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ORIGINAL ARTICLE

Does acromioplasty result in favorable clinical and radiologic outcomes in the management of chronic subacromial pain syndrome? A double-blinded randomized clinical trial with 9 to 14 years' follow-up

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Background: The treatment effect of acromioplasty for chronic subacromial pain syndrome (SAPS) on long-term shoulder function and rotator cuff deterioration has still to be determined. This study aimed to determine the long-term clinical and radiologic treatment effect of arthroscopic acromioplasty in patients with chronic SAPS.

Methods: In this double-blind, randomized clinical trial, 56 patients with chronic SAPS (median age, 47 years; age range, 31-60 years) were randomly allocated to arthroscopic bursectomy alone or to bursectomy combined with acromioplasty and were followed up for a median of 12 years. The primary outcome was the Constant score. Secondary outcomes included the Simple Shoulder Test, visual analog scale (VAS) for pain, VAS for shoulder functionality, and rotator cuff integrity assessed with magnetic resonance imaging or ultrasound.

Results: A total of 43 patients (77%) were examined at a median of 12 years' follow-up. Intention-to-treat analysis at 12 years' follow-up did not show a significant additional treatment effect of acromioplasty on bursectomy alone in improvement in Constant score (5 points; 95% confidence interval, –5.1 to 15.6), Simple Shoulder Test score, VAS score for pain, or VAS score for shoulder function. The prevalence of rotator cuff tears was not significantly different between the bursectomy group (17%) and acromioplasty group (10%).

Conclusions: There were no relevant additional effects of arthroscopic acromioplasty on bursectomy alone with respect to clinical outcomes and rotator cuff integrity at 12 years' follow-up. These findings bring

The medical ethical research committee Zuidwest Holland (protocol No. 14-059) approved all stages of this study.

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the effectiveness of acromioplasty into question and may support the idea of a more conservative approach in the initial treatment of SAPS.
Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Rotator cuff; shoulder; shoulder impingement syndrome; arthroscopy; bursitis; pain; surgery

Shoulder complaints have a prevalence of up to 48 per 1000 person-years, and each year up to 20% of the adult population has pain in the shoulder.[12,35] Furthermore, shoulder complaints account for a huge part of health care costs and are a common reason for sick leave from work.[37,43] The majority of these complaints are primarily attributed to extrinsic compression of the acromion with impingement of the rotator cuff (RC) tendons.[31,40] As a result of the ongoing debate over the extrinsic compression theory, the "impingement" entity has recently evolved to a more generic term, "subacromial pain" syndrome (SAPS).[9,10,36,40,42]

Acromioplasty has been the standard treatment for patients having subacromial pain, with over 20,000 procedures per year in New York State, as well as in the United Kingdom.[22,44] Acromioplasty is considered a successful surgical option in SAPS to reduce mechanical impingement and optimize shoulder function.[22,31] Various authors have claimed that acromioplasty may prevent the RC from developing a full-thickness tear.[1,11,32] Existing randomized controlled clinical trials (RCTs) examining the effect of acromioplasty in SAPS have been pragmatic in nature and focused on the difference between surgery and conservative strategies (eg, supervised exercise therapy).[4,5,13,14,24,25] Thus these study designs have not accounted for the potential impact of bursectomy and placebo effects, resulting in an overestimation of the effect that is attributable to acromioplasty.[2,17,18,21,31,33] One prior RCT has taken those effects into account by randomly allocating SAPS patients to bursectomy alone or to bursectomy combined with acromioplasty. No beneficial effects of acromioplasty were shown 2.5 years after surgery.[15] However, the concept of extrinsic compression leading to RC deterioration implies that clinical shoulder symptoms would increase after many years. Consequently, the value of acromioplasty in the treatment of chronic SAPS and prevention of developing RC tears, while broadly applied, has still to be determined.

The aim of this study was to evaluate the long-term clinical effect of arthroscopic acromioplasty with respect to pain, function, and RC integrity in patients with chronic SAPS. For this purpose, we randomly assigned patients with chronic SAPS either to bursectomy alone or to bursectomy in combination with acromioplasty. Because acromioplasty is expected to reduce extrinsic compression with a consequent effect on shoulder-related complaints, we hypothesized that acromioplasty would improve long-term shoulder function, reduce pain, and prevent the development of RC tears in patients with chronic SAPS.

Materials and methods

Study design and eligibility criteria

The research group recruited patients from a previously described prospective, parallel-group, superiority, double-blinded RCT for long-term evaluation.[15] Patients were invited for follow-up between February 2015 and April 2016 at the orthopedic department of a secondary referral center (Haaglanden Medical Center, The Hague, the Netherlands).

At the start of the trial, eligible patients obtained the diagnosis of SAPS by a shoulder orthopedic surgeon (E.R.A.v.A.) after assessment of medical history, physical examination, radiographs (anteroposterior view with humerus in external and internal rotation and trans-scapular view), and direct magnetic resonance arthrography (MRA) of the shoulder. Mandatory clinical signs for inclusion were as follows: pain located in the deltoid region for at least 3 months; inability to lie down on the affected shoulder; pain during abduction, backward flexion, or internal rotation; positive Neer or Hawkins impingement test; and positive lidocaine impingement test. In addition, conservative treatment for at least 6 weeks (ie, subacromial infiltration, nonsteroidal anti-inflammatory drugs, and supervised exercises) had to be unsuccessful. The exclusion criteria were calcifying tendinitis, biceps tendinitis, partial- or full-thickness RC tear, labral tear, signs of glenohumeral instability, passive restriction of glenohumeral motion, osteoarthritis of the acromioclavicular or glenohumeral joint, rheumatic diseases, cervical radiculopathy, history of shoulder trauma, synovitis, and prior surgery on the affected shoulder.

The study protocol was registered at the Dutch Trial Register (www.trialregister.nl, identifier NTR4723). Each participant gave written informed consent.

Randomization and blinding

An independent data manager randomly assigned all eligible patients, just prior to surgery, either to bursectomy alone or to bursectomy plus acromioplasty. Randomization was performed with 1:1 allocation using a computer-generated random list. Trial participants were blinded for treatment allocation. A blinded independent physician (H.-E.H. or A.K.) clinically assessed each patient. A dedicated musculoskeletal radiologist (W.G.W.), who was uninformed about treatment allocation, performed all radiologic evaluations.

Intervention

Included subjects underwent surgery under general anesthesia in the lateral decubitus position by an experienced arthroscopic shoulder surgeon (E.R.A.v.A.).[15] Three standard arthroscopic shoulder portals