Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome?

A TWO-YEAR RANDOMISED CONTROLLED TRIAL

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We report a randomised controlled trial to examine the effectiveness and cost-effectiveness of arthroscopic acromioplasty in the treatment of stage II shoulder impingement syndrome. A total of 140 patients were randomly divided into two treatment groups: supervised exercise programme (n = 70, exercise group) and arthroscopic acromioplasty followed by a similar exercise programme (n = 70, combined treatment group). The main outcome measure was self-reported pain on a visual analogue scale of 0 to 10 at 24 months, measured on the 134 patients (66 in the exercise group and 68 in the combined treatment group) for whom endpoint data were available.

An intention-to-treat analysis disclosed an improvement in both groups but without statistically significant difference in outcome between the groups (p = 0.65). The combined treatment was considerably more costly.

Arthroscopic acromioplasty provides no clinically important effects over a structured and supervised exercise programme alone in terms of subjective outcome or cost-effectiveness when measured at 24 months. Structured exercise treatment should be the basis for treatment of shoulder impingement syndrome, with operative treatment offered judiciously until its true merit is proven.

Shoulder pain has been reported as the second most common musculoskeletal disorder[1-4] and severely affects patients' perception of their general health.[5] Impingement syndrome has been identified as the most frequent cause of shoulder pain.[6,7] The concept of impingement syndrome was introduced by Neer,[6] who defined its three stages,[8] but as the diagnosis is purely clinical it is somewhat imprecise.[9] It is commonly chronic and recurrent,[10] with treatment including rest and subacromial glucocorticosteroid injections[11] and oral non-steroidal anti-inflammatory drugs.[12] Treatment includes physiotherapy[12-16] and arthroscopic decompression and acromioplasty[17-22] with or without bursectomy.[23] The syndrome has significant economic consequences owing to its treatment costs and to losses incurred through absence from work. One comparison of physiotherapy with arthroscopic acromioplasty has been published.[17,18]

We designed a study to investigate the benefit and cost-effectiveness of arthroscopic decompression with acromioplasty followed by a structured exercise treatment compared to a similar exercise programme alone in the treatment of stage II impingement syndrome.[8] The outcome was assessed at two years.

Patients and Methods

The study was a prospective, randomised controlled, trial approved by the Ethics Committee of the Hospital District. All patients who had suspected shoulder impingement with chronic symptoms not relieved by conservative treatment and who were referred to the Kanta-Häme Central or Riihimäki Regional Hospitals between June 2001 and July 2004 were included. There were 140 patients, 52 men and 88 women with a mean age of 47.1 years (23.3 to 60.0).

The patients were given an information brochure and the risks and benefits of the study arms were discussed. The range of movement in flexion, abduction, and external and internal rotation were measured with a goniometer. Muscle strength was tested manually and graded normal or reduced, and isometric pain provocations were performed. Impingement was tested according to the method of Neer[8,24,25] after 5 ml 1% lidocaine had been injected into the subacromial space. All patients underwent plain radiography and MR imaging of the shoulder.[26] The inclusion criteria were a positive Neer's test, pain in the shoulder which was resistant to rest, anti-inflammatory drugs, subacromial glucocorticosteroid injections,

and physiotherapy, and symptoms that had persisted for at least three months.

All patients had thus been treated with physiotherapy at their primary hospital before inclusion in the study. This included exercise programmes, massage, heat and transcutaneous nervous stimulation. The patients had used non-steroidal anti-inflammatory drugs (NSAIDs) for a mean of 37 days (SD 32) during the three months prior to referral. During this period 83 patients (59%) had been treated with subacromial cortisone injections, the mean number of injections being 1.6 (SD 1.5). Symptoms continued despite these forms of treatment. Some patients received more than one programme of treatment. No patient had been treated by a specialist before recruitment.

The mean duration of symptoms at presentation was 2.5 years (SD 3). Using a visual analogue scale (VAS) of 0 to 10, where zero was no pain and ten extreme, before randomisation the mean disability for the whole study group was 6.4 (SD 2.1), self-reported pain 6.5 (SD 1.9), pain at night 6.3 (SD 2.6) and their working ability was reported to be 5.8 (SD 2.6).

Patients aged 18 to 60 years were accepted if they indicated their willingness to comply with the randomised treatment protocol and follow-up visits, and gave full verbal and written consent. The exclusion criteria were glenohumeral or acromioclavicular osteoarthritis, signs of glenohumeral instability, previous surgery to the affected shoulder, a full thickness tear of the rotator cuff, cervical radicular syndrome, adhesive capsulitis, or neuropathy of the shoulder region. Demographic information was collected and the patients filled in a structured Shoulder Disability Questionnaire.[27,28]

Eligible patients were randomly assigned to the treatment groups using computer-generated numbers sealed in opaque envelopes prepared by an independent statistician not otherwise involved in the study. The random numbers were allocated using 14 as the block size. None of the eligible patients refused to participate. Two patients, one in each group, withdrew after randomisation, by not attending for any intervention or control visits.

Supervised exercise treatment. Information was first given by a trained physiotherapist. A home programme was individually planned for each patient according to the same principles. The aim was to restore painless and normal mobility of the shoulder complex and to increase the dynamic stability of the glenohumeral joint (supra- and infraspinatus, teres minor, and subscapular muscles) and the scapula (trapezoid, rhomboid, serratus anterior, and pectoralis minor muscles).[29] Elasticated stretch bands and light weights were used in training, which was based on long painless series and repetitions aiming at tendon strengthening. The sessions were performed at least four times a week using nine different exercises with 30 to 40 repetitions three times. As the self-assessed ability and strength improved, resistance was increased and repetitions diminished. The progress was evaluated during control visits, of which seven were generally required, and continued until the patient and the therapist considered that the patient was able to maintain the established level independently.

Combined treatment

Operative procedure. One experienced orthopaedic surgeon (HW) performed all arthroscopic decompressions. An interscalenic or supraclavicular brachial plexus block was applied for regional anaesthesia. Bony landmarks were palpated and marked. Glenohumeral stability and passive range of movement were tested. The arthroscope was introduced through a standard posterior portal and a systematic recording of the articular cartilage, labrum and ligaments, biceps tendon, and the intra-articular rotator cuff was performed. The same standard portal was used to reach the subacromial space. Debridement and decompression were done through an anterolateral portal by shaver and/or vaporiser. If the coracoacromial ligament felt tight or thick, it was released. Acromioplasty was then performed, starting anteriorly and progressing posterolaterally with a burr drill. The range of movement was tested under arthroscopic visualisation to check for any local impingement.

Post-operative phase. The patients stayed in hospital overnight. Post-operatively patient-controlled intravenous oxycodon analgesia or a pain catheter to administer local ropivacaine 2 mg/l or bupivacaine 2.5 mg/ml at 3 ml/h to 5 ml/h to the operation site was used until the first post-operative morning, accompanied and/or followed by oxycodone either intramuscularly or orally. All patients received anti-inflammatory analgesics, usually ibuprofen. A collar and cuff sling was used for a week and mobilisation permitted with free active movements, starting with gravity-assisted rotating movements. Sutures and dressings were removed after seven to ten days. Following this, patients received similar individually planned and progressive training programmes to the exercise group. As in the other group, progress was evaluated during physiotherapy control visits, which generally numbered six.

Adjunct treatment. In both groups the use of NSAIDs was allowed as needed. Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training programme.

Follow-up. The main follow-up point was 24 months after randomisation. Examinations were also performed at three, six and 12 months from commencement. One trained physiotherapist (A-ML) from outside the surgical department and hence neutral to both the institution and patients, and who had no involvement with the patients prior to evaluations and was in addition blinded to the mode of treatment, performed all standardised assessments. Patients were instructed not to reveal the type of treatment (exercise or combined) they had received, and they wore a T-shirt to conceal any operation scars. Muscle strength and passive range of movement were assessed and recorded. Neer's impingement test was performed, but without any lidocaine injections. The patients filled in a structured questionnaire including the shoulder disability questionnaire at each

Table I. The resources used, their unit costs, amount of resource use and associated mean (SD) costs in euros at 2004 prices

		Total use, based on complete data of patients attending all follow-up visits		Mean costs (SD), based on complete data of patients attending all follow-up visits	
Variable description	**Unit cost (euro)**	**Combined treatment group (n = 39)**	**Exercise group (n = 53)**	**Combined treatment group (n = 39)**	**Exercise group (n = 53)**
Operation					
Arthroscopy and acromioplasty	1675*	36	12	1546 (593)	379 (708)
Visits at physiotherapist	60.4†	466	744	723 (592)	847 (464)
Operation					
Arthroscopy and labral procedure	2811§	3	1	216 (759)	53 (386)
Visits at physician	82.5†	47	94	99 (126)	146 (245)
Travel costs to services	6†	616	1054	95 (71)	120 (77)
Hospitalisation	513†	7	10	92 (330)	97 (303)
Visits to masseur	36‡	94	166	85 (235)	113 (221)
Operation					
Arthroscopy and open acromioplasty	1916*	1	0	49 (307)	0 (0)
Travel costs to hospital	30.9†	47	26	37 (24)	15 (28)
Medication	¶	455¶	1366¶	12 (25)	26 (43)
Visits to nurse	24.5†	8	38	5 (15)	18 (43)
Visits at chiropractor	41‡	1	13	1 (7)	10 (40)
Manipulation under anaesthesia	707**	0	3	0 (0)	40 (165)
Mean health-care costs				2961	1864
Total health-care costs				154 474	98 773

* benchmarking data on file, National Research and Development Centre for Welfare and Health, Finland

† Healthcare unit costs in Finland in 2001, National Research and Development Centre for Welfare and Health, Finland, Aiheita 1/2003

§ Expert opinion (based on unpublished cost data from Helsinki University Hospital)

** estimated by study group

‡ Finnish Consumer Agency, http:www.kuluttajavirasto.fi

¶ total use in euros by group, 41 different drugs or other therapies, prices taken from Pharmaca Fennica; a pharmaceutical manual used in Finland

visit.[30] In addition to their state of health, the questions also investigated whether the patients had any further treatment to their shoulder since the previous review.

Outcome measures and resource use. Self-reported pain on a VAS of 0 to 10 at 24 months after randomisation was used as the primary outcome measure. The minimal clinically important difference was defined as two points on VAS equalling one unit.[31] Additional outcome measures were disability, pain at night and working ability (VAS), shoulder questionnaire score, the number of painful days during the previous three months, and the proportion of pain-free patients, defined as pain on VAS ≤ 3, at 24 months from randomisation. The same variables were used at three, six and 12 months. Table I gives an overview of the resource use, unit costs and mean costs by resource items. The costs cover the direct health-care and non-health care costs (travel, massage, manipulation) at 2004 prices.

Statistical analyses. Analyses were performed based on the intention-to-treat principle. Power calculations were performed using self-reported pain (VAS) at 24 months as the outcome measure. Using 1.5 (SD 2.5) as a clinically important change, the sample size was estimated to be 45 patients per group, if 5% type I (α) and 20% type II (β) errors were allowed. As the SD of the outcome measure was only a rough estimate, 70 patients were included in both groups.

Statistical analyses were performed using SPSS 14.0 software (SPSS Inc., Chicago, Illinois). An independent samples *t*-test was used for group comparisons (with Levene's test to check whether the *t*-test for equal or unequal variances was applicable), paired samples *t*-test for comparisons within groups over time and the chi-squared test for equal proportions of pain-free patients between groups. In order to adjust for spuriously significant results that might arise from multiple testing, the significance level was set at p = 0.01 and 99% confidence intervals (CI) were reported. For bootstrapping and imputation R 2.4.1 software (Bell Laboratories, http://www.r-project.org) was used.[32]

Complete data were available from 92 patients, who attended all follow-up visits and filled in all questionnaires. Because endpoint outcome data were available from 134 patients, we decided to use imputation for 28 patients with only one missing follow-up either at three, six or 12 months. Only the cost of the missing follow-up was imputed. Cost data were imputed using a two-stage iterative regression approach.[33] With imputation the sample size was increased from 92 with complete information to

Table II. The treatment groups compared at enrolment

	Exercise group (n = 70)	Combined treatment group (n = 70)
Number of women (%)	47 (*67*)	41 (*59*)
Mean age in yrs (range)		
Mean	47.8 (26.8 to 59.2)	46.4 (23.3 to 60.0)
Mean body mass index in kg/cm^2 (range)		
Mean	27.4 (19.5 to 46.3)	27.0 (15.2 to 41.2)
Dominant hand affected (%)	*45 (64)*	*46 (66)*
Marital status (%)		
Single	5 (*8*)	*5 (7*)
Married	*48 (72)*	*43 (62*)
Cohabiting	*7 (10)*	*8 (12)*
Widowed	*1 (1*)	*2 (3*)
Divorced	*6 (9*)	*11 (16)*
Working status (%)		
Currently working	*56 (84)*	*52 (76)*
Entrepreneur	*5 (7)*	*6 (9*)
Student	*0 (0)*	*1 (1)*
Unemployed	*6* (*9*)	*8 (12)*
At home	*0 (0)*	*1 (1)*
Retired	*0 (0)*	*1 (1)*
Mean duration of symptoms in yrs (range)		
Mean	2.6 (0.25 to 20)	2.5 (0.25 to 17)
Mean self-reported pain (range): VAS* 0 to 10		
Mean	6.5 (1.0 to 10)	6.4 (2.0 to 10)
Mean pain at night (range): VAS 0 to 10		
Mean	6.4 (0 to 10)	6.2 (0 to 10)
Mean disability (range): VAS - 0 to 10		
Mean	6.5 (0 to 10)	6.3 (1.0 to 10)
Mean working ability (range): VAS 0 to 10		
Mean	5.9 (0 to 9.0)	5.7 (0 to 9.0)
Mean SDQ† score (range)		
Mean	82.5 (0 to 100)	78.0 (0 to 100)

* VAS, visual analogue scale

† SDQ, Shoulder Disability Questionnaire

120 patients (55 patients in combined treatment and 65 in the exercise group).

In order to assess uncertainty, one-way (cost variables changed ± 50%) and probabilistic sensitivity analyses with 10 000 bootstrapped re-samples were carried out. The latter were performed for both observed and imputed total cost data. Results are given as mean incremental costs and effects with their 99% CI, incremental cost-effectiveness ratios, cost-effectiveness plane and cost-effectiveness acceptability curve. Owing to the short time span of the study, no discounting was carried out.

Results

Patient and treatment process. The groups were similar at enrolment (Table II). During the follow-up 14 patients from the exercise group, one patient between three and six months, four after six to 12 months, and nine between 12 and 24 months underwent operation. A total of 12 patients, who were allocated to the combined treatment group, subsequently refused operation but attended the follow-up visits (Fig. 1). Following randomisation there was a mean delay of 1.2 months (0.2 to 4.6) to the commencement of treatment in the exercise group and

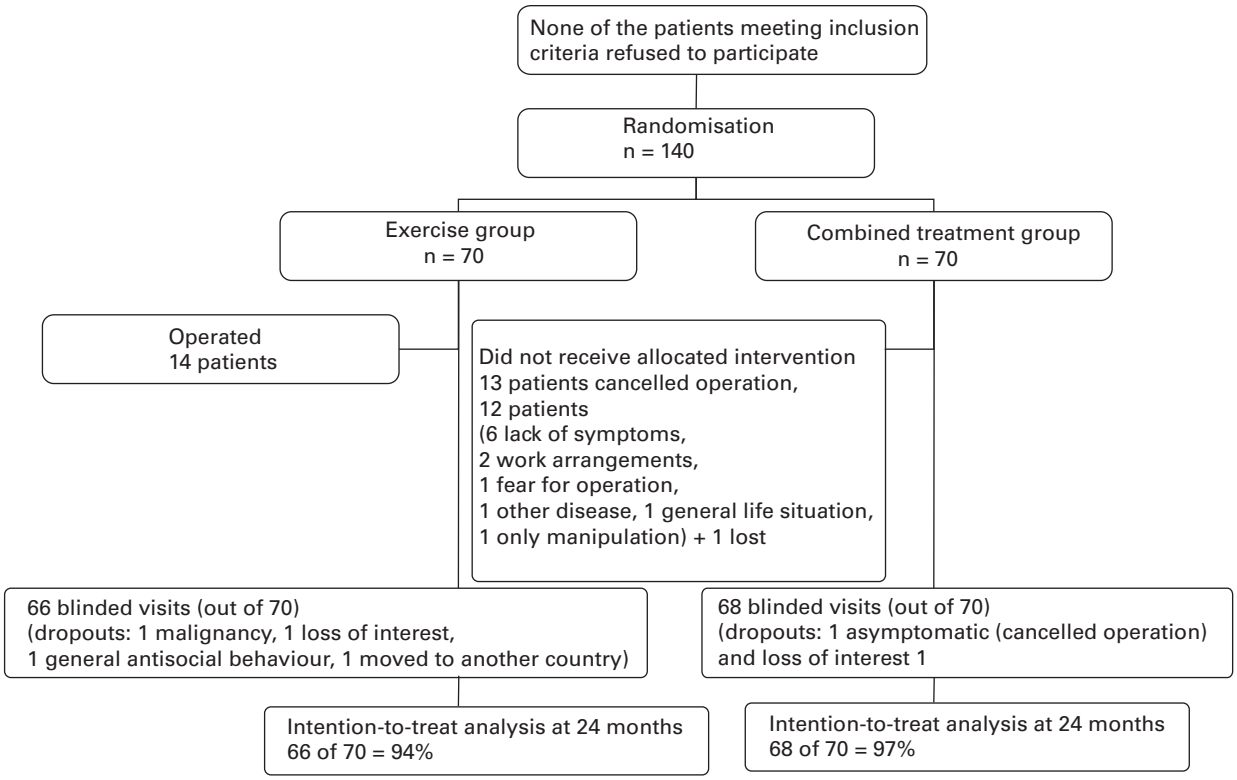

Fig. 1

Consort flowchart showing the details of our study.

8.3 months (1.4 to 11.8) for the patients who underwent arthroscopy.

There were no major surgical complications. Labral lesions which had not been diagnosed in 14 patients on the pre-operative MRI were found and repaired at arthroscopy. In five patients the labral lesion itself was considered the main cause of the symptoms. In nine patients this occurred together with impingement, and the labral repair was combined with acromioplasty. Over the two-year follow-up there were a mean of 1 (0 to 10) and 0.3 (0 to 3) recorded corticosteroid injections in the exercise and combined groups, respectively.

Effectiveness. The follow-up at 24 months was attended by 66 of 70 in the exercise group and 68 of 70 patients in the combined group. A decrease in self-reported VAS for pain exceeding the minimal clinically important difference took place from enrolment to 24 months in both groups: from a mean of 6.5 (0 to 9) to 2.9 (1 to 10) in the exercise group and 6.4 (2 to 10) to 2.5 (0 to 10) in the combined treatment group. The changes were statistically significant in both groups ($p < 0.001$). Differences between the mean changes in the groups over time were not statistically significant ($p = 0.65$). The number of pain-free patients at 24 months was 42 in the exercise group (64%) and 43 in the combined treatment group (65%); the difference was not statistically significant ($p = 0.90$) (Table III). Examination of the change in the primary outcome measure and some of the additional outcome measures at three, six and 12 months suggests that the recovery was faster in the combined treatment group, as the scores showed a greater improvement at the earlier stages (Table IV).

Cost-effectiveness. Table V shows the analysis for cost-effectiveness. The incremental cost-effectiveness ratios of combined treatment compared with exercise treatment is €5431 per incremental minimal clinically important difference unit for 92 patients with complete data, and €5734 for 120 patients with partially imputed cost data. Because there was no statistically significant difference between the cost-effectiveness results based on complete and imputed data, as shown by the mean incremental costs and effects from imputed data lying within the 99% CIs of the complete dataset only results based on the former are presented.

In one-way sensitivity analyses the incremental cost-effectiveness ratios varied from €2740 to €8965 per minimal clinically important difference unit. The extreme values were obtained when the unit cost of acromioplasty was varied ± 50%; the incremental cost-effectiveness ratios was not sensitive to variation in other cost variables. The probabilistic sensitivity analysis showed that the incremental cost was positive in all bootstrapped cases, whereas the incremental effectiveness varied from negative to positive values, i.e., from less to more effective. The bootstrapped mean incremental cost was €1092 (99% CI 590 to 1590) and the

Table III. Results in the intention-to-treat analysis (134 patients at enrolment and 24 months after randomisation)

Variables*	Exercise group (n = 66 at 24 months)	Combined treatment group (n = 68 at 24 months)	99% confidence interval of the difference in means†
Self reported pain: VAS 0 to 10			
at enrolment (mean)	6.5	6.4	-1.01 to 0.77
at 24 months (mean)	2.9	2.5	-1.60 to 0.78
Change from baseline (mean)	-3.7	-3.9	-1.61 to 1.14
Disability: VAS 0 to 10			
at enrolment (mean)	6.4	6.2	-1.13 to 0.75
at 24 months (mean)	2.6	2.0	-1.81 to 0.62
Change from baseline (mean)	-3.8	-4.2	-1.76 to 1.00
Working ability: VAS 0 to 10			
at enrolment (mean)	6.0	5.7	-1.42 to 0.85
at 24 months (mean)	8.0	8.0	-0.82 to 0.85
Change from baseline (mean)	+2.0	+2.3	-0.93 to 1.52
Pain at night: VAS 0 to 10			
at enrolment (mean)	6.5	6.2	-1.46 to 0.93
at 24 months (mean)	2.6	2.0	-1.95 to 0.65
Change from baseline (mean)	-3.8	-4.2	-2.00 to 1.17
SDQ score (0 to 100)			
at enrolment (mean)	82.6	77.7	-14.4 to 4.47
at 24 months (mean)	32.9	24.2	-23.34 to 6.10
Change from baseline (mean)	-50.0	-53.1	-19.11 to 12.75
Reported painful days			
at enrolment (mean)	73.0	69.8	-16.14 to 9.64
at 24 months (mean)	19.7	13.9	-18.16 to 6.52
Change from baseline (mean)	-53.3	-55.0	16.22
Proportion of pain-free patients			
at enrolment (mean)	0.05	0.12	-0.197 to 0.055
at 24 months (mean)	0.64	0.65	-0.224 to 0.203

* VAS, visual analogue scale; SDQ, shoulder disability questionnaire

† Levene's test was used to check whether the *t*-test for equal or unequal variances is applicable

bootstrapped mean incremental effect 0.20 minimal clinically important differences units (99% CI -0.35 to 0.73). The cost-effectiveness plane shows that in most cases (approximately 75%) the combined treatment was more effective but also more costly (quadrant II in Fig. 2a). With the willingness to pay of €8000 for an additional minimal clinically important difference unit, the probability that combined treatment would be acceptable was 56% (Fig. 2b).

Discussion

Our study indicated that at 24 months arthroscopic decompression with acromioplasty followed by a structured exercise treatment (combined treatment) did not differ significantly from a supervised exercise programme (exercise group) in mean self-reported pain on VAS, or in secondary outcome measures of disability, pain at night, shoulder disability questionnaire score, number of painful days, and proportion of pain-free patients. The mean total cost based complete data was €2961 in the combined treatment group, €1864 in the exercise group, i.e., combined treatment was considerably more costly on average. The incremental cost-effectiveness ratio was €5431 per minimal clinically important difference unit. At any level of willingness to pay the probability of combined treatment being cost-effective was 75%. The results from three-, six- and 12-month visits from the start of treatment reflect the recovery of individual patients, counted from their interventions. This differs from the results obtained at the 24-month visit as the natural history of the disease cannot be predicted. However, it seems that the operative group initially recovers faster in all parameters when assessed from the start of the treatment (Table IV).

The first trial comparing operative treatment with physiotherapy was published in 1993 and extended in 1999.[17,18] Another similar comparative study has examined outcome focusing on disability and working capacity.[19,22] Our study spanning June 2001 to October 2006, is the first to examine whether operative treatment provides any additional value over a structured and supervised exercise programme, without any surgical intervention. This not only compares

Table IV. Descriptive date from the three-, six- and 12-month control visits counted from intervention (intention to treat)

Variables*	Exercise group†	Combined treatment group‡	99% confidence interval of the difference in means§
Self reported pain: VAS 0 to 10			
at 3 months (mean)	4.4	3.2	-2.45 to -0.02
at 6 months (mean)	3.7	2.5	-2.40 to -0.01
at 12 months (mean)	3.7	2.3	-2.63 to -0.13
Disability: VAS 0 to 10			
at 3 months (mean)	4.2	3.1	-2.48 to 0.32
at 6 months (mean)	3.0	2.2	-2.10 to 0.59
at 12 months (mean)	3.2	1.8	-2.76 to -0.12
Working ability: VAS 0 to 10			
at 3 months (mean)	7.0	7.0	-1.21 to 1.12
at 6 months (mean)	7.6	7.8	-0.72 to 1.15
at 12 months (mean)	7.4	8.0	-0.41 to 1.46
Pain at night: VAS 0 to 10			
at 3 months (mean)	3.8	2.7	-2.53 to 0.44
at 6 months (mean)	3.2	2.2	-2.54 to 0.42
at 12 months (mean)	3.2	1.7	-2.83 to -0.07
SDQ score (0 to 100)			
at 3 months (mean)	55.6	37.4	-34.01 to -2.45
at 6 months (mean)	43.7	26.6	-32.53 to -1.67
at 12 months (mean)	41.7	24.8	-32.53 to -1.19
Reported painful days*			
at 3 months (mean)	49.1	33.0	-33.06 to 0.90
at 6 months (mean)	31.1	18.8	-28.28 to 3.73
at 12 months (mean)	25.4	13.5	-26.35 to 2.63
Proportion of pain-free patients			
at 3 months (mean)	0.35	0.65	-0.569 to -0.032
at 6 months (mean)	0.57	0.73	-0.399 to 0.087
at 12 months (mean)	0.55	0.71	-0.389 to 0.074

* VAS, visual analogue scale; SDQ, shoulder disability questionnaire

† number at follow-up, 3 mths, 57; 6 mths, 56; 12 mths, 62

‡ number at follow-up 3 mths, 43; 6 mths, 44; 12 mths, 51

§ Levene's test was used to check whether the *t*-test for equal or unequal variances is applicable

Table V. The base case cost-effectiveness results for those patients who completed every or omitted only one questionnaire

Treatment group	Mean cost (Euros) from Table I	Mean incremental cost (∆C)	Change in mean self-reported pain on visual analogue scale (in MCID*-unit)	Mean incremental effectiveness (-∆E)	Incremental cost-effectiveness ratios (∆C/-∆E)
Based on patients with complete data (n = 92)					
Exercise (n = 53)	1864		1.439		
Combined (n = 39)	2961	1097	1.238	0.201	5431
Based on partially imputed cost data (n = 120)					
Exercise (n = 65)	1838		1.431		
Combined (n = 55)	3111	1273	1.209	0.222	5734

* MCID, minimal clinically important difference

the two treatments but evaluates the contribution provided by surgery. In contrast to previous studies, failure of routine physiotherapy and other conservative treatments were criteria for inclusion. In our series 83 patients (59%) had been treated with subacromial steroid injections during the three months prior to entering the study, and the mean duration of their symptoms before enrolment was 2.5 years. According to current standards in clinical practice, this failed non-operative management would make these patients most likely candidates for surgical intervention.

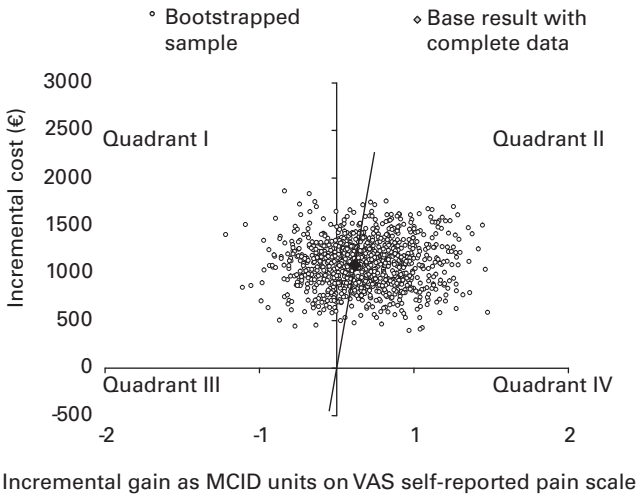

Fig. 2a

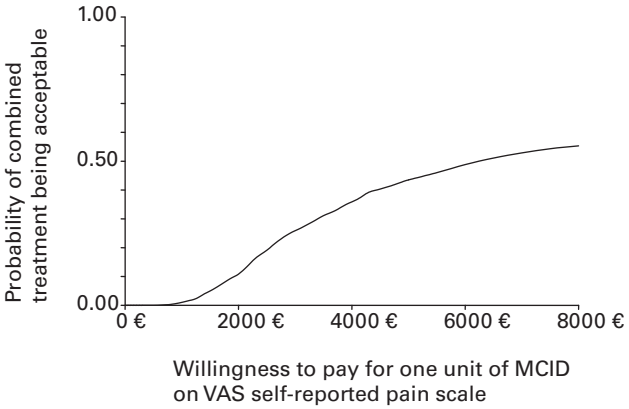

Fig. 2b

Graph showing a) cost-effectiveness plane. The diamond represents the base case result, where mean incremental cost (ΔC) is plotted on the *x* axis and mean incremental effectiveness (ΔE) is plotted on the *y* axis. The incremental cost-effectiveness ratio is the slope joining the origin and the diamond. Since each of the bootstrapped resamples was drawn from the original data with replacement, they have different incremental cost-effectiveness ratios at the cost-effectiveness plane. If a point falls at quadrant I, combined treatment is more costly and less effective than exercise; at quadrant II it is more costly and more effective; at quadrant III less costly and less effective; and at quadrant IV less costly and more effective. In 75% of simulated cases the incremental cost-effectiveness ratio falls at quadrant II, and in 25% of cases at quadrant I, minimal clinically important difference (MCID), visual analogue scale VAS). b) Cost-effectiveness acceptability curve. If the willingness to pay for an additional minimal clinically important difference (MCID) unit is the same as the base case result (incremental cost-effectiveness ratio = €5431), then approximately 50% of the bootstrapped resamples fall on the right side of the line (threshold line) at the plane. With different values of willingness to pay we can calculate the proportion of re-samples, which fall on the right side of the corresponding threshold line and thus are said to be cost-effective (acceptable). This proportion is then interpreted as a probability of combined treatment being acceptable.

As our patients were evaluated at follow-up by an independent blinded assessor, the risk of introducing bias by the tendency of the operated patients to please the surgeon should have been eliminated. The willingness to participate in the study may have been due to the thorough information provided at the basic health-care unit from which most of the patients were recruited. The selection bias was minor, as all patients fulfilling the inclusion criteria were willing to participate, although two lost interest immediately after the randomisation representing a dropout bias of only 4%. The randomisation process was successful in producing two similarly matched groups. Although a minority of patients from the exercise group wished to have surgical treatment and in the combined treatment group a few declined operation, this did not compromise the investigation and reflects the situation in clinical practice. All operations were performed by one experienced senior arthroscopist, which is a further strength of this study.

Accurate diagnosis of the impingement syndrome requires a thorough patient history and a careful clinical examination followed by special investigations to exclude other conditions. The use of MR imaging without contrast might explain failure to diagnose labral lesions in a few patients which were found at arthroscopy. These patients were included in the intention-to-treat analysis, as it is assumed that a similar proportion of lesions existed in the exercise treatment group.

The age limits for inclusion were set at 18 to 60 years, in conformity with previous studies, although it is acknowledged in younger age groups that glenohumeral instability is the most common cause of symptoms from the shoulder,[34] with the frequency of rotator cuff tears increasing with age.[35-37] In this study, only four patients were under 30 years old.

We acknowledge that following randomisation the exercise group commenced their treatment with a mean delay of 1.2 months, whereas the operative group waited a mean of 8.3 months before operation. This may have acted in favour of the exercise group. Nevertheless, the waiting time was still brief compared to the duration of the complaint before randomisation, which suggests this possibility is unlikely.

Cost-effectiveness analysis suggests that the combined treatment is not cost-effective compared to exercise treatment. As health-care funding is limited, the effectiveness of acromioplasty needs to be higher than that observed in this study. Further research is essential to identify the patients who will obtain the greatest benefit from operative treatment. The effect difference between the treatment arms was small at 24 months in all outcome measures, which inclines treatment towards cost-minimisation. Longer follow-up is needed to learn more of the natural course of impingement syndrome in addition to long-term effects of the treatments.

Acromioplasty seems not to be an effective additional treatment over supervised exercise for patients with shoulder impingement syndrome when evaluated at two years, and the costs are much higher than for exercise therapy alone. The interpretation of the long-term effects of any treatment is not straightforward, as the natural history of the condition is unknown. The decision whether to operate should be based on clear indications favouring operative treatment, which have not yet been established.

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