Investigation plan

OPERATIVE VERSUS CONSERVATIVE MANAGEMENT OF ROTATOR CUFF DISEASE (SUBACROMIAL IMPINGEMENT AND ROTATOR CUFF TEAR)
A prospective, randomized, controlled trial

Site of research:
Central Finland Hospital, Keskussairaalantie 19, Fin-40620 Jyväskylä, Finland

Oulu University Hospital, Oulu, Finland

Principal investigator:
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Research plan: Paloneva, J., *et al.*

1. Background

Painful shoulder is one of the most common musculoskeletal causes of primary care consultation (1). Every 10th individual suffer from pain or disability of the shoulder. Shoulder problems become more common with increasing age. As many as every fifth of those aged 75-80 years is suffering from shoulder problems (2-4). Rotator cuff disease (subacromial impingement syndrome and rotator cuff tears) is the leading cause of prolonged pain and restricted range of motion of the shoulder as well as a significant cause of sick leave.

In the US, approximately 4.5 million physician visits and 40,000 inpatient surgeries are performed for diseases of the rotator cuff every year. The total costs are approximately $ 600 000 000 (5). Half of the shoulder operations are subacromial decompressions and one fourth rotator cuff repairs (6). Operative treatment is associated with a long sick leave and rehabilitation period. The average duration of sick leave before and after subacromial decompression is 91 and 91 days, respectively. Correspondingly, the duration of sick leave associated with rotator cuff repair is 87 and 112 days (6).

Thus, rotator cuff problems have a significant effect on public health and are associated with high economical impact. Despite the high prevalence and expenses associated with disorders of the rotator cuff, there is little evidence to support or refute the efficacy of common interventions of subacromial impingement syndrome or rotator cuff tears. Therefore, optimal treatment supported by strong clinical evidence (operative vs. conservative, method and timing of surgery) cannot be offered to the patients (7, 8).

1.1.2 Anatomy of the shoulder

Glenohumeral joint is the most mobile human joint. Four muscles (*m. supraspinatus*, *m. infraspinatus*, *m. teres minor* and *m. subscapularis*) arising from the scapula and connecting to the head of the humerus are called rotator cuff muscles of the shoulder joint. The rotator cuff is an important soft tissue structure surrounding the glenohumeral joint. *M. supraspinatus* helps to abduct the upper limb, *m. teres minor* laterally rotates the arm and assists in its adduction, *m. infraspinatus* laterally rotates the arm and *m. subscapularis* medially rotates the arm and adducts it.

1.1.3 Pathophysiology, symptoms and findings

Rotator cuff disease is classically thought to be a continuum that ranges from an acute inflammation of the tendons to a full-thickness rotator cuff tear (9). Impingement has been classified into three stages: Stage I is associated with acute rotator cuff tendinitis. Stage II (also called as subacromial impingement syndrome) involves chronic inflammation and degeneration of the tissues. Full-thickness rotator cuff tear is seen in stage III. Depending on the classification, partial tears are included in either stage II or III (10).

1.1.4 Symptoms and signs of subacromial impingement stages I and II

Impingement stage I is an acute and reversible condition. Stage II involves prolonged symptoms that begin insidiously and may progress. Symptoms may also appear after strain or trauma. Pain is the most prominent manifestation. Pain is typically felt in the deltoid region and it often radiates to the upper arm. Painful arc between 60-120 degrees of abduction and disturbed humeroscapular rhythm

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are typical. Weakness and restricted range of motion of the shoulder may be present. The impingement sign test (passive shoulder flexion while preventing scapular rotation by pressing with a hand on acromion) cause pain. Local anaesthetic injected in the subacromial bursa relieves pain in the impingement sign test (9).

1.1.5 Rotator cuff tear

Rotator cuff tears are most commonly found in the supraspinatus tendon. Tear is usually associated with a degenerative process although the symptoms often become manifested after a minor trauma. Clinical examination reveals pain and weakness as well as restriction of active range of motion. Pain in abduction (painful arc) and external rotation is typical. Patients with a large tear often have difficulties in elevating the upper limb.

1.2 Previous research pertaining to rotator cuff disease and problems

The aim of interventions of rotator cuff disorders is to control pain and restore the function of the shoulder. The treatment of impingement stage I is conservative. The challenges of management of rotator cuff disease are associated with chronic rotator cuff disorders (stages II and III).

The interventions of disorders of the rotator cuff are heterogeneous. There is insufficient evidence to support or disprove the efficacy of common interventions of subacromial impingement stage II and rotator cuff tears. Evidence based knowledge to judge which patients benefit from surgery does not exist.

1.2.1 Impingement syndrome stage II

The first line of management of stage II impingement syndrome is conservative (rest, pain medication, physiotherapy and subacromial corticosteroid injections).

The most common surgical intervention of stage II impingement syndrome is arthroscopic decompression (bursectomy with partial resection of the anterior-inferior part of the acromion). The effectiveness of surgical management of stage II impingement has been questioned in three recent studies. These randomized controlled trials (RCT) compared arthroscopic subacromial decompression to supervised exercises and suggest that there are no statistically significant differences in the results between these two treatment modalities (11-13).

All these RCTs contain a significant methodological defect. According to generally accepted guidelines, conservative treatment with active physiotherapy should be conducted for several months before considering acromioplasty. The treatments before randomization were not defined in any of these trials. According to a study performed by our group, effective conservative treatment (physiotherapy) before referral to orthopaedic surgeon was defectively carried out in majority of cases (16). It is evident that the above-mentioned trials contain individuals that would have recovered during a short period of physiotherapy**.** The effectiveness of acromioplasty has not been studied after conservative treatment performed according to the common recommendations.

Arthroscopic decompression is an increasingly common shoulder operation despite the recent evidence questioning the effectiveness of surgery (15). We hypothesize that surgery and rehabilitation would provide equivalent pain and function outcomes.

1.2.2 Rotator cuff tears

The first line of management of rotator cuff tears is non-operative. According to different sources, the symptoms relieve in 33-90 % of the patients. The reported results of rotator cuff repair are good. An acceptable result has been reported in 70-95 % of the patients (4).

However, rotator cuff tears are associated with several controversial issues such as the role of non-operative management, the indications for and timing of surgery and the method of surgical repair (4). Rotator cuff tears do not always cause significant pain or disability; tears have been reported in 34-38 % of asymptomatic individuals and in 30-50 % in cadaver studies (4, 17, 18). Partial or full-thickness tears have been found in more than 50 % of asymptomatic individuals over 60 years of age (19). Half of patients heal spontaneously and even a large tear is not always incompatible with a good over-head function (20). An acute tear after a high-energy trauma of a young (under age 50) individual is considered as an indication for surgery. On the other hand, an aged patient suffering from a chronic tear associated with low demands of activities of daily living as well as poor quality of rotator cuff tendons and muscles are thought to be suitable for conservative treatment (4). The greatest challenges of treatment of rotator cuff tears are encountered with the extensive number of patients between these two extremes.

There is little evidence to support or refute the efficacy of common interventions for rotator cuff tears (7, 22). Only one randomized controlled trial comparing surgical repair of rotator cuff tears to conservative treatment has been reported (23). In this trial pain was 1.7 cm lower (VAS, max 10 cm) and functional index 13 points higher (Constant score, max 100) in favour of surgery after one year follow-up. Although statistically significant, the clinical significance of these data has not been established. The contents of conservative treatment before randomization was not characterised. Therefore, it has to be assumed that the conservative treatment had been carried out ineffectively.

The guidelines for surgical decision making have been insufficiently characterized and level I evidence for any intervention is scarce. The need for randomized controlled trials comparing operative to conservative treatment is obvious (22).

When starting this trial, funded by the Academy of Finland, in 2008, only the trials by Brox and Haahr had been reported. The newly published papers in this field show that there is an increasing interest in defining the effectiveness of rotator cuff surgery. The fundamental issue regarding the superiority of surgery or physiotherapy is unresolved. The present trial aims at responding this need.

2. Objectives

2.1 Research objectives

The objective is to search out evidence-based data for surgical and non-surgical treatments of rotator cuff disease, including subacromial impingement stage II and full-thickness rotator cuff tear, after initial non-surgical treatment.

This trial included two pre-specified subgroup analyses: The effectiveness of surgical treatment of {1} impingement stage II (including partial tears) and {2} full-thickness rotator cuff tears compared to non-surgical treatment.

We also aim at offering patients the most efficient and effective treatment and reduce the number of operations that do not have sufficient effectiveness. The data obtained facilitate the development of guidelines for management of rotator cuff disease.

2.2 Hypotheses

We test the following specific null hypothesis: there are no differences in outcome of surgical and non-surgical interventions for rotator cuff disease (subacromial impingement syndrome stage II) and full-thickness rotator cuff tear according to age, level of daily living activities, quality of life or the size or the number of tendons involved.

We postulate that there may be subgroups of patients suffering from rotator cuff disease that benefit from surgery whereas other subgroups are best treated conservatively.

3. Research methods and material

This trial is registered with ClinicalTrials.gov, numbers NCT00695981 and NCT00637013.

3.1 Research methods

The research setting is prospective, randomized and controlled. The study is a multicentre trial and will be performed in Central Finland Central Hospital (CFCH, Jyväskylä, Finland) and Oulu University Hospital (OUH, Oulu, Finland).

3.1.1 Clinical examination and patient history

For trial flow chart, see *Figure 1*. Members of the group examines and informs the patients about the trial. The inclusion criteria are; age over 35 years, duration of symptoms at least three months, and the patient accepts both treatment options (operative and conservative). The exclusion criteria are; previous shoulder operations, inability to co-operate, rheumatoid arthritis, severe osteoarthritis of the glenohumeral or acromioclavicular joint, irreparable rotator cuff tear, progressive malign disease, adhesive capsulitis, high-energy trauma before symptoms, cervical syndrome and shoulder instability.

In addition, the patients included in the impingement stage II trial must have pain in abduction of the shoulder and painful arc, pain in two of the three isometric tests (0 and 30 degrees of abduction, or

external rotation) and a positive result in the impingement test (a subacromial injection of lidocaine reduces pain). Patients with a partial rotator cuff tear are included.

In addition, the patients included in the rotator cuff tear study must have a full-thickness rotator cuff tear in MRI arthrography performed after the 3-4 months period of conservative treatment. The primary cause of the tear must be degenerative.

Patients suitable for the study will subsequently be examined by a physiotherapist. The physiotherapist records the patient history and makes the baseline measurements (Baseline I): basic information of the patients, pain in rest, in exercise, and at night (VAS), objective shoulder function (Constant score), and the quality of life (RAND-36), pain medication used, use of medical services, activities of daily living.

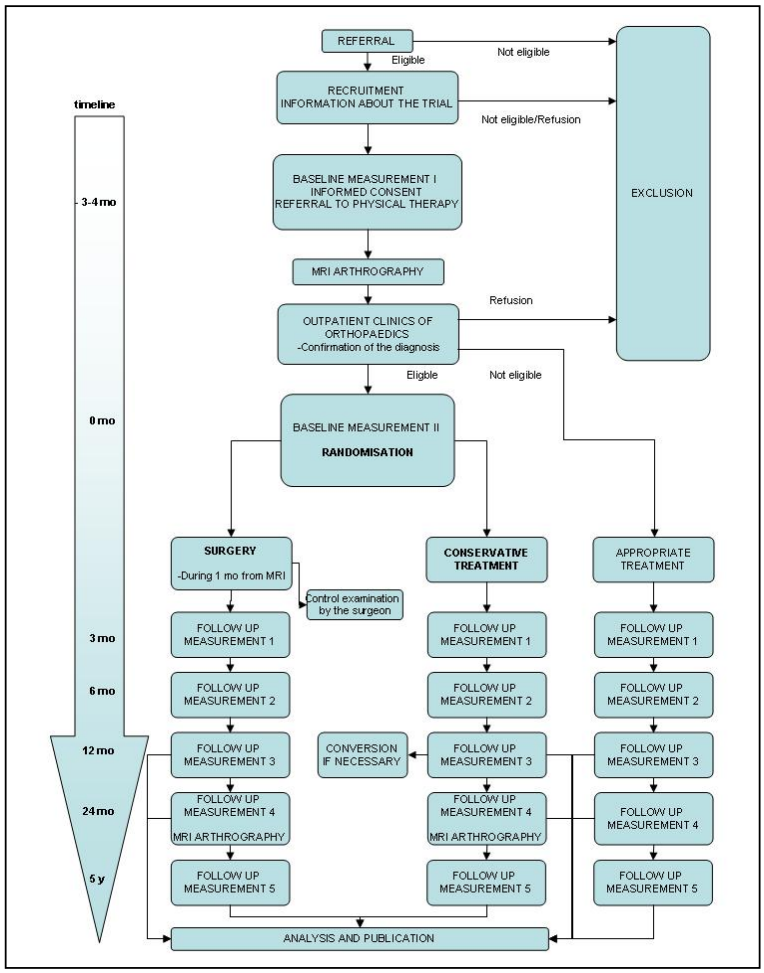

Figure 1. Trial flow chart

After baseline measurements, the patients are advised to start active physiotherapy. They receive a referral to outpatient physiotherapy. The referral is accompanied by a letter describing a rehabilitation program following generally accepted guidelines. The participation (contents and frequency of training) is recorded during the control visits.

After the 3-4 months period of conservative treatment, an MRI arthrography of the shoulder is performed. Radiographs and MR images will be systematically evaluated by two independent radiologists. A specialist in the outpatient clinics of orthopaedic surgery confirms the diagnosis and assigns the patients still suffering from significant symptoms to the group of impingement stage II or rotator cuff tear. The orthopaedic surgeon is not a member of the group. The baseline measurements will be repeated by the physiotherapist (Baseline II). After baseline measurements, the patients will be randomized to operative or conservative group.

Physiotherapist examines every patient after 3, 6, 12, 24 months, and 5 years. The same data as in the baseline examination will be recorded. In addition, the length of sick leave, complications, treatment drop out as well as the costs associated with the treatment will be recorded. The physiotherapist is not blinded.

Patients excluded from the randomization will undergo the same follow-up protocol than patients included in the study.

3.1.2 Clinical management

The rehabilitation program of patients randomized to non-operative treatment will be guided by physiotherapist. The standardised home-based rehabilitation program consists of exercises that are simple and can be performed at home.

Patients randomized to surgical treatment will be operated according to the generally accepted current practice. The post operative rehabilitation program will be guided by the physiotherapist. All operated patients will be routinely examined six to eight weeks postoperatively by the operating surgeon.

Non-surgical treatment will be considered failed if no improvement in the parameters mentioned above has been observed after six to twelve months and the patient complains significant problems due to pain or disability. These patients will be offered appropriate surgical intervention.

Healing or potential progression of defects in rotator cuff and glenohumeral joint will be evaluated by MRI arthrography 24 months after the randomization.

3.1.3 Outcome variables

The primary outcome variables of both study sections (impingement stage II and tear of the rotator cuff) are the change in pain (VAS) and objective shoulder function (Constant score) after two years from randomization.

3.1.4 Determination of the sample size

The sample size was evaluated using iterative models (β=0.85 and α=0.05). The calculations are based on a 30 % difference between the groups. When statistically significant, the 30 % difference is likely to be also clinically significant. The number of patients is approximately 200: 100 patients will receive surgical treatment and another 100 will be randomized to non-surgical treatment. Determination of the sample size was based on an article by Haahr, J.P. and colleagues (12).

3.1.5 Randomization

Patients suitable for the trial according to the inclusion and exclusion criteria will be randomized to surgical and non-surgical groups according to a computer generated, blocked randomization list. The block size varies randomly (approximately ten) and is stratified according to gender and type of rotator cuff disease (impingement stage II or full-thickness rotator cuff tear).

3.1.6 Statistical analysis

All analyses will be performed on the intention-to-treat principle. The data will be analyzed by using statistical longitudinal data methods suitable for the measurement scale of the outcome in question. Baseline adjusted models will be used if there are differences between the groups in the outcomes at baseline. Based on patient history, demographic and follow-up data we aim at determining subgroups of patients gaining the most benefit from either operative or conservative intervention.

3.1.7 Cost-effectiveness

The cost-effectiveness of the treatments will be evaluated by determining the quality of life (RAND-36) and pain (VAS) of the patients at baseline before treatment and 3, 6, 12, 24 months and 5 years after the treatment given. The effectiveness will be measured by change in quality of life or pain. The use of health and social services will be measured after 6 and 12 months.

3.2. Research material

Patients. All patients referred to CFCH and OUH suffering from subacromial impingement stage II or rotator cuff tear are potential candidates for the trial. CFCH and OUH are public hospitals offering orthopaedic treatment to the population of 250 000 (CFCH) and 270 000 (OUH) in the surrounding communities. Annually, approximately 1200 patients are referred to these hospitals by general practitioners due to shoulder disorders.

3.3 Materials management plan

4.3.1 Every patient receives a code number that will be used throughout the trial. All data will be recorded in forms designed for the project. 4.3.2 Data will be used for statistical analyses as described in section 4.1. Data will be used for research purposes according to a written permission granted by all individuals included in the trial. 4.3.3 The physical data (forms) will be stored in a Clinical Research File (CRF), established for every individual. Data will be transferred into electronic format and saved in a server located in Central Finland Central Hospital (CFCH). The server is protected by username and password. All physical data containing personal information will be stored in the hospital in a locked room. 4.3.4 Anonymous data will be made available on request after the trial has been finished. 4.3.5 Central Finland Hospital District is the owner of the research material. Only members of the research group will be able to access these data.

3.4 Ethical issues and research permits

A detailed application for the ethical board of the Hospital District has been presented and approved (Dnro 23/2007, May 23rd, 2007).

Participation in the study is voluntary. Patients will be informed about the study, and the current knowledge as well as the risks associated with both treatment options. The patients will also receive written material about their disease and the trial. The patients will be informed that they can leave the study without any negative consequences. Patients accepting the terms of the study will give a written informed consent. All recognisable personal data will remain confidential.

The clinical management of the patients will be carried out according to generally accepted methods. There are no data showing superiority of any method used in this trial to each other. If non-operative treatment fails to provide relief to the symptoms in six to twelve months, adequate surgical intervention will be offered.

3.5 Risk management

The size of population for recruitment was identified as a critical factor. The number of patients was estimated to be sufficient. To accelerate randomization of the patients, the project was converted into a multicentre trial in 2010. The trial has been actively recruiting patients since 2008.

4. Implementation

4.1 Timetable

Recruitment of the patients began in 2008. The patients will be evaluated 3, 6, 12, 24 months and 5 years after intervention.

5. Researchers and research environment

5.1 Research group and merits

Principal investigator	Juha Paloneva, MD, PhD, specialist in orthopaedics and traumatology, Central Finland Central Hospital (CFCH
Co-PI	Ilkka Kiviranta, MD, PhD, professor, specialist in surgery, specialist in orthopaedics and traumatology, orthopaedist-in-chief, University of Helsinki, Helsinki University Central Hospital, Finland
Graduate student	Sanna Cederqvist, MD, PhD student, resident surgeon, Central Finland Central Hospital (CFCH), Oulu University Hospital, Oulu, Finland
Experts in shoulder surgery	Tapio Flinkkilä, MD, PhD, associate professor, specialist in orthopaedics and traumatology, Oulu University Hospital, Konsta Pamilo, MD, PhD, Central Finland Hospital, Jyväskylä, Finland; Tero Ridanpää, MD, Central Finland Central Hospital, Jyväskylä, Finland;

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	Kai Sirniö, MD, PhD, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland;
Expert in rehabilitation	Jari Ylinen, MD, PhD, associate professor, head of the dept. of physical and rehabilitation medicine, CFCH
Recruitment of the patients	Sanna Cederqvist, MD (OUH), Tero Irmola MD, Juho Liukkonen MD, Heidi Lehtokangas MD (CFCH), resident surgeons
Clinical consultant	Juhana Leppilahti, MD, Professor, Department of Surgery, Division of Orthopedic and Trauma Surgery, Oulu, Finland; Juho Liukkonen, MD, Department of Emergency Medicine, Central Finland Hospital, Jyväskylä, Finland;
Biostatistician	Hannu Kautiainen Primary Health Care Unit, Kuopio University Hospital, Finland and Folkhälsan Research Center, Helsinki
Radiologist	MD, PhD, Department of Radiology, Helsinki University Hospital, Helsinki, Finland
Saara-Maija Hinkkanen	Physiotherapist, randomization, baseline and follow-up measurements
Nina Sevander-Kreus	Physiotherapist, randomization, baseline and follow-up measurements

5.2 Infrastructure. The trial will be performed in Central Finland Central Hospital and Oulu University Hospital. These hospitals provide the infrastructure (personnel, facilities, and equipment for clinical examination and operations as well as office material and equipment) required by the trial. The examination of the patients including radiographs and MRIs as well as operative treatment and routine postoperative control examination by the operating surgeon belong to the routine clinical practice and do not cause expenses to the project.

Follow-up MRIs 2 years after randomization will be performed at Terveystalo Imaging Services, Jyväskylä, and in Oulu University Hospital, at the Department of Radiology.

5.3.1 National and international collaboration

Oulu University Hospital provides expertise in shoulder surgery, recruitment and examination of patients as well as operative and conservative treatment.

Helsinki University Central Hospital provides collaboration in implementation of national guidelines, produced by our team, for treatment of shoulder disorders in the Hospital District of Helsinki and Uusimaa.

Finnish medical association Duodecim provides expertise in developing national guidelines for management of shoulder disorders.

6. Expected research results and possible risks

6.1 Expected scientific and societal impact. The project provides level I evidence for the treatment of rotator cuff disease. The results help physicians to decide whether the patient should be operated or directed to conservative management. The patients can be offered evidence-based treatments.

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6.2 Potential for scientific breakthroughs. By providing level I evidence on the effectiveness of common surgical shoulder operations there is a potential to more efficiently identify subgroups of patients that recover using conservative treatment or benefit from surgery. It may also be possible to safely reduce the number of operations that do not have sufficient efficacy. This will be a clinical breakthrough and is associated with a significant economical impact.

6.3 Applicability and feasibility. The approach of the trial is pragmatic. The results can be applied to real life clinical practice and recommendations as is.

6.4 Publishment. The project is likely to produce at least 15 publications which will be reported in international and domestic peer-reviewed publication series, and one doctoral thesis. Awareness among potential end-users will also be raised by presenting the results in international and domestic congresses.

7. Key literature

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