Manipulative therapy for shoulder complaints in general practice

Bergman, Geert Jan Derk

Summary

Shoulder complaints constitute a widely recognized medical, social, and economical problem. They are characterized by functional disability due to pain in the shoulder either at rest or provoked during shoulder movement or as a result of restriction of the range of motion of the shoulder. In the Netherlands, shoulder complaints are treated according the Guidelines for Shoulder Complaints of the Dutch College of General Practitioners (Wait-and-see policy, possibly supplemented with analgesics and NSAID's, corticosteroid injections (in the subacromial space or glenohumeral joint) and referral for physiotherapy, which is considered in complaints persisting for six weeks or more). This treatment according to the guidelines provides short term benefit for many patients, but it can not prevent the often unfavorable long term course of the complaint. Pain or dysfunction of the cervical spine, the upper thoracic spine, and the adjacent ribs (shoulder girdle) often accompany shoulder complaints. Dysfunctions of the shoulder girdle strongly predicts development of shoulder complaints representing a threefold risk increase, and is also a predictor for poor outcome of shoulder complaints. This is acknowledged in the Guidelines, but no therapeutic advice is given since only scarce evidence exists. In clinical practice, a dysfunction of the shoulder girdle can be treated by manipulative therapy, which aims to restore normal function of the shoulder girdle. Therefore, the objective of this current randomized trial is to study the clinical and cost-effectiveness of manipulative therapy of the shoulder girdle in addition to usual medical care by the general practitioner, in treatment of shoulder complaints.

In ***chapters 1 and*** 2, the background and the design of the study are presented. This randomized trial is part of a comprehensive prognostic cohort study on shoulder disorders, with randomized controlled intervention studies in sub cohorts. In the cohort study, approximately 2,000 patients with shoulder complaints will be included and followed for six months. The overall aim of this research program was to enable evidence based treatment of shoulder complaints. Potential eligible patients with shoulder complaints were recruited in 50 general practices in Groningen, the Netherlands. The general practitioner started initial treatment (usual medical care) at presentation, checked the criteria for eligibility, and referred the patient. Shoulder complaints were defined as pain at rest or during movement of the upper arm in the area between the neck and the elbow. Main selection criteria included manifest shoulder complaints, a dysfunction of the shoulder girdle, 18 years of age or older, and no consultation or treatment for shoulder complaints in the past three months. There was no limitation in the duration of complaints before the first consultation. A baseline assessment at the research center was scheduled within two weeks of presentation. In the research center, the inclusion criteria were verified before randomization by a structured medical history and a physical assessment. Patients were evenly randomly allocated to either manipulative therapy additional to usual

medical care or to usual medical care alone. Manipulative therapy according to a predetermined protocol included specific manipulations (low-amplitude, high-velocity thrust techniques) and specific mobilizations (high-amplitude, low-velocity thrust techniques) to improve overall joint function and decrease any restrictions in movement at single or multiple segmental levels in the cervical spine, upper thoracic spine, and adjacent ribs. The choice of applied techniques was determined by the manual therapist based on location of the dysfunction and technique preferences. Within the boundaries of the protocol, treatment could be reassessed and adapted to the patient's condition. A maximum of six treatment sessions could be given over a 12-week period. Patient outcome measures were recorded at baseline, at six weeks (during the intervention period), at 12 weeks (at completion of the intervention period), at 26 weeks, and at 52 weeks. The primary outcome measure were patient perceived recovery, severity of three main complaints, shoulder pain, functional disability, general health, and costs. All data analyses on the basis of treatment assignment (intention-to-treat principle) were carried out according to a predetermined protocol.

In *chapter 3*, the main clinical results are presented. A total of 385 patients were referred to the research center, of which 150 participated in the trial. Seventy-one patients were allocated to usual medical care only, and 79 patients were allocated to manipulative therapy as add-on to usual medical care. Both groups were highly comparable regarding demographic and prognostic variables and baseline values of outcome measures. Patients consulted their general practitioner 2.4 times on average with a small difference in average number of visits between groups. Patients in the intervention group received 3.8 treatment sessions from a manipulative therapist on average. In the six and 12 weeks measurements, there was a consistent difference in favor of additional manipulative therapy, but none of the differences at six weeks reached statistical significance. At 12 weeks after randomization, a statistically significant difference in favor of manipulative therapy with respect to the proportion of patients reporting full recovery or very large improvement was found. Also, at 12 weeks, there was a significant difference between groups for the mean improvement in severity of the main complaint and shoulder pain favoring manipulative therapy. In the follow-up period, the proportion of patients reporting full recovery or very high improvement continued to be higher in patients that received manipulative therapy. A significant difference was found in perceived recovery and patients reporting feeling cured at 52 weeks. The severity of the main complaint was significant lower in patients treated with manipulative therapy at 26 weeks and at 52 weeks. Results on shoulder pain and disability consistently favored patients receiving additional manipulative therapy, but only shoulder disability reached a statistical significant difference at 26 weeks. Based on these results, it was concluded that manipulative therapy of the cervicothoracic spine and the adjacent ribs in addition to usual medical care by the general practitioner accelerates recovery of shoulder complaints.

The clinical results on the physical examination of the shoulder and the shoulder girdle are presented in *chapter 4*. The physical examination was

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used to establish the severity of pain and mobility of shoulder complaints, cervicothoracic spine, and adjacent ribs. We tried to overcome multiple testing for separate physical tests for which the outcome is likely to be associated. The challenge is to reduce the number of variables in such a way that they are clinically sensible and statistically manageable. We used factor analysis to identify different clinically meaningful components from these variables, and thereby reduce the number of outcomes measures. The factor analysis resulted in four factors: 'shoulder pain', 'neck pain', 'shoulder mobility', and 'neck mobility'. Each factor constituted a set of well matched physical tests. For neither of the identified factors, our trial showed clinically relevant or statistically significant results at six weeks. At 12 weeks, the mean changes of all factors favored manipulative therapy, but only the factor 'neck pain' reached statistical significance. At 26 weeks, differences in the factors 'shoulder pain', 'shoulder mobility', and 'mobility neck' statistically favored manipulative therapy. As demonstrated, factor analysis is a useful manner to summarize data of a physical examination. The results show that manipulative therapy, in addition to usual medical care by the general practitioner, diminishes severity of shoulder and neck pain and improves shoulder and neck mobility.

Besides clinical effectiveness, an economic evaluation of manipulative therapy in treatment of shoulder complaints was conducted, as presented in ***chapter 5***. Cost data were collected from a societal perspective, using a cost-diary over a period of 26 weeks. The cost-diary included the following costs. Direct health care costs such as costs due to treatment by general practitioners, therapists, complementary health therapists, specialists, professional home care, and hospitalization. Direct non-health related costs included out of pocket expenses and costs for paid and unpaid help. Indirect costs included loss of production due to sick leave from paid and unpaid work. The total costs were higher for patients receiving additional manipulative therapy compared to patients that received usual medical care only (€1,167 vs. €555). This is explained mainly by the costs of the manipulative therapy itself and the higher costs due to sick leave from work. The largest proportion of the total cost was due to sick leave from work, especially in manipulative group, in which two patients had extremely high sick leave. This markedly influenced the balance between costs and effects. After adjustment for these extreme values, the differences in costs were small and, consequently, the extra costs for one additional recovery is low. The cost-effectiveness ratio showed that additional manipulative treatment is more costly, but also more effective than usual medical care alone. After adjustment for patients with extreme costs, the cost-effectiveness acceptability curve demonstrated that a 50%-probability of recovery with manipulative therapy within six months after initiation of treatment was achieved at relative low costs.

Since manipulative therapy of the cervical spine aims to restore normal spinal function, including increased range of motion, the range of motion of the cervical spine is an important clinical issue. Apart from insight in range of motion, it can also be used to measure changes in a patient over time or to compare independent groups of patients, which can be important in the

assessment of therapeutic interventions. Over the years, numerous measurements techniques have been developed to establish cervical range of motion, but there is limited agreement among therapists or researchers which method should be used. Our study used the Flock of Birds system, a six-degrees-of-freedom electromagnetic tracking device. The accuracy and reliability of this measurement technique was evaluated before the present study and considered feasible for use in a randomized trial. However, an additional study on clinical interobserver reliability was considered necessary for the interpretation the trial results. A study was conducted to establish the interobserver reliability of the Flock of Birds system for measuring cervical range of motion, as presented in ***chapter 6***. Two observers independently and in random order assessed the cervical range of motion in thirty subjects with a dysfunction in the neck and shoulder region (symptomatic subjects) and thirty subjects without known pathology (asymptomatic subjects). Measurements included rotation in neutral position, in flexed position, and in extended position, flexion-extension and lateral bending (all active and passive). Interobserver reliability was analyzed by means of Intraclass Correlation Coefficient (ICC) and interobserver agreement by the limits of agreement and the percentage of paired observations within 5°, 10°, and 15°. For asymptomatic as well as symptomatic subjects, the interobserver reliability ranged from moderate to good, depending on the cervical motion tested, and considerable limits of agreement between observers were found. The interobserver reliability of the Flock of Birds system is sufficient for measuring active rotation in neutral position, flexion-extension, and lateral bending of the cervical spine, but not for combined movements such as rotation in extended position. Because of considerable limits of agreement in neck movements, a large improvement in range of motion must be measured before deciding on effectiveness of interventions.

Since measuring cervical range of motion over time is an outcome in our clinical trial, data about the normal variation of the cervical range of motion over time is important for the interpretation of study results. Unfortunately, hardly any scientific research exists about normal variation of cervical range of motion over time. In ***chapter 7***, the results of a study to quantify the variation of cervical range of motion over time in subjects without a dysfunction of the neck or shoulder region as well as in subjects with a dysfunction in either region measured by the Flock of Birds system are reported. Active and passive cervical range of motion was assessed in three different sessions six weeks apart in 48 subjects without a manifest dysfunction in neck and shoulder region (asymptomatic subjects) and 58 subjects with a dysfunction in the neck and shoulder region (symptomatic subjects). The following movements were measured: flexion-extension, lateral bending, and axial rotation in neutral, in flexed and in extended position. A wide range of variation of active and passive cervical range of motion was found at the six weeks and 12 weeks measurement in the asymptomatic group as well as in the symptomatic group. Highest variation was found during passive range of motion testing as compared to the active range of motion. The symptomatic group showed larger variation than the

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Despite our initial intention to demonstrate changes in cervical range of motion due to manipulative therapy, the results of the interobserver reliability study and the quantification of the normal variation over time led the conclusion that valid results in cervical range of motion could not be obtained. However, this study makes clear that valid measurement of the (changes of) mobility of the cervical spine is a useless undertaking.

In *chapter 8*, the main findings, pragmatic issues, and methodological aspects of conducting a randomized trial in general practice and the measurement of the range of motion of the neck are critically reviewed. Our study has focused on patients with shoulder complaints and a dysfunction of the shoulder girdle and the effects of manipulative treatment in these patients. Based on the findings and their critical review, we recommend the following revisions of the practice guidelines: a physical assessment of the shoulder girdle should be performed in all patients with shoulder complaints in stead of only in patients with no manifest disorder in the shoulder joint. The physical assessment of the shoulder girdle should consist of active axial rotation, flexion-extension and lateral bending and inform for experienced intensity of pain in these movements and estimate cervical movement restriction. In patients with shoulder complaints and a dysfunction of the shoulder girdle, referral to manipulative therapy is preferred after proper reduction of the intensity of shoulder pain.