CHAPTER 3

Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial.

Treatment of degenerative rotator cuff tears.

Okke Lambers Heerspink
Jos van Raay
Rinco Koorevaar
Pepijn van Eerden
Robin Westerbeek
Esther van ‘t Rier
Inge van den Akker-Scheek
Ron Diercks

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ABSTRACT

Background: Good clinical results have been reported for both surgical and conservative treatment of rotator cuff tears. Primary aim of this randomized controlled trial was to compare functional and radiological improvement following surgical and conservative treatment of degenerative rotator cuff tears.

Methods: We conducted a randomized controlled trial that included 56 patients with a degenerative full-thickness rotator cuff tear between January 2009 and December 2012; 31 patients were treated conservatively, in 25 patients rotator cuff repair was performed. Outcome measures – Constant-Murley Score, VAS pain and VAS disability – were taken preoperatively and after 6 weeks and 3, 6 and 12 months. MRI was performed preoperatively and at 12 months postoperatively.

Results: 12 months postoperatively the mean CMS in the surgery group was 81.9 (SD 15.6) versus 73.7 (SD 18.4) in the conservative group (p=0.08). VAS pain (p=0.04) and VAS disability (p=0.02) were significantly lower in the surgery group at 12 months follow-up. In a subgroup analysis significantly better postoperative scores on CMS were observed in surgically treated patients without a retear compared to conservatively treated patients [88.5 (6.2) vs. 73.7 (18.4)].

Conclusion: In our population of patients with degenerative rotator cuff tears who were randomly treated by surgery or conservative protocol we did not observe differences in functional outcome as measured with CMS one year after treatment. However, significant differences in pain and disabilities were observed in favor of surgical treatment. Best outcomes in function and pain were seen in patients with an intact rotator cuff postoperatively.
INTRODUCTION

Rotator cuff tears are a common cause of shoulder complaints. Every year 250,000 rotator cuff repairs are performed in the United States, yet controversy remains about optimal treatment of these tears. Surgical repair as well as conservative treatment is described. Acceptable results are reported for both treatment modalities.

Those who favor surgical repair worry that tear progression over time will lead to increased disability with conservative treatment of full-thickness tears. The rotator cuff has limited capabilities for healing without repair, yet conservative treatment often yields acceptable outcome. Additionally, after surgical repair retear of the rotator cuff is described in 0-94.4% of cases. Moreover, it is stated that despite surgery the healing capacity of tendons is affected by degeneration. Several case series describe results of both treatments. Mean improvement in Constant-Murley score (CMS) for physiotherapeutic treatment of full-thickness rotator cuff tears ranges from 13.2 to 30.0. Improvement in CMS following surgical therapy ranges from 24.0 to 43.1. These overlapping results point to comparable outcomes following both treatment modalities. Scientific evidence is limited, as only two randomized controlled trials are comparing the two modalities and they present conflicting results. In a study of Kukkonen no difference between the treatments was found, and in a study of Moosmayer surgical repair was favourable.

We undertook a randomized controlled trial to compare outcomes in patients who underwent surgical repair or conservative treatment for degenerative rotator cuff tears. We hypothesized that surgical repair and conservative treatment of degenerative rotator cuff tears provide comparable outcomes. Our primary aim was to compare functional outcome following surgical and conservative treatment. Secondly, MRI assessed cuff integrity one year postoperatively. Intact repairs were compared to patients with a retear and conservatively treated patients.
MATERIALS AND METHODS

This randomized controlled trial was conducted at one university hospital and two regional hospitals. Institutional Review Board approval was obtained for this randomized controlled trial (registration number M08.062126). The trial is registered in the Netherlands Trial Registry (NTR TC 2343).

PATIENT SELECTION

Patients with degenerative, non-traumatic full-thickness rotator cuff tears were included in this study from January 2009 until December 2012. Exclusion criteria were traumatic onset of complaints, previous surgical treatment of the shoulder, frozen shoulder, radiological and symptomatic osteoarthritis of the glenohumeral or acromioclavicular joint, arthritis/rheumatoid arthritis, diabetes mellitus, cognitive disorders, neurological disease affecting function of the upper extremity and language barriers impairing participation. After written informed consent all patients were randomized into a surgical and a conservative group. Randomization was done using opaque sealed envelopes. The randomization was performed by hand, using 100 prefilled envelopes (50 for each treatment arm). As described in the Discussion section of our paper, the inclusion of patients for this trial was difficult. We eventually had to terminate the inclusion preliminary, resulting in an unequal number of participants in the conservative and surgical group. Because we were dealing with a surgical vs. conservative therapy set-up, patients and outcome assessors could not be blinded for type of treatment. For this study 92 patients suspected of a degenerative rotator cuff rupture were screened with MRI. The trial included 56 patients, 25 of which were treated surgically and 31 conservatively. At one-year follow-up, one patient in the surgical group wasn’t able to perform a MRI due to claustrophobia. Six patients in the conservatively treated group were lost to follow-up, one was deceased at final follow-up, and two patients had moved; three discontinued the intervention. One patient in the surgical group was lost to follow-up 3 months postoperatively. A patient flow diagram is included as Figure 1.
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FIGURE 1: Flow diagram.
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INTERVENTIONS

SURGERY GROUP (N=25)
Surgical procedures were performed by two qualified and experienced surgeons (JvR, CTK). Surgery was scheduled within 6 weeks of inclusion and was done under general anaesthesia, supplemented with an interscalenus brachial plexus block. The operation was performed in beach-chair position using an anterolateral mini-open approach. The coracoacromial ligament was detached from its insertion and the subacromial bursa was excised. The anteroinferior part of the acromion was removed. The footprint of the rotator cuff on the greater tuberosity was debrided and a bleeding bony bed was created. Side-to-side repair and repair augmented with bone anchors were performed depending on the shape of the rupture. A side-to-side repair was performed in six patients. In 14 patients the repair was augmented using bone anchors. In two patients the tear could not be repaired, in two patients no rotator cuff rupture was found despite MRI-supported diagnosis. These four patients were excluded for primary per-protocol analysis, but included in the intention-to-treat analysis. The deltoid muscle was reattached to the acromion by transosseal refixation.

Following surgery, the patient received a sling for six weeks. Patients were referred for physical therapy and treatment was commenced according to a standardized protocol. In the first 6 weeks only passive movements were allowed. Passive GH movement was performed to prevent loss of mobility. The mobility of elbow and wrist was passively maintained. Circumduction exercises were allowed. After 6 weeks active guided treatment was started and was expanded to active treatment. Strength development was started three months postoperatively.

CONSERVATIVE GROUP (N=31)
Conservative treatment consisted of subacromial steroid infiltration, physiotherapy and analgesic medication. Following inclusion patients were given a subacromial infiltration. The subacromial space was injected by a posterior approach. When the first infiltration gave no pain relief, a second infiltration was performed under radiological or ultrasound guidance. The number of subacromial infiltrations was limited to a maximum of three. Further conservative treatment options consisted of analgesic medication with non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol and/ or tramadol. Patients were referred to a physiotherapist. The Department of Physical Therapy of Martini Hospital, Groningen,
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In addition to explaining the cause of the symptoms and the rehabilitation protocol, the physiotherapist advised about activities of daily living (ADL). Passive glenohumeral (GH) and scapulothoracic (ST) movements were performed; static and dynamic exercises were started. Aim of these exercises was to improve GH and ST musculature. Poor posture was corrected. In weeks 4 to 6 exercises were gradually increased and deltoid training was started. In weeks 6 to 12 rehabilitation was aimed at further optimization of mobility and strength regeneration of the remaining cuff and deltoid. Physical therapy was continued until patients reached an optimum range of motion and an improvement in strength was achieved. Three patients were dissatisfied with the result of conservative treatment and a decision was made to perform rotator cuff repair (discontinued intervention). In two of these patients data was available until 3 months post-treatment, in the other patient until 6 months post-treatment.

OUTCOME ASSESSMENT

Outcome was assessed in both study groups at randomization (T0), 6 weeks (T1), 3, 6 and 12 months (T2, T3, T4) following surgery for the surgical group and inclusion for the conservative group. After inclusion and at one year follow-up an MRI of the affected shoulder was taken. Functional outcome (primary outcome) was determined with the Constant-Murley score (CMS). The CMS combines a shoulder function test (65 points) with a subjective evaluation of shoulder complaints by the patient (35 points). Secondary outcome measures were:

1. Dutch Simple Shoulder Test (DSST). A questionnaire of 13 yes/no questions relating to the perception of symptoms of shoulder pain and function in the last 24 hours.
2. Visual Analogue Scale for pain and disability. Mean pain and disability during the last week was measured using a Visual Analogue Scale. Zero represents no pain and restriction, and 10 the most likely pain and disability.
3. Radiological outcome. Muscle degeneration was assessed on the MRI taken at inclusion. Location of the tear, size and retraction was determined. The MRIs were analyzed by three musculoskeletal radiologists (PE, RW), agreement was reached on a consensus basis. The Patte score, which assesses the degree of tendon retraction in the frontal plane on MRI, was used to describe the amount of retraction. Full-thickness tears with little tendon retraction were assessed as grade 1, tendon...
retraction to the level of the humeral head as grade 2, and tendon retraction to the level of the glenoid as grade 3. Retraction was also described in millimeters. Muscle atrophy was described using the Warner classification in the sagittal plane on MRI. This classification is based on the relation of the muscle to a straight line connecting either the coracoid to the scapular spine (assessing the supraspinatus) or the coracoid to the tip of the scapula (assessing the infraspinatus).

**STATISTICAL ANALYSIS**

Baseline and follow-up characteristics are presented as proportion, mean (± SD) or median (interquartile range) in case of a skewed distribution. Differences at baseline between the two treatment groups were tested using Mann-Whitney U-tests in case of continuous variables and Chi-square tests in case of categorical variables.

To study the effect of the two different treatments, all follow-up analyses were performed as ‘per protocol analyses’. Patients lost to follow-up (n=4) or with a discontinued intervention (n=3) were excluded, as were four patients whom rotator cuff repair could not be performed due to an intact rotator cuff or irreparable tear (see Figure 1). Using Mann-Whitney U-tests and chi-square tests, differences between treatment groups at follow-up (T4) were assessed. A line figure was created to display the course of the mean CMS from T0 to T4 in the surgery and conservative groups. In addition, differences in mean improvement on the CMS from T0 to T4 in patients treated surgically or conservatively were tested using a Mann-Whitney U-test.

Next, a subgroup analysis was performed among the group of patients who had surgery. This group was divided into patients with and without an intact cuff at follow-up. These two groups were compared to conservatively treated patients using Mann-Whitney U-tests and chi-square tests.

Lastly, patients lost to follow-up (n=4), discontinued interventions (n=3) and exclusions (n=4) were described in a subgroup analyses. An intention-to-treat analysis, in which the last observation of these patients was carried forward, was performed on the T4 CMS. All statistical analyses were performed using SPSS software v. 20.0 (SPSS, Chicago). Statistical significance was defined at the 5% (P-value ≤ .05) level.
RESULTS

BASELINE CHARACTERISTICS

Patient baseline characteristics are presented in Tables I and II. At baseline no significant differences between the two groups in functional or radiological characteristics were found at that point.

Table I: Functional Baseline Characteristics (SD).

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>Conservatively</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>25 (44.6)</td>
<td>31 (55.4)</td>
<td></td>
</tr>
<tr>
<td>Sex (% man)</td>
<td>60</td>
<td>64.5</td>
<td>0.73</td>
</tr>
<tr>
<td>Age</td>
<td>60.8 (7.2)</td>
<td>60.5 (7.0)</td>
<td>0.90</td>
</tr>
<tr>
<td>Side (% R)</td>
<td>48</td>
<td>64.5</td>
<td>0.21</td>
</tr>
<tr>
<td>Dominance (%R)</td>
<td>80.0</td>
<td>83.9</td>
<td>0.71</td>
</tr>
<tr>
<td>Complaints in months</td>
<td>12.5 (4.8; 25.6)</td>
<td>12.0 (7.8; 24)</td>
<td>0.76</td>
</tr>
<tr>
<td>CM score baseline</td>
<td>55.6 (18.4)</td>
<td>56.9 (15.0)</td>
<td>0.77</td>
</tr>
<tr>
<td>DSST baseline</td>
<td>5.5 (2.3)</td>
<td>6.1 (2.7)</td>
<td>0.37</td>
</tr>
<tr>
<td>VAS pain baseline</td>
<td>6.7 (1.7)</td>
<td>6.3 (1.3)</td>
<td>0.30</td>
</tr>
<tr>
<td>VAS disability baseline</td>
<td>6.2 (1.7)</td>
<td>5.8 (2.1)</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Table II: Radiological baseline characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>Conservative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supraspinatus</td>
<td>25</td>
<td>31</td>
</tr>
<tr>
<td>Additional infraspinatus tears</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Additional subscapularis tears</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
OUTCOME

Postoperative functional outcome measurements are presented in Table III for 20 surgically and 25 conservatively treated patients. Mean improvement in CMS one year following surgical treatment was 27.1 (SD 22.5), following conservative treatment 16.7 (SD 18.0) (p=0.09). A significant difference in mean improvement between surgically and conservatively treated patients was seen on DSST and the VAS pain.

Table III: Functional outcome at one-year follow-up (SD) in Constant Murley score (CMS), Dutch simple shoulder test (DSST), visual analogue scale (VAS) pain and disability.

<table>
<thead>
<tr>
<th></th>
<th>Surgery n=20</th>
<th>Conservative n=25</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant Murley (CMS)</td>
<td>81.9 (15.6)</td>
<td>73.7 (18.4)</td>
<td>0.08</td>
</tr>
<tr>
<td>Change in CMS</td>
<td>27.1 (22.5)</td>
<td>16.7 (18.0)</td>
<td>0.09</td>
</tr>
<tr>
<td>DSST</td>
<td>11.0 (2.8)</td>
<td>9.7 (3.6)</td>
<td>0.13</td>
</tr>
<tr>
<td>Change in DSST</td>
<td>5.9 (3.2)</td>
<td>3.8 (3.4)</td>
<td>0.03</td>
</tr>
<tr>
<td>VAS pain</td>
<td>2.2 (1.9)</td>
<td>3.2 (2.1)</td>
<td>0.04</td>
</tr>
<tr>
<td>Change in VAS pain</td>
<td>-4.7 (2.4)</td>
<td>-3.0 (2.4)</td>
<td>0.02</td>
</tr>
<tr>
<td>VAS disability</td>
<td>2.1 (1.7)</td>
<td>3.5 (2.3)</td>
<td>0.02</td>
</tr>
<tr>
<td>Change in VAS disability</td>
<td>-4.1 (2.5)</td>
<td>-2.4 (2.9)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

SUBGROUP ANALYSIS: POSTOPERATIVE RETEAR

Table IV presents the results of the one-year postoperative control MRI in patients with (n=14) and without (n=5) a postoperative retear compared to conservatively treated patients. One patient in the surgical group was excluded from this subgroup analysis; due to claustrophobia MRI one year after treatment was not possible. The retear rate was 73.7%. In the surgery group no significant preoperative differences in age, baseline CMS, retraction or atrophy between patients with or without a postoperative retear were seen (table IV). Mean postoperative scores on CMS, VAS pain and VAS disability were significantly better in the subgroup of patients with an intact rotator cuff at follow-up than in conservatively treated patients [88.5 (6.2) vs. 73.7 (18.4) on CMS and 1.4 (0.89) vs. 3.2 (2.1) on VAS pain respectively]. Figure 2 presents the course of mean CMS from inclusion to final follow-up in the three groups.
FIGURE 2: Outcome in time measured with mean Constant Murley score (CM score) of group of patients with intact repair, retears and conservatively treated.

**SUBGROUP ANALYSIS: LOST TO FOLLOW-UP AND EXCLUDED PATIENTS**

Patients lost to follow-up with a discontinued intervention or excluded patients were not part of the per-protocol analysis. To study the effect of these patients on the outcomes of our different study groups, an intention-to-treat analysis was performed in which the last observation of these patients was carried forward. Mean CMS at follow-up decreased in the conservative group by including the patients who were lost to follow-up, resulting in a significant difference between surgery and conservative treatment (mean CMS at one year 81.6 (14.9) vs. 71.5 (18.1), p=0.02).
**Table IV:** Subgroup analysis of patients with and without postoperative retear (SD). Constant Murley score (CMS), dutch simple shoulder test (DSST), visual analogue scale (VAS).

<table>
<thead>
<tr>
<th></th>
<th>Postoperatively intact cuff</th>
<th>Postoperative retear</th>
<th>Conservative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functional and radiological baseline characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>5</td>
<td>14</td>
<td>25</td>
</tr>
<tr>
<td>Age</td>
<td>62.2 (3.9)</td>
<td>60.4 (8.0)</td>
<td>60.8 (7.1)</td>
</tr>
<tr>
<td>Baseline CM score</td>
<td>64.5 (18.6)</td>
<td>52.1 (18.8)</td>
<td>57.6 (14.8)</td>
</tr>
<tr>
<td>Warner 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>80%</td>
<td>61.5%</td>
<td>37.0</td>
</tr>
<tr>
<td>3</td>
<td>20%</td>
<td>15.4%</td>
<td>18.5</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>15.4%</td>
<td>18.5</td>
</tr>
<tr>
<td>Retraction (mm)</td>
<td>18.4 (8.6)</td>
<td>22.5 (9.7)</td>
<td>25.1 (14.3)</td>
</tr>
<tr>
<td>Patte 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>80%</td>
<td>33.3%</td>
<td>26.6</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>53.3%</td>
<td>46.7</td>
</tr>
<tr>
<td>3</td>
<td>20%</td>
<td>13.3%</td>
<td>26.7</td>
</tr>
<tr>
<td><strong>Functional outcome at one-year follow-up</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMS</td>
<td>88.5 (6.2)</td>
<td>73.2 (20.4)</td>
<td>75.6 (16.2)*</td>
</tr>
<tr>
<td>VAS pain</td>
<td>1.4 (0.89)</td>
<td>3.0 (2.4)</td>
<td>3.0 (1.9)*</td>
</tr>
<tr>
<td>VAS disability</td>
<td>1.6 (0.89)</td>
<td>3.0 (2.6)</td>
<td>3.3 (2.0)*</td>
</tr>
<tr>
<td>DSST</td>
<td>12.8 (0.44)</td>
<td>9.2 (4.0)*</td>
<td>10.1 (3.1)*</td>
</tr>
</tbody>
</table>

*P* = <0.05
DISCUSSION

This randomized controlled trial was designed to compare outcome following surgical or conservative treatment of degenerative rotator cuff tears. One year after start of treatment no significant difference was found in CMS, our primary outcome, between surgically and conservatively treated patients. VAS pain and VAS disability at final follow up were significantly better in the surgically treated than the conservatively treated patients, albeit differences were small. In 73% of surgically treated patients a retear of the rotator cuff was diagnosed on MRI. The best functional outcome and lowest pain scores were found in patients with an intact rotator cuff repair at final follow-up.

In our study no significant difference was found in CMS between surgical and conservatively treated patients. In the intention-to-treat analysis we found a significant difference between the two groups (10.1 points). Relevancy can be questioned as below 10.4 points the CMS does not reach a minimal clinically important level. Despite the conflicting results of two previously conducted RCTs, our results can be considered comparable to those RCTs. Kukkonen et al. concluded that surgical treatment yields no significantly better CMS than conservative treatment. Moosmayer et al. also conducted a randomized controlled trial comparing operative and conservative treatment of degenerative and traumatic rotator cuff tears. In their study a higher percentage of patients were documented with a successful cuff repair, which might explain why they initially report significantly better outcomes for surgical treatment than for conservative treatment in their study. However, the difference in CMS between their two groups at 5 year follow up was small (5 points) which is below clinically important level.

In our study, best postoperative scores on function, pain and disability were observed in patients with an intact rotator cuff at final follow-up. This is supported by previous research. It should be noticed that 73% of cuff repairs failed. In six patients a side-to-side rotator cuff repair was performed and it was successful in only one patient. This could be explained by Gerber’s study, showing that tendon-to-bone healing in rotator cuff repair has a higher chance of success than tendon-to-tendon healing.

At baseline no significant differences were found between patients with a retear or intact rotator cuff in terms of age, baseline CMS, retraction or atrophy perhaps helping to predict
successful outcome. So far there exists mainly moderate quality studies describing prognostic factors for rotator cuff repair. Patient numbers in the present study were too small to perform a multivariate analysis to identify prognostic factors for surgical or conservative treatment.

In the group of patients treated conservatively one patient developed a frozen shoulder nine months after conservative treatment. The low CMS score one year after the start of the intervention had a pronounced influence on the group results, especially because of the small number of patients included. Despite randomization, the number of patients with a larger cuff tear was higher in the group of conservatively treated patients. Selection bias might have occurred which might have affected the results of the conservative group negatively.

**STRENGTHS AND LIMITATIONS**

So far two randomized controlled trials comparing surgical and conservative treatment for rotator cuff tears were available. These trials compare treatment of small to medium sized supraspinatus tears. In our randomized controlled trial we included larger tear sizes and patients with multiple tendon involvement. We therefore think this series represent a less selected group of patients with a degenerative rotator cuff tear. We took MRIs of all patients before treatment and at one year follow-up, and a clear difference in end result was shown between intact repairs and retears in follow up.

The results of this study do need to be viewed in light of certain limitations. Most importantly, our sample size was small with 56 patients. Inclusion of patients in this trial was difficult, as most patients had already received conservative treatment or were specifically referred for surgical treatment. These patients were not motivated for conservative treatment and refused to participate in a randomized controlled trial. Although inclusion was terminated preliminary, no significant differences in baseline clinical and radiological characteristics between the two groups are observed as shown in Table I and II of our paper. As we found no significant difference in outcome between surgical and conservative treatment in the primary outcome measurement (CMS) and our sample size is small, a beta-error could have occurred. Still, outcome of this study is comparable to other randomized controlled trials comparing rotator cuff repair with conservative treatment in patients with a degenerative rotator cuff tear.
At the moment of inclusion of patients, experience of the surgeons with arthroscopic rotator cuff repair was small. To avoid that included patients were treated in the learning curve of this procedure, choice was made to perform single row mini open cuff repair. No differences regarding healing rates between open and arthroscopic surgery is described. A disadvantage of open rotator cuff repair can be that additional concomitant pathology, for example long head biceps tendon pathology, is not treated.

**CONCLUSION**

In our population of patients with degenerative rotator cuff tears who were randomly treated by surgery or conservative protocol we did not observe difference in functional outcome one year after treatment. Small significant differences in pain and disabilities were observed in favor of surgical treatment though. Best outcomes in function and pain were seen in surgically treated patients with an intact rotator cuff postoperatively. Additional research is needed to establish whether successful surgery can be predicted in patients with a degenerative rotator cuff tear; this could eventually lead to a recommendation for conservative or surgical treatment for individual patients.
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