Two different training programmes for patients with COPD: A randomised study with 1-year follow-up

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Summary

Purpose: To compare the effects on exercise capacity and health related quality of life (HRQoL) of two exercise programmes; one programme including endurance training and one including only resistance training and callisthenics. A second purpose was to find out whether the severity of chronic obstructive pulmonary disease (COPD) affected the training response and whether the interventions had a long-term effect.

Methods: Sixty-three patients were stratified according to severity of COPD and randomised to two training groups. Group A had a mixed programme including endurance training. Group B had resistance training and callisthenics. All trained twice weekly for 8 weeks. A symptom-limited ergometer test, 12-min walking test, dynamic spirometry, blood gas analysis at rest and HRQoL were measured before and after the training period. Follow-up tests were conducted at 6 and 12 months after training.

Results: Forty-two patients fulfilled the trial. In group A (n = 20) peak exercise capacity increased by 7 W (P < 0.001) and 12-min walking distance (12MWD) by 50 m (P < 0.01), whereas group B (n = 22) did not change in any of these variables. HRQoL did not change significantly in either group. Training response was similar in patients with moderate and severe disease. One year post-training 12MWD had returned to pre-training level in group A, and below pre-training level in group B (P < 0.05).

Conclusions: Exercise capacity in patients with severe and moderate COPD improved by intensive endurance training, two sessions a week for 8 weeks. The
Introduction

Pulmonary rehabilitation is now a generally accepted approach for patients with moderate to severe chronic obstructive pulmonary disease (COPD). Exercise training is an important part of the rehabilitation programme but it is still unclear how the training should be performed in terms of the mode of training, intensity, frequency and duration. The American College of Sports Medicine (ACSM) recommends that a programme for healthy, elderly people should include endurance training, strength training and flexibility training. For patients with COPD endurance training has yielded the best documented results so far, and high intensity training has been found to be more effective than low intensity training. Peripheral muscle weakness is considered to contribute to exercise limitation in COPD and resistance training has been shown to increase strength in patients with COPD. It is however still unclear whether a resistance programme affects exercise capacity or not or if endurance training is an indispensable part of pulmonary rehabilitation.

In some studies extensive and expensive treatment models including many sessions a week have been used and have resulted in impressive improvements. These programmes are not always possible to conduct within existing resources in clinical practice. Programmes with less frequent sessions are less costly, but not necessarily efficient to the patients. Some authors have found exercise twice a week efficient while others have not. Most studies have been done with exercise sessions three times a week or more. It has been recommended that endurance training for patients with COPD should, as a minimum, consist of three sessions a week for at least 6–8 weeks. At present, however, many clinics in Sweden offer their patients training only twice a week during out-patient rehabilitation.

Physical training alone has been shown to affect health-related quality of life (HRQoL). Findings that have not been confirmed by others. Both moderately and severely ill patients may benefit from training but it is unclear whether certain exercise programmes are equally beneficial to both groups.

In healthy subjects the effects of training usually are lost after 10–32 weeks of detraining. Studies on long-term effects of exercise in COPD patients have found persistency of some effects for a year or longer during follow-up, but most of these studies include some form of maintenance training. Whether there can be any long-term effects of a short training intervention for moderate to severely ill COPD patients, without offering a maintenance programme, is unclear.

The aim of the present study was to compare the effects of an exercise programme including endurance training with a programme of resistance training and callisthenics alone, when exercising twice a week for 8 weeks and to investigate whether severity of the disease affected the training response. Furthermore, the aim was to find out whether the intervention had a long-term effect.

Methods

Subjects

Seventy-one COPD patients (36 women) were consecutively invited to take part in the study when being referred for training to the Physiotherapy Unit of the Pulmonary Section at the Central Hospital in Västerås, Sweden. All were smokers or ex-smokers. The study was approved by the Medical Ethics Committee of Uppsala University and all subjects gave informed consent.

Only patients with the diagnosis of COPD, an FEV₁/FVC-ratio < 0.7 after bronchodilatation, a smoking history of more than 10 years and forced expiratory volume in 1 s (FEV₁) < 60% of predicted value were included. Exclusion criteria were other diseases that could interfere with training (e.g. ischemic cardiac disease, musculo-skeletal problems) and an increase of FEV₁ > 20% following inhalation of a bronchodilator.

Study design (Fig. 1)

After dynamic spirometry and arterial blood gas analysis each subject underwent a symptom-lim-
HRQoL was measured by the St. George’s Respiratory Questionnaire (SGRQ) and anxiety and depression by the Hospital Anxiety and Depression Scale (HAD).

At the pre-trial tests eight subjects were excluded from the study because of cardiac problems or a bronchodilator response (FEV₁) of more than 20%. The remaining 63 subjects were divided into those with severe disease (FEV₁ < 40% of predicted value), and moderate disease (FEV₁ 40–59% of predicted value).

After the stratification, the subjects with moderate and severe disease, respectively, were blindly randomised (in blocks of four) to an exercise programme including endurance training, resistance training and callisthenics (group A) or a programme of only resistance-training and callisthenics (group B). All subjects trained for eight weeks, twice a week and each session lasted for about 75 min in groups of three to six subjects. After 8 weeks of training, the pre-trial tests were repeated. A criterion for fulfilling the training was participation of at least 12 of the 16 sessions. Pre- and post-training tests were performed less than 2 weeks before and after the exercise period, respectively.

Follow-up measurements were made at 6 and 12 months post-training. Measurements during follow-up were dynamic spirometry, blood-gas analysis at rest, 12-min walking test and HRQoL.

### Testing

FEV₁ and vital capacity (VC) (P K Morgan Ltd., Rainham, England) were stated as the best of three acceptable manoeuvres in accordance with the American Thoracic Society guidelines for standardisation of spirometry 1987.

For arterial blood gas analysis at rest (Bergman and Beving, Copenhagen, Denmark) a blood sample was taken from arteria radialis and PaO₂, PaCO₂ and SaO₂ were analysed.

The peak exercise capacity in watt (peak W) was determined by a symptom-limited incremental cycle ergometer test (RE 830, Rodby Elektronik AB, Enhörna, Sweden) with continuous ECG registration (Megacart, Siemens Elema AB, Solna, Sweden). After 1 min of pedaling at a work rate of 10 W, the work rate was increased by 10 W per minute until exhaustion.

Twelve-minute walking test was performed in a 34 m level corridor. Two tests were done for practice, and a third test served as baseline. After training and during follow-up only one test was performed each time. To prevent bias from the testing supervisor, no encouragement was given, except telling the subjects the time with standard

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**Figure 1** Flow-chart showing inclusion, stratification, randomisation and participation throughout the study.
intervals (after 4, 6, 8 and 11 min). During the test, oxygen saturation (SpO₂) was registered by a non-invasive pulsoxymeter (Nellcor Incorp., Hayward, USA). Peak expiratory flow (PEF), heart rate, SpO₂ and breathing frequency were measured and subjects rated their exertion and breathlessness on the Borg scales RPE and CR-10 before starting, after 6 min, at the end of the walk and 5 min after walking, respectively.

HRQoL was assessed by SGRQ. The questionnaire has three domains: “Symptoms”, “Activity” and “Impact” and, in addition, a “Total” score is calculated. The highest (worst) possible score for every component is 100. The HAD was used to measure anxiety and depression. The highest (worst) score possible for anxiety and depression, respectively, is 21. Both questionnaires are self-administered.

Training

The endurance training consisted of interval training on an ergometer cycle (Monark, Varberg, Sweden). After 6 min warming up at a low work load (20–30% of peak W), ten 3-min intervals with reciprocal high/low work loads followed (total ergometer time 36 min). The lower work rate was 30–50% and the higher work rate was at least 80% of baseline peak W. After every interval, perception of exertion and breathlessness were assessed using the Borg-scales RPE and CR-10, respectively. After the higher work load intervals, target ratings were ≥ 15(RPE) and/or ≥ 5 (CR-10). The subjects’ ratings and the therapist’s observations were used to choose the appropriate level of work load for the next interval, according to the above limits. After cycling the subjects stretched the muscles in thighs and legs. Once a week, the endurance training was followed by resistance training (30 min), and once a week instead of resistance training followed by 15 min of callisthenics and 15 min of relaxation.

During resistance training, the subjects exercised in their own rhythm for about 30 min, taking as long breaks to recover between different moments as they needed. The David Back Clinic apparatus (David Fitness and Medical, Helsinki, Finland) and a usual treatment bench were used. The programme consisted of exercises for the arms and shoulders (David 400, 420 and 610), legs (David 200 and 300), and abdominal muscles (sit-ups). Resistance was initially chosen so that the subjects were able to perform 15 lifts (approximately 65% of one repetition maximum). When 20 lifts were accomplished, resistance was increased. Sit-ups were done on a bench in the supine position with knees bended (soles on mattress).

The callisthenics were done in the sitting position during approximately 15 min. The main emphasis was on unsupported arm exercises (shoulder flexion and circumduction, scapular elevation and depression) mobility exercises for thorax and neck (flexion, extension, rotation and lateral flexion; including stretching), and breathing exercises. The callisthenics were followed by 15 min relaxation ad modum Jacobson. All subjects were taught pursed-lip-breathing technique to use during exercise.

In conclusion, endurance training was performed twice a week in group A, resistance training and callisthenics were performed once a week in group A and twice a week in group B.

All subjects were encouraged to be physically active at home during the 8 weeks, but no special home-training programmes or diaries were used. Subjects with hypoxia (SpO₂ < 90%) during exercise were administered supplementary oxygen by a nasal cannula while exercising, just enough to keep the saturation at or above 90%. SpO₂ was monitored with non-invasive pulseoximetry during exercise.

Statistical analysis

Analysis of variance (ANOVA), the Student’s t-test for paired observations (parametric variables) and Wilcoxon’s signed ranks test (SGRQ and HAD) were used to compare the results before and after training in each group. Comparisons of changes between groups were made by analyses of covariance, Student’s t-test for unpaired observations (parametric) and Mann–Whitney test (SGRQ and HAD). Spearman’s rank correlation was used to estimate the association between changes in physical function, quality of life and lung function during training and at follow-up. To calculate changes over time during the follow-up Friedman’s test and Wilcoxon signed rank tests were used for related/paired observations. A P-value < 0.05 was considered statistically significant. Results are referred to in the text as mean ± standard error of mean. For significant difference between the groups, if one group increased their 12MWD by 35% and the other by 5%, a group size of 21 patients would yield a power of 80% if α = 0.05.

Results

Twenty subjects in group A and 22 in group B completed the trial. There were no baseline
differences between the groups (Tables 1 and 2). Twenty-one subjects (11 in group A) did not complete the training intervention, 10 due to exacerbations, eight due to lack of motivation or psychological problems, and three due to back pain. The drop-outs had lower PaO₂ (8.8 kPa) and a shorter 12MWD (700 m) than those who completed the trial (9.6 kPa and 831 m, respectively, \( P < 0.05 \)). Otherwise no differences were found between drop-outs and other participants. During the 12 month follow-up, 10 subjects dropped out (three in group A) (Fig. 1). Three subjects died, one moved from the area and six subjects got other serious diseases.

In group A, peak exercise capacity improved by \( 7 \pm 2 \text{W} (11\%) \quad (P < 0.001) \) (Fig. 2), and 12MWD increased by \( 50 \text{m} \pm 72 \text{m} (6\%) \quad (P < 0.01) \) (Table 2). Group B did not improve significantly in any of these variables (Fig. 2, Table 2). The difference in peak watt (\( \Delta W \)) differed between the groups (\( P < 0.05 \)), whereas the difference of improvement of 12MWD (\( \Delta 12\text{MWD} \)) did not reach statistical significance (\( P = 0.07 \)) between groups. After the 8 weeks of training, the ratings of perceived exertion and the ratings of dyspnoea at rest were significantly different between the groups (\( P < 0.01 \) and \( < 0.05 \), respectively) (Table 2). The SGRQ and HAD scores did not change significantly by training in any of the groups, (Table 2), although a tendency towards lower scores (improvement) emerged in group B for the SGRQ item “activity” (\(-3.6 \pm 4.5\) points, \( P = 0.07 \)) and total score (\(-2.0 \pm 3.2\) points, \( P = 0.08 \)). There was no correlation between the change in peak watt or 12MWD and the changes in SGRQ.

Lung function (spirometry) and blood gases were not influenced by the training period in neither group.

Twenty-seven subjects (13 in group A) had severe and 15 and 15 (7 in group A) moderate disease (Fig. 1). Apart from spirometry they differed significantly only in peak watt at baseline (56 W \( \pm 3 \) vs. 72 \( \pm 8 \), \( P < 0.05 \)). There was no difference in the effect of training between those with severe and moderate disease (Fig. 3).

At 6 months the 12MWD did not differ significantly from baseline level in either group (Table 3).

### Table 1 Characteristics of the patients who completed the training programme, \( n = 42 \)

<table>
<thead>
<tr>
<th></th>
<th>Group A, ( n = 20 )</th>
<th>Group B, ( n = 22 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (F/M)</td>
<td>10/10</td>
<td>11/11</td>
</tr>
<tr>
<td>Age (years)</td>
<td>65 ( \pm 2 )</td>
<td>68 ( \pm 2 )</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>23.0 ( \pm 0.9 )</td>
<td>22.8 ( \pm 0.8 )</td>
</tr>
<tr>
<td>Pack-years</td>
<td>29 ( \pm 3 )</td>
<td>30 ( \pm 4 )</td>
</tr>
<tr>
<td>VC (l)</td>
<td>2.7 ( \pm 0.1 )</td>
<td>2.6 ( \pm 0.1 )</td>
</tr>
<tr>
<td>VC (% predicted)</td>
<td>78 ( \pm 3 )</td>
<td>76 ( \pm 3 )</td>
</tr>
<tr>
<td>FEV₁ (l)</td>
<td>1.0 ( \pm 0.2 )</td>
<td>1.0 ( \pm 0.2 )</td>
</tr>
<tr>
<td>FEV₁ (%predicted)</td>
<td>37 ( \pm 3 )</td>
<td>38 ( \pm 2 )</td>
</tr>
<tr>
<td>PaO₂ (kPa)</td>
<td>9.5 ( \pm 0.3 )</td>
<td>9.8 ( \pm 0.3 )</td>
</tr>
<tr>
<td>PaCO₂ (kPa)</td>
<td>5.6 ( \pm 0.2 )</td>
<td>5.3 ( \pm 0.1 )</td>
</tr>
<tr>
<td>SaO₂ (%)</td>
<td>93.8 ( \pm 0.5 )</td>
<td>94.2 ( \pm 0.5 )</td>
</tr>
</tbody>
</table>

Mean \( \pm \) standard error of mean. BMI: body mass index; VC: vital capacity; FEV₁: forced expiratory volume in 1s; PaO₂: arterial oxygen tension; PaCO₂: arterial carbon dioxide tension; SaO₂ %: oxygen saturation of arterial blood.

### Table 2 Exercise capacity and health related quality of life at baseline and after 8 weeks of training.

<table>
<thead>
<tr>
<th></th>
<th>Group A, ( n = 20 )</th>
<th>Group B, ( n = 22 )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>8 weeks</td>
</tr>
<tr>
<td>12MWD (m)</td>
<td>854 ( \pm 42 )</td>
<td>893 ( ^* ) ( \pm 46 )</td>
</tr>
<tr>
<td>RPE at rest</td>
<td>7.2 ( \pm 0.4 )</td>
<td>6.3 ( ^* ) ( \pm 0.1 )</td>
</tr>
<tr>
<td>CR-10 at rest</td>
<td>1.0 ( \pm 0.3 )</td>
<td>0.3 ( ^* ) ( \pm 0.1 )</td>
</tr>
<tr>
<td>HAD depression</td>
<td>4.8 ( \pm 0.6 )</td>
<td>4.3 ( ^* ) ( \pm 0.6 )</td>
</tr>
<tr>
<td>HAD anxiety</td>
<td>6.4 ( \pm 0.7 )</td>
<td>5.8 ( ^* ) ( \pm 0.8 )</td>
</tr>
<tr>
<td>SGRQ symptom</td>
<td>54.7 ( \pm 4.5 )</td>
<td>49.9 ( ^* ) ( \pm 4.8 )</td>
</tr>
<tr>
<td>SGRQ activity</td>
<td>63.0 ( \pm 3.7 )</td>
<td>63.7 ( ^* ) ( \pm 3.9 )</td>
</tr>
<tr>
<td>SGRQ impact</td>
<td>38.4 ( \pm 3.9 )</td>
<td>34.2 ( ^* ) ( \pm 3.9 )</td>
</tr>
<tr>
<td>SGRQ total</td>
<td>48.5 ( \pm 3.4 )</td>
<td>46.9 ( ^* ) ( \pm 3.5 )</td>
</tr>
</tbody>
</table>

Mean \( \pm \) standard error of mean. 12MWD: walking distance in 12 min; RPE: Borg scale for ratings of perceived exertion; CR-10: Borg scale for dyspnoea; HAD: hospital anxiety and depression scale; SGRQ: St. George’s Respiratory Questionnaire.

\(^*\) Significant difference from baseline \( P < 0.05 \).

\(^{1}\) Significant difference between groups \( P < 0.05 \).
There was a further decline in 12MWD from 6 to 12 months in group B \((P<0.05)\), but not in group A \((P = 0.09)\). At 12 months post-training the 12MWD was not significantly different from baseline in group A \((P = 0.19)\), whereas it had declined in group B \((-79 \text{ m} \pm 24 \text{ m}, P<0.05)\) (Fig. 4), but the difference between the groups was not significant.

The difference between groups in CR-10 scores for dyspnoea at rest was still evident 6 months post-training \((P<0.05)\) but not after 12 months, whereas the RPE-difference at rest persisted throughout the follow-up \((P<0.05)\) (Table 3).

Lung function showed small, but significant decline in VC at 12 months post-training in group
A (-0.2 L, \(P < 0.05\)) compared to baseline (Tables 1 and 3). There was no correlation between changes in 12MWD and lung function during the study. There were no changes in \(P_{aO_2}\), \(P_{aCO_2}\) or \(S_{aO_2}\) during the time of the study (14 months).

At 12 months post-training there was a tendency towards lower scores in SGRQ symptoms in group A compared to baseline (-7.5 \(\pm\) 4.3, \(P = 0.07\)). No other changes in SGRQ or HAD emerged during follow-up in either group.
Men and women were equally represented in the training groups and there was no difference in response to training between the genders.

Discussion

The present study showed that two sessions a week for 8 weeks of a combined exercise programme, including endurance training, increased exercise capacity in patients with severe or moderate COPD. It also showed that the training response did not differ between subjects with severe and moderate disease. There was, however, only a minor improvement and no effect could be demonstrated in quality of life assessments. In the present model, resistance training and callisthenics alone was neither sufficient to influence exercise capacity nor HRQoL. The small increase in functional exercise capacity by the endurance training programme was lost 6 months post-training, but decline from baseline was prevented for at least 12 months post-training. Significant difference between groups after the intervention was found only in increase in peak W and in dyspnoea and perceived exertion at rest. As the response to training was smaller than we predicted, the power was probably too low to detect other differences between the groups.

Our results differ somewhat from the findings of Ringbaek et al., who did not find any improvement in exercise capacity when exercising twice a week for 8 weeks. Their target intensity of training was somewhat lower and the training sessions shorter than in the current study which may explain the different outcome in the two studies. Five studies of supervised exercise three times a week for 8–12 weeks comparing the effects of strength training with controls, endurance training with resistance training or a combination of both supported that endurance training increased exercise capacity, whereas the effect of resistance training on exercise capacity varied. Some authors found that resistance training could increase endurance but did not add anything to peak exercise capacity or 6 min walking distance while others found that even resistance training could increase peak exercise capacity. According to this, an endurance test might be the most sensitive test and therefore preferred when testing changes in physical performance. The resistance training was more intensive in the above quoted studies than in the current one and it could be argued that the intensity of the resistance training in our study was too low and/or the sessions too few to influence peak W or 12MWD. In the present study, the intensity of endurance training was similar to previous studies but was performed only twice a week instead of three times a week. Thus, the relatively small effects of endurance training in the present study might be because of a lower total dose of training.

Two recent meta-analyses showed that multidisciplinary pulmonary rehabilitation improves physical function and HRQoL. In some of the papers included in the meta-analyses HRQoL improvement has been found after training intervention alone. In the present study, physical function, but not HRQoL, depression or anxiety scores were improved in group A. In the meta-analysis by Lacasse et al., based on 15 studies, the effects on peak W (weighted mean difference) was 5.5 W (95% CI 0.49–10.23) and in most of these trials HRQoL improved.7 The lack of effect on HRQoL in the present study, which has included a similar number of patients as most of the trials included in the meta-analysis indicates that the relationship between peak exercise capacity and HRQoL is not strong. This is in line with previous findings. In 12MWD in group A, although statistically significant, was small, 50 m. In the meta-analysis by Lacasse et al. a weighted mean difference of 49 m (95% CI 26–72 m) was found in 6-min walking distance. As a test of a longer duration (12 min) would need a larger absolute improvement for a similar effect, the outcome of the present study is inferior to what was described in the meta-analysis. HRQoL has been shown to correlate better with walking distance than with peak W. The small difference in walking distance in our study might explain the lack of effect on HRQoL. As the intensity of the endurance training in our study was similar to other studies the small effect on walking distance probably indicates that two sessions a week for 8 weeks was a suboptimal dose of training. Another possible explanation to lack of effect in HRQoL is that the groups in the current study were small and that the study was not powered to study HRQoL as a primary outcome.

Another important difference between our and previous trials is that we have used SGRQ while in all the above studies the Chronic Respiratory Disease Questionnaire (CRDQ) was used to evaluate HRQoL. These two instruments focus on different aspects of HRQoL in COPD. There is also a difference in the scoring scales which might affect sensibility to smaller changes (seven-graded in CRDQ, whereas most issues in SGRQ have two grades).
In the present study, subjects with severe disease responded to training similarly to subjects with moderate disease. This finding is particularly interesting in view of a recent meta-analysis in which it was concluded that no effects of rehabilitation could be expected with a shorter intervention than 6 months in subjects with severe COPD, whereas subjects with moderate COPD responded even to shorter programmes. Casaburi et al. found that subjects with severe COPD improved their exercise capacity after a 6-weeks programme. The intensity of the endurance training of their study and the present one was higher than in most of the studies on subjects with severe disease included in the meta-analysis. The different outcomes between studies analysing effects on subjects with severe COPD per se, might therefore be caused by a difference in the intervention.

The small, but significant, increase in functional exercise capacity (12MWD) in group A during the 8 weeks of training wore off with time during follow-up. This was expected, as no maintenance programme was offered. Some authors have found it a challenge to maintain the effects of training, even with some kind of maintenance programmes. COPD is a progressive disease, and in a recent paper, patients with severe COPD were found to decrease their 6MWD on average by 26 m a year during a 2-year study, non-survivors showing even a larger decrease. They concluded that timed during a 2-year study, non-survivors showing even a larger decrease. They concluded that timed during a 2-year study, non-survivors showing even a larger decrease.

In the present study, at 12 months post-training (14 months from baseline) group A had returned to baseline 12MWD, whereas in group B 12MWD was significantly shorter than baseline. Although 12MWD was not significantly different between the groups during follow-up, there was a significant difference between the groups with regard to the RPE score at rest. This strengthens the impression that the subjects in group A preserved their physical function throughout the study better than the subjects in group B. This is an encouraging finding, indicating that a temporary, minor increase in exercise capacity during training may have effect in the long run by holding back decline from baseline. The preservation of 12MWD in group A during the 14 months of the study was possibly due to the short training intervention. The groups were however small which makes firm conclusions difficult.

Similar to some other studies, the dropout was large in the present study. However, in patients with severe COPD, hidden comorbidities and frequent exacerbations are to be expected, which makes it reasonable to assume that the current study reflects “real life” in pulmonary rehabilitation.

We conclude that exercise capacity in patients with severe to moderate COPD was significantly improved by a 8 week training programme, two sessions a week, only when intensive endurance training was included in the programme. The improvement in exercise capacity was small and HRQoL was not improved. Severity of illness did not affect exercise response. Exercise capacity was back to baseline levels 6 months post-training. The results indicated that the temporarily improvement might have slowed down decline in baseline functional exercise capacity for at least 1 year.

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References

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