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ABSTRACT

Purpose: To compare changes in functional exercise capacity, dyspnea, functional status, and depression in patients after 8 weeks (24 sessions) and 12 weeks (36 sessions) of pulmonary rehabilitation (PR). **Methods:** A prospective sample of 31 participants in our PR program completed outcome measures prior to and during the eighth and twelfth weeks of the program. The 6-minute walk test (6MWT) and a stairs climbing test (ST) measured functional exercise capacity. Perceived dyspnea (PD) was measured with a 6-20 scale. The Pulmonary Function Status Scale (PFSS) measured functional status, and the Cardiac Depression Scale (CDS) measured depression. **Results:** Statistically significant improvements were seen in the 6MWT, PD during 6MWT, and ST after 8 weeks and after 12 weeks of PR, but the improvements between 8 and 12 weeks were small and not statistically significant. After 8 weeks, PFSS total scores suggested increased difficulty carrying out daily tasks that moderated by 12 weeks. CDS scores showed modest, but not statistically significant improvements, after 8 and 12 weeks. **Conclusion:** Statistically significant and clinically important improvements in 6MWT, ST, and dyspnea occur after 8 weeks and 12 weeks of PR, but the changes between 8 and 12 weeks were not large enough to be statistically significant or clinically important. Neither 8 nor 12 weeks was sufficient to produce statistically significant changes in functional status and depression.

INTRODUCTION

Multidisciplinary pulmonary rehabilitation (PR) programs are accepted as an effective treatment for patients with chronic lung disease. The primary goal of rehabilitation, to restore the patient to the highest possible level of independent function, usually is accomplished by helping patients to be more active through exercise training and to reduce and gain control of symptoms.[1] A review of randomized controlled trials of pulmonary rehabilitation in patients with chronic obstructive pulmonary disease (COPD) concluded exercise relieves dyspnea and fatigue and enhances patients' sense of control over their condition and that rehabilitation forms an important component of the management of COPD.[2] Despite general consensus that pulmonary rehabilitation is efficacious, there is little agreement about what constitutes the most effective and efficient pulmonary rehabilitation program.[3]

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The duration of PR programs varies widely. The evidence-based guidelines developed by the American College of Chest Physicians and American Association of Cardiovascular and Pulmonary Rehabilitation[1] were based on 14 controlled trials of lower extremity exercise training that varied in duration from 4 weeks to 6 months. Similarly, meta-analyses published by Lacasse et al[4] and Cambach et al[5] examined PR programs ranging in duration from 6 weeks to continuous. Lacasse et al[4] concluded duration of the program did not affect maximum exercise capacity measured as peak workload (watts) during an incremental cycle ergometer test. However, analysis of the effect of PR on functional exercise capacity, measured as walking distance, showed heterogeneity among the study results. A post-hoc analysis showed a significant difference between programs of 6 months duration and shorter programs, which Lacasse et al[4] hypothesized as the source of heterogeneity.

Pulmonary rehabilitation programs 8 weeks or less in duration have shown varying results. Young et al[6] reported statistically significant improvements in 6-minute walk distance, dyspnea, and quality of life measures after a 1-month (7 sessions) program. However, increases in walk distance did not reach the minimally clinically important difference of 54 meters[7] until 3 months after completing the formal rehabilitation program. Ringbaek et al[8] concluded that their program of 8 weeks (16 sessions) was insufficient to produce significant improvements in 6-minute walk distance or quality of life measures. Conversely, Singh et al[9] found significant improvements in shuttle walking test distance, treadmill endurance, and quality of life measures after 7 weeks (14 sessions) of PR.

Several studies have specifically examined the effect of program duration. Green et al[10] conducted a randomized controlled trial of comparable twice-weekly PR programs of 4 and 7 weeks duration. Subjects who completed the 7-week program had greater improvements in all outcome measures than those in the 4-week program. The differences in improvements reached statistical significance for the total Chronic Respiratory Disease Questionnaire score and the domains of dyspnea, emotion, and mastery. The 7-week group improved in the shuttle walk and treadmill

endurance test, but the differences between the 4 and 7-week groups were not statistically significant. The authors concluded that 7 weeks of PR provide greater benefit to patients.

The randomized, controlled trial of Bendstrup et al[11] featured exercise training 3 times weekly for 12 weeks. Data were collected at 6 and 12 weeks with a follow-up after 24 weeks. The increase in 6-minute walk distance was significant after 6 weeks, but further improvements were small. This indicated a shorter PR program might be sufficient. However, the differences between the control and treatment groups for the Activities of Daily Living score and the Chronic Respiratory Disease Questionnaire score did not become statistically significant until 12 and 24 weeks, respectively.

The literature in pulmonary rehabilitation suggests that shorter duration rehabilitation programs may be effective in increasing functional exercise capacity and health status in the short term. The purpose of our study was to compare the outcomes of functional exercise capacity, dyspnea, functional status, and depression of patients after 8 weeks (24 sessions) and 12 weeks (36 sessions) of pulmonary rehabilitation. Both pressure from third party payers and our desire to serve as many patients as efficiently as possible led us to question whether we could attain similar outcomes in a shorter period.

METHODS

Study Design

The study was a one-way repeated measures design with time as the independent variable. Subjects were tested before PR, and during regularly scheduled sessions of the program in the eighth week (sessions 22-24) and eleventh or twelfth weeks (sessions 31-35). Due to scheduling problems, some data were collected in the session immediately preceding or following the eighth week.

Walk distance data collected from previous patients showed a mean difference of 76 m between the initial and final tests. Since this exceeded the minimal clinically important difference of 54 m,[7] we used the latter value to determine that a sample of 9 patients would provide 80% power needed to detect a clinically important difference between the initial and final walk tests at $P < 0.05$. Recognizing that the difference we observed might be less, and allowing for some dropouts, all patients who started the PR program during the study period were invited to participate.

Subjects

Forty-eight participants in a 12-week (36 sessions) multidisciplinary PR program of education and exercise were invited to participate in this study. Admission criteria for the program included a diagnosis of chronic obstructive pulmonary disease or restrictive pulmonary disease, physician referral, tobacco free, and no acute cardiac disease. Data from 31 patients who completed the program were analyzed. Of the remaining 17 patients, 10 did not complete the program, 5 could not participate because their insurance carriers required testing at intervals different from those specified by the study protocol, 1 declined to participate in the study, and 1 was excluded due to problems with data collection. The Institutional Review Board of the Brattleboro Memorial Hospital approved the study and all subjects provided written informed consent. Table 1 provides information about the subjects.

Table 1. Characteristics of Subjects

	n	Mean	SD	Range
Gender				
Male	12			
Female	19			
Age (yr)	31	68.3	9.28	45 - 83
FEV_1 (% of predicted)	31	47.2	17.09	22 - 90
Primary diagnosis				
Emphysema	20			
Asthma	2			
Chronic bronchitis	2			
Pulmonary fibrosis	2			
Bronchiectasis	1			
Interstitial lung disease	1			
Lung cancer	1			
Restrictive lung disease	1			
Sarcoidosis	1			

FEV_1 = forced expiratory volume in one second

Measurement Procedures

Before beginning the PR program, all prospective participants were interviewed by the program coordinator and completed the Pulmonary Function Status Scale (PFSS) and Cardiac Depression Scale (CDS) with the assistance of the coordinator, if needed. In addition, participants received a physical therapy examination by the principal investigator in the 30 days prior to starting PR. During this evaluation, participants performed the initial 6-minute walk test (6MWT) and timed stairs test (ST), and were introduced to the perceived dyspnea scale (PD).

6 minute walk test (6MWT)

One of the most frequently used outcome measures for PR programs, the 6MWT demonstrates good test-retest reliability and convergent validity with standard measures of pulmonary impairment.[12] Our subjects performed one 6MWT on a course 90 feet long and received standard written instructions and verbal encouragement. Due to space and time constraints, we were unable to use the recommended minimum 100-foot course or to conduct the recommended 3 trials per test, a limitation common to many PR programs.[13]

Timed stairs test (ST)

Participants were timed while descending and ascending two flights of stairs as quickly as possible, using a handrail if needed. The first flight had 10 steps and the second flight had 8 steps. The total vertical distance was 12 feet. This test resembles that of Rejeski et al[12] except that we timed both the descent and ascent of the stairs. Rejeski et al[12] reported the reliability of repeated trials of the ST and

its convergent validity with VO_{2peak}, FEV_1, and self-reported disability in patients 55 to 80 years with COPD.

Perceived dyspnea (PD)

During the 6MWT and stairs test subjects rated their dyspnea using a modification of the 6 – 20 Borg Rate of Perceived Exertion scale.[14,15] To clarify to patients that they were rating their dyspnea words describing breathing were added to the descriptive phrases accompanying the scale. Subjects rated their dyspnea at the start of the 6MWT, after 2 and 4 minutes, and at the end of the test. The final PD was recorded for statistical analysis. During the ST subjects rated their dyspnea at completion of the test.

Pulmonary function status scale (PFSS)

The PFSS[16] is a 35-item, self-administered questionnaire, which assesses the functional status of patients with chronic pulmonary disease. Three subscores, evaluating daily activities/social functioning (22 items), psychological functioning (10 items), and sexual functioning (3 items) are calculated as well as a total score. Each subscore ranges from 1–5; total score ranges from 3–15. A lower score indicates more impaired functional status due to difficulty in performing a specific activity, or performing the activity less frequently. The PFSS has been shown to have content, construct, and concurrent forms of validity and to have test-retest reliability.[16]

Depression scale (CDS)

Developed to assess depression in cardiac patients, the CDS[17] is a 26 item, self-administered questionnaire, with each item measured on a 1 to 7 Lichert scale. Responses to individual items related to sleep, anhedonia, uncertainty, mood, cognition, hopelessness, and inactivity are summed to a total score. A higher score indicates greater depression.

Pulmonary Rehabilitation Program

Participants received one hour of exercise and one hour of education 3 times per week for 12 weeks. Heart rate, blood pressure, oxygen saturation, and PD were monitored before, during, and after the exercise session. Supplemental oxygen was provided to maintain oxygen saturation at or above 88%. All exercises were modified to meet individual needs.

Aerobic exercise was performed utilizing the treadmill, and at least one other type of exercise equipment (eg, stationary bicycle, upper body ergometer, rowing machine, or Nustep) (Nustep Inc, 511 Venture Dr, Ann Arbor, MI). Each participant received an exercise prescription set by the PR medical director at 75% to 85% of the maximal workload achieved during a preprogram graded exercise stress test. After beginning exercise at a subtherapeutic level to become familiar with the equipment and to increase endurance to 20 minutes, participants were instructed to increase exercise intensity to maintain a 13 – 15 level ('somewhat short of breath' to 'short of breath') on the PD scale. Each participant progressed to 20 to 40 continuous minutes of aerobic exercise and exceeded the maximum workload they achieved during the exercise stress test.

Participants also performed progressive resistance exercises for the arms with weights ranging from 1 pound hand weights to 18 pound exercise bars and standing leg exercises. Participants were instructed to increase resistance so that they would feel challenged by 1 set of 10 repetitions of each exercise. Static stretching exercises for the arms and legs were also included.

The PR coordinator, a respiratory therapist, directed the multidisciplinary educational component. Educational topics included lung anatomy and physiology, pulmonary diseases, medications, nutrition, breathing techniques, lung function tests, exercise stress testing and exercise prescription, stress reduction, home exercise, energy conservation in daily activities, and advance directives. Experts from the hospital or community, including the PR coordinator, physical therapists, occupational therapists, registered dieticians, pharmacists, psychologists, and hospice representatives, lead the educational sessions. Weekly support group sessions were also provided.

Data Analysis

Thirty-one patients completed the study. Some subjects did not complete all tests at the 3 time-points, however, so statistical tests were performed on variables for which complete data were available. Probability plots and one-sample Kolmogorov-Smirnov tests were analyzed to determine if the sampled populations were normally distributed before computing inferential statistics.[18] Because the variable 6MWT was normally distributed, differences in walk distance at the 3 test periods were analyzed using one-way analysis of variance for repeated measures followed by paired t-tests for multiple comparisons. The variable ST was not normally distributed, so the differences were analyzed by the Friedman test followed by Wilcoxon Signed Ranks test. Because PD, PFSS, and CDS are ordinal-level measurements, the differences among 3 tests were analyzed using the Friedman test followed by Wilcoxon Signed Ranks tests for paired multiple comparisons. Data were analyzed using Systat Version 10.0 (Systat Software Inc, 501 Canal Blvd, Point Richmond, Calif) statistical software.

RESULTS

Table 2 summarizes the results for each measure.

Six-Minute Walk Test

Thirty-one patients completed all 3 tests. The mean distance walked was significantly different between the 3 tests ($P < 0.001$). The mean distance increased by 50 meters (95% CI = 36.8 – 63.1, $P < 0.001$) after 8 weeks of PR and by 60 meters (95% CI = 42.1 – 77.9, $P < 0.001$) after 12 weeks. The mean increase of 10.1 meters (95% CI = -5.5 – 25.7) between weeks 8 and 12 was not significant ($P = 0.196$).

There were significant differences in PD during the 3 walk tests ($P < 0.001$). The median PD decreased from 15

Table 2. Summary Statistics for Performance Measures Recorded Before and After 8 and 12 Weeks of Pulmonary Rehabilitation

Measurement	N	Initial	8 weeks	12 weeks
6MWT (m)	31	310.2 ± 88.3	360.1 ± 101.7*	370.2 ± 110.8*
6MWT PD	31	15.0	13.0*	13.0*
ST (s)	29	33.2 ± 20.6	27.3 ± 10.9*	26.4 ± 12.3*
ST PD	29	12.0	11.0	11.0
PFSS Total	26	9.9	7.8	8.4
Activities/Social Function	26	3.7	3.7	3.5
Psychological Function	26	4.1	4.0	3.8
Sexual Function	10	3.5	4.0	3.5
CDS	28	97.0	96.5	92.0

* Measurements at 8 and 12 weeks are significantly different as compared to initial test (P <0.001), but are not different from each other.

6MWT = 6-Minute Walk Test. Values are mean ± standard deviation
PD = Perceived Dyspnea. Values are medians
ST = Stairs Test. Values are mean ± standard deviation
PFSS = Pulmonary Function Status Scale. Values are medians
CDS = Cardiac Depression Scale. Values are medians

"short of breath" to 13 "somewhat short of breath" at 8 weeks (P = 0.001) and remained at this level at 12-weeks.

Stairs Test

Twenty-nine patients completed all 3 tests. The time required to descend and climb stairs was significantly different between the 3 tests (P < 0. 001). The average time decreased by 6 seconds (95% CI = 0.87 – 11.0, P < 0.001) after 8 weeks and by 7 seconds (95% CI = 0.71 – 12, P < 0.001) after 12 weeks. The difference of 0.8 seconds (95% CI = -0.9 – 2.6) between 8 and 12 weeks was not significant (P = 0.164).

The differences in PD ratings during the stair test were not significant among the 3 tests. Perceived dyspnea decreased from a level 12 (between 'fairly easy to breath' and 'somewhat short of breath') to 11 ('fairly easy to breathe') after 8 weeks and remained at this level in week 12.

Pulmonary Function Status Scale

Twenty-six patients completed the Daily Activities/ Social Functioning and Psychological Functioning subscales and 10 patients completed the Sexual Functioning subscale at the 3 test periods. The differences in the PFSS total score were not significant among the 3 tests; nor were the differences in the subscale scores.

Depression Scale

Twenty-eight patients completed the CDS at all 3 test periods. The differences in the CDS total score were not significant among the 3 tests.

DISCUSSION

After 8 weeks our patients were walking longer distances and reporting less dyspnea during the 6MWT and descending and climbing stairs faster. The 6MWT increase of 50 m (95% CI 36.8 – 63.1) is consistent with the 54 m change suggested by Redelmeier et al[7] as the threshold of clinical importance for the 6MWT. In addition, our results are consistent with Cambach et al[5] and Lacasse et al[4] who reported average improvements in walking distance of 49 m and 56 m respectively.

Although the increase in mean distance of 10.1 m from week 8 to week 12 was not statistically significant, some patients and clinicians might consider the increase to be clinically important. The 95% confidence interval (-5.5 – 25.7 meters) for the mean of 10.1 indicates the data are consistent with the interpretation that walk distance may decrease or increase between weeks and 8 and 12 of PR. Thus, our data are not conclusive on this question. A trend analysis[19] using single degree of freedom polynomial contrasts was performed to further elucidate the changes in walk distance during PR. This analysis revealed a quadratic trend across the 3 tests (p = 0.05), meaning the improvement in walk distance is not linear (Figure 1). It appears that most of the changes in patient motivation, pacing skills, and peripheral muscle and cardiac conditioning brought about by participation in PR[20] occur by 8 weeks. It is also likely that differences in patients' ages, severity of disease, and co-morbidities may affect the rate of change for the 6MWT and other outcome measures.

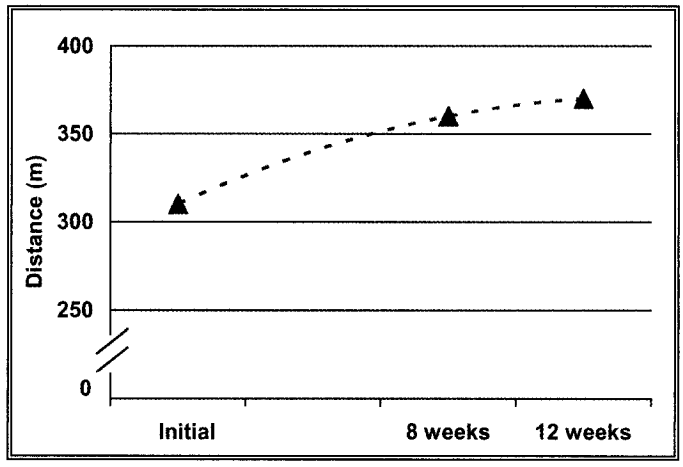

Figure 1. The dashed trend line shows the curvilinear change (P = 0.05) in walk distance over the 6MWTs administered during 12 weeks of pulmonary rehabilitation. Distance walked was significantly different between initial test and 8 and 12 weeks (P<0.001), but there was no difference in distance walked between 8 and 12 weeks (P=0.196).

To measure changes in functional status, we used the 1998 version of the PFSS. Although 11 patients showed improvement in PFSS total score, the improvement for the group overall was small (8%) and not statistically significant for either the PFSS total score or any of the 3 subscores. We estimate a sample of 58 patients would be needed to have 80% power to declare the mean difference of 0.70 (SD = 1.85) in the PFSS total score we observed

after 12 weeks significant at $P < 0.05$. In contrast to our results, Bowen et al[20] and Haggerty et al[21] reported significant improvements of 10% to 22% in total and subscale scores on an earlier version of the PFSS with a different scoring system in 164 patients who participated in PR programs of variable duration.

As a self-report questionnaire, the PFSS is limited by the patient's motivation, recall, and perception of improvement[3] and may be insensitive to detecting small changes in function. Our patients rated themselves toward the higher end of the ordinal scale on most items of the PFSS at the initial test. The median scores were 3.5, 3.7, and 4.1 for the Sexual Function, Psychological Function, and Activities/Social Function subscores, respectively. A rating of 3 indicates the patient has 'moderate difficulty' performing the task; a rating of 4 indicates 'little difficulty' performing the task. To achieve statistically significant and clinically important changes in the PFSS, most of the patients would need to have changed their ratings to 4 or 5. To rate a 5 on the PFSS, the patient would have to believe they could perform the task 'without difficulty.' It is unlikely that patients with chronic respiratory impairments would consider themselves able to perform the activities of daily living on the PFSS 'without difficulty' regardless of how effective the PR program. The insensitivity of the ordinal rating scale may explain why the PFSS data contradict the patients' anecdotal reports of improved functioning in daily activities. Also, more individualized training in self-care, including activities of daily living and instrumental activities of daily living may be needed to meet each patient's unique functional needs at home and in the community and for them to perceive changes in functional ability.

Depression and anxiety are common sequelae of chronic respiratory disease,[22] but to our knowledge, there is no disease-specific outcome measure for this population. Instead generic instruments such as the Beck Depression Inventory (BDI)[23] are frequently used to measure depression. Unlike the BDI, the CDS addresses both depression and anxiety in a single score and was developed for individuals with cardiovascular disease, a patient group that also frequently undergoes outpatient rehabilitation. Because the CDS contains no cardiac specific content, Hare and Davis[17] suggested it could be used to measure depression in other populations, and the American Association for Cardiovascular and Pulmonary Rehabilitation has suggested it as an outcome tool for PR.[24]

Fifteen of 28 patients reported less depression on the CDS after 8 and 12 weeks of PR. However, the improvement was small (< 1% after 8 weeks, 5% after 12 weeks, and 4.7% between 8 and 12 weeks) and not statistically significant. The majority of patients' scores were within one standard deviation of the mean score (80.3 ± 27.8) reported by Hare and Davis[17] for their test population suggesting that our patients were not severely depressed. A post-hoc statistical power analysis suggested 86 subjects would be needed to have 80% power to declare mean difference of 2.5 (SD = 7.9) we observed after 8 weeks significant at $P < 0.05$.

Because we were unable to find any other published reports that used the CDS, we are unable to compare our results directly with other studies. Using the Hospital Anxiety and Depression scale, Withers et al[25] reported significant decreases in depression among 95 patients with COPD after 6 weeks of PR. Kozora et al[26] found significant decreases in depression as measured by the BDI in a group of 30 patients with COPD after 3 weeks of PR compared to a nonrandomized, medical comparison group of COPD patients not participating in PR. Both Withers et al[24] and Kozora et al[25] provided psychosocial services as part of their PR programs, and Withers et al[24] employed a clinical psychologist as a member of the multidisciplinary PR team. Their success suggests that PR programs consider including specific medical or behavioral interventions as part of a comprehensive PR program to help patients manage depression.

Patients with chronic pulmonary disease face the challenge of maintaining their functional capacity while experiencing diminished physiological function. Two studies raise the important question of whether longer PR programs help participants to maintain the gains in functional exercise capacity attained in 7 to 8 week programs. Grosbois et al[27] found that 18 months of physical therapist-supervised exercise maintenance once or twice a week or daily home exercise maintenance were equally effective in maintaining improvements in maximal workload attained after 7 weeks (21 sessions) of outpatient PR. However, in subjects who did not participate in exercise maintenance, maximal workload returned to baseline after 18 months. Swerts et al[28] reported that after an 8-week (24 sessions) PR program, subjects who completed an additional 12 weeks (10 additional sessions) of supervised training maintained their increased exercise tolerance 6 months and one year after beginning the program. Subjects who received only written instructions to continue exercise at home after the 8-week PR program showed a decline in exercise tolerance after one year. Additionally, only 27% of subjects in the latter group were still exercising at home one year later, while 100% of subjects who had 20 weeks of PR continued their home exercise. That patients are more likely to continue exercising after a longer PR program agrees with the literature on life style change, which suggests people are more likely to continue their new behavior after 6 months of training.[29] Future research should investigate ways to facilitate long-term behavioral changes in patients who have completed a PR program.

A number of limitations result from the study's observational nature and relatively small convenience sample. First, because the study was conducted within an on-going PR program in a small hospital, only patients referred to the PR program were eligible for the study. This introduced the possibility of sampling bias. Second, although the sample size provided adequate statistical power to evaluate changes in ST time, distance walked in the 6MWT, and PD during the 6MWT, the sample provided low power to evaluate changes in PD during the ST, and functional status and depression. Failing to detect a significant change in these variables may be a Type II error. Third, although the PR

program included patients with obstructive or restrictive forms of lung disease, the sample was too small to analyze the outcomes of obstructive vs. restrictive patients as separate groups. A further limitation is that we did not examine any long-term outcomes such as continued participation in exercise after formal PR, or hospital and health care utilization rates.

In conclusion, using a within-subject research design, we evaluated the changes in 6MWT distance, stair-climbing time, perceived dyspnea while walking and climbing stairs, functional status, and depression after 8 weeks (24 sessions) and 12 weeks (36 sessions) of PR. After 8 weeks, our patients made significant improvements in distance walked in 6 minutes, perceived dyspnea while walking, and stair climbing time but not in functional status or depression. With 12 more sessions of PR over 4 additional weeks, patients continued to increase walk distance and functional status, and to decrease stair climbing time and depression while perceived dyspnea remained unchanged. Additional research is needed to definitively determine whether patients in PR for more than 8 weeks continue to increase exercise performance, and functional and psychological status. Additional research can also determine what specific self-care training, medical or behavioral interventions, and psychosocial supports most effectively reduce patients' symptoms and increase their capacity to participate in physical and social activities.

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