as before the manipulation. At every follow-up visit, the patient filled out a structured questionnaire that including questions about shoulder pain, disability (SDQ), working ability, use of painkillers, and other therapy received for shoulder pain.

Table I Demographic and clinical characteristics of subjects at baseline

Characteristics	Manipulation group	Control group
No. of patients	65	60
Women (%)	71	65
Age (y)	53 (8.4)	53 (8.6)
Working ability (0-10)*	5.0 (0.4)	5.9 (0.4)
Duration of pain (mo)	7.4 (0.3)	7.0 (0.3)
Pain intensity (0-10)†	6.6 (0.3)	6.4 (0.3)
SDQ (0-28)‡	22.7 (4.9)	21.7 (4.6)
Range of motion		
Shoulder flexion (°)	104 (24)	109 (24)
Shoulder abduction (°)	78 (22)	80 (20)
Shoulder inner rotation (cm)	38 (11)	42 (10)
Shoulder outer rotation (°)	18 (12)	18 (12)

Data are presented as mean (SD), unless otherwise indicated.

*Scored on an 11-point scale where 0 represents total disability to work and 10 indicates work ability at its best.

†Scored on an 11-point scale where 0 represents no pain at all and 10 is unbearable pain.

‡Pain evaluated in 14 activities of daily living during previous 24 hours, with "perceived pain" receiving 2 points, "cannot say" receiving 1 point, and "no pain" receiving 0 points.

Ethics

The Ethics Committee of Jorvi Hospital (Espoo, Finland) approved the study in November 1997 (registration No. 371803).

Sample size and statistical analysis

Power calculations were carried out before the study to attain a power at least equal to 0.80 at the .05 significance level. A clinically significant difference between the groups in the primary outcome measure, pain intensity (on a scale of 0-10), was considered to be 1.5 (SD, 2.5). Accordingly, 45 patients per group were needed.

The Student *t* test was used for the statistical testing of continuous variables and the χ^2 test for the contingency tables. An analysis of variance was used in the evaluation of the effect of the baseline information on changes in shoulder symptoms and shoulder mobility and in testing the significance of differences between the groups during follow-up.

RESULTS

The demographic and clinical characteristics of the patients at baseline are presented in Table I. The 2 groups were similar. Chronic disorders were noted in the groups equally, with the most frequently reported being hypertonia (21 patients), diabetes mellitus (18 patients), and asthma (5 patients).

Follow-up information was obtained for 88% of the subjects at the 6-week follow-up examinations, with 10 being absent from the manipulation group and 5 from the control group. At 3 months, information was

Table II Outcomes in manipulation and control groups at 6-week and 3-, 6-, and 12-month follow-up examinations

Characteristics	Manipulation group	Control group	Difference (95% confidence interval)
6 wk after randomization			
No. of patients	55	55	
Working ability (0-10)†	6.6	6.2	0.4 (−4.2 to 1.28)
Pain intensity (0-10)‡	4.9	4.7	0.2 (−0.64 to 1.02)
SDQ (0-28)§	18.9	19.2	−0.3 (−2.3 to 1.7)
Shoulder flexion (°)	133	129	4 (−3.8 to 11.8)
Shoulder abduction (°)	125	115	10 (−3.2 to 23.2)
Shoulder internal rotation (cm)	30	34	4 (−1 to 9)
Shoulder external rotation (°)	38	33	5 (−2 to 12)
3 mo after randomisation			
No. of patients	51	50	
Working ability (0-10)†	7.1	7.1	0 (−0.8 to 0.8)
Pain intensity (0-10)‡	3.9	3.7	0.2 (−1.06 to 1.10)
SDQ (0-28)§	14.5	14.2	0.3 (−2.69 to 2.75)
Shoulder flexion (°)	144	136	8 (0 to 16)
Shoulder abduction (°)	150	141	9 (−6 to 24)
Shoulder internal rotation (cm)	22	25	−3 (−7.4 to 2.4)
Shoulder external rotation (°)	48	42	6 (−3 to 15)
6 mo after randomisation			
No. of patients	38	45	
Working ability (0-10)†	7.8	7.3	0.5 (−0.6 to 1.6)
Pain intensity (0-10)‡	2.0	2.8	−0.8 (−1.8 to 0.2)
SDQ (0-28)§	9.6	11.3	−1.7 (−5.3 to 1.9)
Shoulder flexion (°)	151	146	5 (−5 to 15)
Shoulder abduction (°)	151	142	9 (−4 to 22)
Shoulder internal rotation (cm)	16	18	−2 (−7.4 to 3.4)
Shoulder external rotation (°)	59	53	6 (−2 to 14)
12 mo after randomisation			
No. of patients	3	42	
Working ability (0-10)†	8.3	8.2	0.1 (−0.8 to 1.0)
Pain intensity (0-10)‡	1.5	2.2	−0.7 (−1.8 to 0.4)
SDQ (0-28)§	6.6	6.6	0 (−3.2 to 3.2)
Shoulder flexion (°)	157	154	3 (−5 to 11)
Shoulder abduction (°)	161	154	7 (−5 to 19)
Shoulder internal rotation (cm)	11	12	−1 (−4.1 to 6.1)
Shoulder external rotation (°)	65	61	4 (−4.2 to 12.2)

∗Significant difference between groups in 95% confidence intervals.

†Scored on an 11-point scale where 0 represents total disability to work and 10 indicates work ability at its best.

‡Scored on an 11-point scale where 0 represents no pain at all and 10 is unbearable pain.

§Pain evaluated in 14 activities of daily living during previous 24 hours, with "perceived pain" receiving 2 points, "cannot say" receiving 1 point, and "no pain" receiving 0 points.

obtained for 81%, with 14 participants missing from the manipulation group and 10 from the control group. At 6 months, information was obtained for 66%, with 27 participants missing from the manipulation group and 15 from the control group. At 12 months, information was obtained for 63% of the participants, with 28 of 65 patients missing from the manipulation group and 18 of 60 from the control group. The initial information regarding dropouts did not differ from the remaining participants as a whole or between the 2 intervention groups.

In outpatient care, the most frequently used treatment was a prescription for analgesics. During the 3 months preceding the randomization, the patients had used analgesics for approximately 36 days and had been on sick leave for 17 days, equally in both treatment groups. No differences were noted between the groups regarding reported physiotherapy, massage, or chiropractic manipulation during the 3 months preceding the randomization.

The right shoulder was affected in 42 patients and the left in 83. Only 1 shoulder was affected in all patients, and for 41, it was the dominant shoulder. The mean duration of shoulder pain was 7 months in both groups, and it varied from 3 to 22 months. During manipulation, a typical cracking sound was

heard in all of the manipulated shoulders and shoulder mobility increased. There were no major complications during manipulation.

Table II shows the symptoms and shoulder mobility during the follow-up. The patients in the manipulation group had slightly better shoulder mobility at the 6-week and 3-month follow-up examinations, with the difference between groups being statistically significant for shoulder flexion 3 months after manipulation. At the 6-month and 1-year follow-up examinations, there was only a slight difference between the 2 groups in pain intensity and no difference in disability (SDQ).

In the multiple regression models, we found no combination of treatment group, age, gender, chronic disorder, and duration of shoulder pain that predicted shoulder pain in the follow-up period.

DISCUSSION

Only a few follow-up studies have thus far recorded the time of recovery from frozen shoulder. In our study, shoulder pain subsided essentially and glenohumeral mobility was restored nearly to normal approximately 1 year after the onset of shoulder symptoms (half a year after randomization). This finding is in contrast to the findings in the medical literature, according to which the course of the illness is notably longer-lasting.[17,19] We assume that there is selection bias in case series, in which patients with prolonged illness are over-represented, as Chambler and Carr[6] also presented.

To our knowledge, no randomized controlled trial has been undertaken on manipulation for frozen shoulder. There has been controversy on the effectiveness of manipulation under anesthesia. Some authors consider manipulation an effective intervention, whereas others claim that it is traumatizing and may even exacerbate pain.[21]

In our trial, the recovery was surprisingly similar in the 2 treatment groups and consistent with regard to all of the outcome parameters. The difference in favor of the manipulation group for mobility and pain was small and clinically unimportant. Exercise within pain limits, as used for the control group in this study, has previously been shown to be more effective than intensive physical therapy in frozen shoulder patients.[8]

In this study, a series of successful manipulations under anesthesia had limited effect in the follow-up period, probably because of the recurrence of adhesions in the first weeks after manipulation. We did not note major complications with manipulation, but small injuries of the joint were possible, as has been verified on arthroscopy after manipulation.[14]

Randomization led to good comparability between the 2 treatment groups in our study. Patients in the 2 groups had used other treatments equally, and as there was no difference in outcome between the 2 groups, no cost-effectiveness analysis was indicated. A blinded assessor gathered questionnaire data at baseline and during the entire follow-up period and also measured glenohumeral mobility; this procedure increased the reliability of the findings.

A limitation of the trial was the comparatively high dropout rate at long-term follow-up, with 20% at 3 months and around one third at later follow-up, which was probably because of the inconvenience of having to be seen at the clinic. The aim of the manipulation was to give relief within 2 days. As the short-term results showed no difference and the manipulation was an immediate intervention, we consider it unlikely that the loss of long-term follow-up has led to significant bias.

In conclusion, the patients' condition improved more quickly than expected. In both groups, shoulder symptoms and findings had essentially already diminished 6 months after randomization. The exercise program that patients received instruction for and carried out themselves was as effective as the same program that complemented manipulation under anesthesia. It remains to be shown in future trials whether a training program is more effective than no treatment at all.

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