

ORIGINAL ARTICLE

The Correlations Between Disease Specific Quality of Life, Short Form-36 and Clinical Variables in Patients With Ankylosing Spondylitis

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Objectives: This study aims to assess the correlations between disease specific quality of life (QoL), general health status and clinical variables in patients with ankylosing spondylitis (AS), and also to determine a cutoff value for the disease specific QoL questionnaire.

Patients and methods: A total of 124 patients (80 males, 44 females; mean age 40.6±11.1 years; range, 20 to 65 years) who fulfilled the modified New York criteria for AS were included in this cross-sectional study. All patients received a comprehensive rheumatologic assessment including disease specific instruments for disease activity, functional status, spinal mobility and QoL. Furthermore, short form-36 (SF-36) was used to determine general health status. Pain levels of the patients were assessed with visual analog scale (VAS). Pearson's analysis was used to assess correlation among variables, with moderate, strong, or very strong correlations if the value was between 0.40-0.69, 0.70-0.89, and 0.90-0.99, respectively. To determine a cutoff value for the ankylosing spondylitis quality of life (ASQoL) score, the area under the receiver operating characteristic curve (AUC) was computed according to clinical parameters which have the strongest correlations with ASQoL.

Results: The mean ASQoL score was 8.8±4.9. There was a significantly positive correlation between ASQoL and disease activity, functional status, spinal mobility and pain VAS whereas there was a significantly negative correlation between ASQoL and the SF-36 subscale scores except for mental health and emotional role ($p<0.001$). The strongest positive correlation was found between ASQoL and the Bath Ankylosing Spondylitis Disease Activity Index ($r=0.721$, $p<0.001$) whereas the strongest negative correlation was found between ASQoL and the first question of SF-36 ($r=-0.844$, $p<0.001$). A cutoff value of eight in ASQoL showed good discriminative properties for impaired QoL where sensitivity and specificity were simultaneously maximized according to disease activity (AUC=0.84 [95% confidence interval (CI): 0.770-0.908, $p<0.001$]) and the patients' global health status (AUC=0.85 [95% CI: 0.782-0.923, $p<0.001$]) in patients with AS.

Conclusion: There was a strong correlation between ASQoL and disease activity as well as the patients' global health status in patients with AS. A cutoff value of eight in ASQoL could be used with good discriminative properties for impaired QoL in AS.

Keywords: Ankylosing spondylitis, outcome measures, quality of life.

Ankylosing spondylitis (AS) is a chronic inflammatory rheumatic disease that can have a profound impact on health status and quality of life (QoL).¹ Disease progression results in substantial functional limitations and impairment of health related QoL. One of the important targets in AS management is to improve QoL such as in other rheumatic disorders.² Recognizing complex

relationships between clinical features and QoL can help us to develop further management strategies to improve the QoL in patients with AS.

Patient reported outcomes have an important role in the evaluation of health status in clinical practice, and provide valuable information in addition to traditional biomedical assessments.³ Although the Assessment of Spondyloarthritis

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International Society has recommended using patient reported outcomes in their core assessment domains such as disease activity and functional limitation, they did not recommend measuring QoL as a core domain in their handbook to assess spondyloarthritis due to uncertainty over the existing questionnaires.⁴ Different generic and disease specific instruments are available in measuring QoL. However, there is an important concern that the broad scope of the generic instruments might not adequately reflect health status in populations with specific disorders.⁵ The ankylosing spondylitis quality of life (ASQoL) is the most commonly used disease specific QoL tool for assessing the impact of AS and its treatment on QoL in clinical settings and research studies. The ASQoL is a validated disease specific QoL measure which gives important information on limitation of activities and participation that are not covered in other AS specific outcome measures. Although many studies have assessed the psychometric properties of disease specific QoL questionnaires in AS, it seems that the interpretation and meaning of questionnaire results are still unclear and more evaluation is needed.⁶⁻⁹ Furthermore, information on cutoff is currently lacking for ASQoL. We believe that the dichotomization of QoL scale will facilitate integration of QoL scores in decision making for the treatment of patients. In this study, we aimed to assess the correlations between disease specific QoL, general health status and clinical variables in patients with AS, and also to determine a cutoff value for the disease specific QoL questionnaire.

PATIENTS AND METHODS

This cross-sectional study was conducted at Pamukkale University Faculty of Medicine between May 2014 and August 2014. A total of 140 patients with AS who were admitted to the outpatient clinic of physical medicine and rehabilitation department of Pamukkale University Faculty of Medicine were screened for eligibility. Patients who met the modified New York criteria¹⁰ for AS and aged over 18 years were included. The criteria for exclusion were other concomitant rheumatic diseases (such as fibromyalgia, rheumatoid arthritis, etc.) or cognitive or psychiatric disorders that could influence QoL. Sixteen patients had to be excluded since 10 had a fibromyalgia,

one had rheumatoid arthritis and five had psychiatric disorders. Therefore, 124 AS patients (80 males, 44 females; mean age 40.6 ± 11.1 years; range, 20 to 65 years) were included. After a detailed physical examination that included anthropometric measurements to determine body mass index (BMI), the participants' demographic information was obtained. The patients were assessed for pain level according to the 10 cm visual analog scale (VAS) from 0 (no pain) to 10 (maximum pain). All patients were assessed by the same physician. The study protocol was approved by the Pamukkale University Ethics Committee (registration number: 60116787-020/26226, date of approval: April 29, 2014). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) was used to evaluate disease activity using six self-reported questions pertaining to fatigue, spinal and peripheral joint pain, localized tenderness and morning stiffness. This index uses 10 cm VAS to measure the severity of symptoms in patients with AS. The final BASDAI score has a range of 0 to 10; a lesser number represents less severe disease activity.¹¹ Moreover, a cutoff score of four or more is used to define active disease.¹²

The Bath Ankylosing Spondylitis Functional Index (BASFI) was used to determine the degree of functional limitation in patients with AS. The BASFI includes 10 questions answered using a 10 cm VAS, with a recall period of the past week. The mean of the 10 questions gives the BASFI score between 0 and 10, with a higher score indicating more functional limitation.¹³ The Turkish versions of the BASDAI and BASFI were shown to be reliable and valid.^{14,15}

The Bath Ankylosing Spondylitis Metrology Index (BASMI) was used to quantify the mobility of the axial skeleton in AS patients. The BASMI consists of four spinal measures and one hip mobility measure combined into one index. Each measure is assigned a score of 0 to 2 with the higher score indicating greater impairment in mobility.¹⁶

The ASQoL is a disease-specific instrument designed to measure the impact of AS on health related QoL from the patient's perspective.

The ASQoL includes 18 yes or no questions related to the impact of disease on sleep, mood, motivation, coping, activities of daily living, independence, relationships, and social life with a total score of 0-18. Lower ASQoL scores represent a better QoL.¹⁷ It was shown that the Turkish version of the ASQoL was reliable and valid.¹⁸ The Turkish validated version of the ASQoL was used in this study.

In order to examine the self-reported health status, short form-36 (SF-36) instrument was used in this study. The SF-36 is the most widely used general health status questionnaire that provides scores across eight health domains: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, mental health and role limitations due to emotional problems. Each domain is scored ranging from 0 to 100, and higher scores indicate better QoL.¹⁹ The concept of the first question primarily reflects the overall health status at which patients consider themselves well or not. AS patients were classified into two subgroups according to the replies to this first question of SF-36 as having better (Excellent, Very good, Good) or impaired (Fair or Poor) global health status.⁷ The reliability and validity of the Turkish version of SF-36 were also shown.²⁰

Statistical analysis

The ASQoL can distinguish between groups of patients that are known to differ by some factor that would be expected to influence the scores for good discriminative properties. Sample size was calculated as 120 patients to determine the significance of the differences on clinical parameters when patients were compared according to cutoff value of ASQoL score with a power of 85% or above based on the data obtained from the other studies. All statistical analyses were performed using the IBM SPSS for Windows version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to describe demographic characteristics. The Kolmogorov-Smirnov test was used to analyze normal distribution assumption of the data. As the distributions were normal, parametric tests were used in statistical evaluation. Pearson's correlation analysis was used to assess correlation among parametric variables. We determined

the Pearson's correlation coefficient for each of the comparisons, classifying them as moderate, strong, or very strong correlations if the value was between 0.40 and 0.69, 0.70 and 0.89, and 0.90 and 0.99, respectively.²¹ For each total ASQoL score, sensitivity and specificity were computed and graphed in a receiver operating characteristic (ROC) curve according to clinical parameters which have the strongest correlations with ASQoL, disease activity and also the patients' global health status which was evaluated by the first question of SF-36. The ROC curve was used to select optimal cutoff ASQoL scores for screening patients who had impaired QoL. Discriminant statistics such as sensitivity, specificity and Youden index for each possible ASQoL cutoff score were also obtained. For continuous variables, the significance of the differences was analyzed using Student's t test to compare clinical features according to cutoff value of ASQoL. In all analyses, *p* values <0.05 were considered as statistically significant.

RESULTS

The disease duration of the AS patients was between 0.5 and 40 years with a mean of 8.3 ± 8.2 years. The prevalence of peripheral arthritis involvement and positive family history were found in approximately one third of AS patients. Demographic characteristics of AS patients included in this study are given in Table 1. In the present study, the lowest SF-36 subgroup score was in general health. Vitality, bodily pain and physical role subgroups followed it, respectively. The mean ASQoL score was found to be 8.8 ± 4.9 . Clinical characteristics of the study population are also summarized in Table 1.

There was a positive strong correlation between ASQoL and BASDAI ($r=0.721$, $p<0.001$), furthermore a positive moderate correlation between ASQoL and BASFI, BASMI, pain VAS was demonstrated ($r=0.582$, $r=0.400$, $r=0.618$, $p<0.001$, respectively). However, ASQoL scores were not related to duration of disease, age and BMI of patients ($p>0.05$). When the correlation coefficients were analyzed, ASQoL showed the strongest positive correlation with BASDAI. Significant negative correlations were also found between ASQoL and the SF-36 subscale scores except for mental health and emotional role. There

Table 1. Demographic and clinical characteristics of patients with ankylosing spondylitis (n=124)

	AS patients		
	n	%	Mean±SD
Age (year)			40.6±11.1
Sex			
Male	80	64.5	
Female	44	35.5	
Disease duration (year)			8.3±8.2
Body mass index (kg/m ²)			25.5±3.7
Educational level			
Primary school	56	45.2	
High school	30	24.2	
University	38	30.6	
Family history			
No	86	69.4	
Yes	38	30.6	
Peripheral involvement			
Absent	88	71	
Present	36	29	
Extraarticular findings			
Absent	94	75.8	
Present	30	24.2	
Low back pain VAS			4.3±2.9
BASDAI			3.7±2.4
BASFI			2.8±2.6
BASMI			2.4±2.6
ASQoL			8.8±4.9
Short Form-36			
Physical function			70.1±24.0
Social function			67.6±27.3
Bodily pain			51.9±23.1
Vitality			51.2±22.4
Emotional role			66.1±39.9
Physical role			55.4±38.9
Mental health			60.6±19.9
General health			42.1±18.4

AS: Ankylosing spondylitis; SD: Standard deviation; VAS: Visual analog scale; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; ASQoL: Ankylosing spondylitis quality of life.

was a negative moderate correlation between ASQoL and SF-36 subscale scores of bodily pain, general health, physical role, physical function, and social function ($r=-0.624$, $r=-0.580$, $r=-0.510$, $r=-0.510$, $r=-0.432$, $p<0.001$, respectively). The strongest negative correlation was found between ASQoL and the first question of SF-36 which evaluates the patients' global health status ($r=-0.844$, $p<0.001$). Moreover, SF-36 subscale score of vitality also had weak correlation with ASQoL ($r=-0.337$, $p<0.001$). Correlations between ASQoL and clinical parameters are given in Table 2.

Table 2. Relationship between clinical features and disease specific quality of life in patients with ankylosing spondylitis

	ASQoL Pearson's correlation coefficients (r)	p
Age	0.060	0.507
Body mass index	0.053	0.558
Duration of disease	0.114	0.206
BASDAI	0.721	<0.001
BASFI	0.582	<0.001
BASMI	0.400	<0.001
Low back pain VAS	0.618	<0.001
SF-36 First Question	-0.844	<0.001
SF-36		
Physical function	-0.510	<0.001
Social function	-0.432	<0.001
Bodily pain	-0.624	<0.001
Vitality	-0.337	<0.001
Emotional role	-0.157	0.081
Physical role	-0.510	<0.001
Mental health	-0.150	0.097
General health	-0.580	<0.001

ASQoL: Ankylosing spondylitis quality of life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; VAS: Visual analog scale; SF-36: Short Form-36.

Receiver operating characteristic curve for ASQoL scores was estimated using the agreement between ASQoL scores and clinical parameters which have the strongest correlations with ASQoL in the absence of gold standard to determine the impaired QoL (Figure 1). Disease activity and the patients' global health status which have the strongest correlation with ASQoL were used to determine the cutoff value of ASQoL. The area under the ROC curve (AUC) was 0.84 when comparing whether QoL was impaired or not with ASQoL scores according to higher disease activity (AUC=0.84 [95% confidence interval (CI): 0.770-0.908, $p<0.001$]). Furthermore, AUC was 0.85 when comparing whether QoL was impaired or not with ASQoL scores according to the patients' global health status (AUC=0.85 [95% CI: 0.782-0.923, $p<0.001$]). If we select a single cutoff value, we could use the ASQoL score >8 for impaired QoL where sensitivity and specificity were simultaneously maximized with a higher value for the Youden index considering disease activity and the patients' global health status as well. In this study, when the cutoff value >8 was

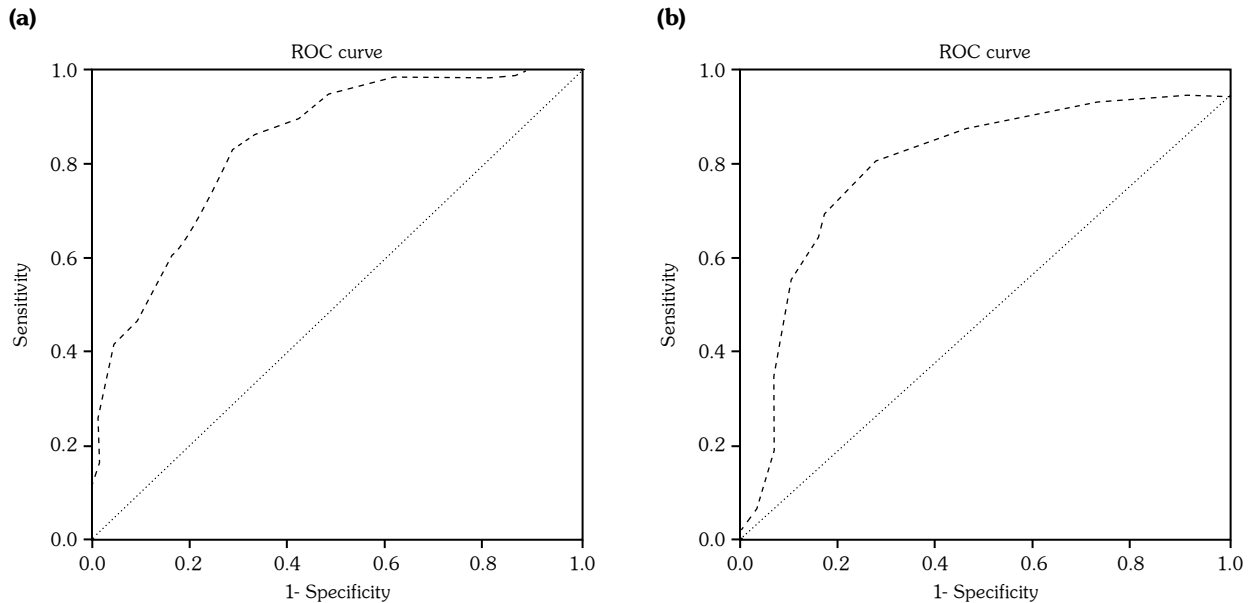


Figure 1. (a) Receiver operating characteristic curve for impaired quality of life according to disease activity. Area under the curve: 0.84. (b) Receiver operating characteristic curve for impaired quality of life according to global health status. Area under the curve: 0.85.

ROC: Receiver operating characteristic.

used, sensitivity was found 82.8% and specificity was 71.2% considering higher disease activity. On the other hand, when the patients' global health status was considered, sensitivity and specificity were 85.1% and 73.7%, respectively. Therefore, a single cutoff value of >8 could be used with a higher sensitivity for each most related domain.

When patients were compared according to their disease specific QoL, it was observed that patients with impaired QoL (ASQoL >8) had significantly higher disease activity and pain VAS ($p < 0.001$), in addition poorer functional status, spinal mobility and SF-36 subscale scores except for mental health and emotional role scores

Table 3. Comparison of clinical features according to disease specific quality of life in patients with ankylosing spondylitis

	ASQoL ≤8 (n=57)	ASQoL >8 (n=67)	p*
	Mean±SD	Mean±SD	
BASDAI	2.1±1.4	5.1±2.1	<0.001
BASFI	1.3±1.4	4.0±2.7	<0.001
BASMI	1.3±1.7	3.3±2.9	<0.001
Low back pain VAS	2.6±2.1	5.8±2.7	<0.001
Short Form 36			
Physical function	83.5±13.2	58.7±25.3	<0.001
Social function	79.2±19.9	57.7±27.0	<0.001
Bodily pain	66.3±18.7	39.7±19.2	<0.001
Vitality	58.1±19.1	45.3±23.4	0.001
Emotional role	73.7±35.5	59.7±42.5	0.052
Physical role	76.3±32.9	37.7±34.6	<0.001
Mental health	61.6±18.4	59.8±21.2	0.608
General health	53.4±15.2	32.4±15.2	<0.001

ASQoL: Ankylosing spondylitis quality of life; SD: Standard deviation; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; VAS: Visual analog scale; * Student's t-test.

compared to patients with better QoL (ASQoL ≤ 8) ($p < 0.001$) as shown in Table 3.

DISCUSSION

In this cross-sectional study, we investigated disease specific QoL and related variables in patients with AS. Our results demonstrated significantly positive correlation between ASQoL, and BASDAI, BASFI, BASMI, pain VAS whereas significantly negative correlations between ASQoL and the SF-36 subscale scores except for mental health and emotional role. Moreover, a cutoff value of eight in ASQoL showed good discriminative properties for impaired QoL according to disease activity and the patients' global health status in patients with AS.

There is a rapidly growing interest in the assessment of QoL, particularly in chronic rheumatic diseases over the last decade. It is increasingly recognized that the generic and disease specific instruments are complementary.^{22,23} However, few studies provide information on interpretation of results, which is important for their application in clinical trials and clinical care. In the present study, the most preferable general health status questionnaire, SF-36, was used for assessing the impact of AS on health related QoL along with ASQoL, which is a disease-specific tool. In a study conducted on 962 patients with AS, the lowest scores in SF-36 were noted in general health, physical role, bodily pain and vitality subscales.⁹ Similarly, in another study, physical role, emotional role, bodily pain and general health subgroups of SF-36 were found to be the most significantly affected dimensions in patients with AS.²⁴ Ozgul et al.² also suggested that AS has a negative influence mainly in physical role, general health and bodily pain dimensions of SF-36 in their series of 101 patients with AS. In another study, consistent with these studies, it was reported that most affected domains of SF-36 were bodily pain, vitality, and physical role.⁵ Reported results indicate that AS affects mostly physical domains of QoL. These findings are consistent with previous studies indicating that the physical domain was significantly more impaired than the mental one.²⁵⁻²⁷ In accordance with these findings, we also found that the lowest SF-36 subgroup score was in general health. Vitality,

bodily pain and physical role subgroups followed it, respectively.

All instruments measure related aspects of health and disease that may have impact on normal function; therefore, a relationship between these instruments was expected. For instance, when the relationship between a disease specific and a generic QoL instrument was examined, studies which evaluated the QoL via SF-36 reported a moderate correlation between ASQoL and SF-36.^{7,8} It was suggested that correlations between the ASQoL and the SF-36 scales were moderate, indicating that they assess related but distinct concepts. Similarly, in another study, a significant correlation between ASQoL and SF-36 was demonstrated.⁹ Our results are also consistent with these studies, showing significant correlations between ASQoL and the SF-36 subscale scores except for mental health and emotional role.

It is important for clinicians to be aware of complicated relationships between clinical variables and QoL. In a cross-sectional study, it was concluded that BASDAI, BASFI, fatigue and pain are the most significant variables associated with QoL in patients with AS.⁹ Thus; disease activity, functional status, fatigue and bodily pain could be considered as the most significant variables affecting QoL in AS patients. In another study, ASQoL was found to be correlated with disease activity, functional status, spinal mobility, severity of total pain, night pain, fatigue and morning stiffness. BASDAI showed the strongest correlation with ASQoL.²⁸ In a recent study, it was suggested that the impairment of QoL in patients with AS was mainly associated with disease activity and worsening of functionality.²⁹ Similarly, in a retrospective case series study, it was concluded that poor QoL is significantly correlated with high disease activity, poor functional status and decreased spinal mobility in AS.³⁰ In consistent with these studies, we also demonstrated significantly positive correlation between ASQoL and BASDAI, BASFI, BASMI, and pain VAS. When the correlation coefficients were analyzed, BASDAI showed the strongest positive correlation with ASQoL. Severity of total pain, functional status and spinal mobility followed it, respectively.

A binary definition of QoL, as proposed in this study, could facilitate the definition

of a recommended target value for a given QoL scale. Recently published cross-sectional studies proposed a cutoff for QoL scale in older adults.^{31,32} However there is still no gold standard measurement or evaluation method to determine the impaired QoL in patients with AS. To determine the impaired QoL value, ASQoL sensitivity and specificity indexes were computed using it for patients with impaired QoL according to clinical parameters which have the strongest correlations with ASQoL; higher disease activity (BASDAI ≥ 4), and also the patients' global health status which was evaluated by the first question of SF-36. To our knowledge, there was no clinical study in the literature which gives information about cutoff value for ASQoL. In a cross-sectional study, the patient acceptable symptom state which reflects the overall health state that patients consider themselves well has been suggested as eight for ASQoL, confirming our data.³³ Patients' opinions of their symptom state were recorded with a "yes" as opposed to a "no" answer to the question; "Considering all the different ways your disease is affecting you, if you were to stay in this state for the next few months, do you consider that your current state is satisfactory?" in that study.³³ The question evaluating the patient acceptable symptom state is similar to the first question of SF-36. When we also select a single cutoff value, we could use the ASQoL score >8 for impaired QoL with a higher value for the Youden index considering disease activity and global health status as well. Furthermore, when patients were evaluated according to ASQoL score >8 , AS patients who had impaired QoL had significantly higher disease activity and pain VAS, in addition to poorer functional status, spinal mobility and SF-36 subscale scores.

A potential limitation of our study is its cross-sectional design. In addition, demographic characteristics and disease specific instruments were the patient related data we collected, so we were not able to assess the separate contribution of all possible confounders that have been associated with QoL in patients with AS which reduced the statistical power of our study. We excluded the other concomitant rheumatic diseases such as fibromyalgia and rheumatoid arthritis that could influence QoL in accordance with the other QoL studies which may be thought as a bias. Concomitant rheumatic diseases were excluded

in order to create a more homogenous cohort of patients with typical AS. Finally, the present study was performed only in one clinic; therefore, the sample may not be the representative of the whole AS population.

In conclusion, there was a moderate correlation between ASQoL and the SF-36 subscale scores except for mental health and emotional role which suggests that they measure different aspects of QoL. Moreover, a cutoff value of eight in ASQoL could be used to determine the impaired QoL in AS.

Declaration of conflicting interests

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