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ORIGINAL ARTICLE

Value of Egy-Score in Prediction of HCV Response to Sofosbuvir-Based Therapy

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Abstract

Background: **Liver fibrosis (LF) develops as a result of nearly all chronic liver injuries. In order to foretell the development of the illness and monitor the effectiveness of therapy interventions, it is important to assess LF. The Egy-Score is a brand-new noninvasive score that could be utilized to predict severe LF.**

Objective: **This research's objective is to look at whether Egy-Score can be used as a noninvasive panel of biomarkers for fibrosis for predicting the response to new hepatitis C antiviral treatments in Egyptian patients, determine if Egy-Score will be affected broadly by treatment or not.**

Patients and methods: **This study involved 100 HCV-infected patients, including chronic hepatitis and cirrhotic patients, who received new hepatitis C antiviral therapy. The patients were recruited from Kafr Elsheikh liver institute and liver clinic of Alexandria fever hospital, Egypt, and selected according to the Egyptian protocol for the treatment of hepatitis C virus.**

Results: **Our study reported that cut-off for baseline EGY score to predict responder patients from nonresponder in all studied patients was ≤2.92, sensitivity was 77.53, Specificity 90.91, PPV was 98.6, NPV was 33.3. Cut off for baseline EGY score to predict responder patients from nonresponder in cirrhosis group was <4, sensitivity was 92.68, specificity 66.67, PPV was 92.7, NPV was 66.7.**

Conclusion: **EgyScore showed good sensitivity, specificity, positive and negative predictive values of HCV response to sofosbuvir-based therapy, and overall accuracy for detecting different stages of hepatic fibrosis and cirrhosis in patients with chronic hepatitis C.**

Keywords: Egy-score, HCV, Liver fibrosis, Sofosbuvir based therapy

1. Introduction

Cirrhosis can develop as a result of liver fibrosis (LF), a type of chronic liver damage. Almost all chronic hepatic damage causes LF, which occurs as a response. A precise evaluation of the fibrosis degree or existence of cirrhosis is essential for the proper therapy of people suffering from chronic hepatitis C infection (CHC) and to provide a diagnosis. While sampling mistakes and interobserver variations are difficulties with the procedure, the hepatic biopsy was traditionally regarded as the standard technique for defining the fibrosis stage.[1]

Because of the restrictions and invasive nature of hepatic biopsies, there was a lot of interest in developing noninvasive assays to evaluate LF in CHC patients. Numerous noninvasive procedures, from advanced imaging technologies to serum marker assays, have been demonstrated to have been effective tools for the assessment of LF in CHC

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individuals. For the purpose of detecting fibrosis or cirrhosis, numerous blood tests were suggested as alternatives to liver biopsies.[2]

These blood tests can be divided into direct and indirect LF indicators. Direct indicators are molecules produced by extracellular matrix turnover that reflect the fibrotic process' activity. Indirect indicators represent changes in the functions of the liver and meet the need for simple and easy-to-use indicators.[1]

For the assessment of liver disease, the majority of direct indicators are not frequently requested, although the majority of indirect indicators are frequently utilized and easily accessible. Platelet count, aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ratios, and prothrombin index are a few examples of indirect indicators.[3]

Collagens (like type IV collagen and its fragments and procollagen I C-peptide, procollagen III N-peptide), glycoproteins and polysaccharides (like hyaluronic acid, laminin, and tenascin and YKL40), collagenases and their inhibitors (like metalloproteinases and metalloproteinase tissue inhibitors), as well as cytokines (like transforming growth factor β1 and platelet-derived growth factor) are examples of direct indicators. Because of individual indicators' lack of accuracy in assessing LF, algorithms or indices combining indicators panels were developed.[4]

The FibroTest, AST to platelet ratio index, FIB4, FORNS' indices, HepaScore, FibroMeters, FibroIndex, FibroSpect II, as well as the European liver fibrosis index, represent the most frequently utilized panels. The development and validation of these indicators began with CHC individuals, and they are currently being used to treat other chronic hepatic illnesses. Noninvasive diagnostic methods are unreliable for distinguishing between the intermediate fibrosis stages.[5]

Thus, we still require novel and more precise biomarkers to evaluate LF. EgyScore is a comparatively recent panel of biomarkers used to evaluate the hepatic fibrosis stage in chronic hepatic disease patients. It has been initially studied in a variety of patient groups (autoimmune hepatitis, chronic hepatitis B, and C). EgyScore is the outcome of a six-parameter regression equation (CA199, age, albumin, total bilirubin, alpha-2-macroglobulin, and platelet count).[1]

This research's objective is to determine whether Egy-Score can be used as a noninvasive panel of biomarkers for fibrosis for predicting the response to new hepatitis C antiviral treatments in Egyptian patients, as well as to determine if Egy-Score will be affected broadly by treatment or not.

2. Patients and methods

This study involved 100 HCV-infected patients, including chronic hepatitis and cirrhotic patients, who received new hepatitis C antiviral therapy. The patients were recruited from Kafr Elsheikh liver institute and liver clinic of Alexandria fever hospital, Egypt, and selected according to the Egyptian protocol for the treatment of hepatitis C virus.

Two groups of 50 patients each were formed from the 50 patients:

Group I: chronic hepatitis patients. (50 patients).

Group II: cirrhotic patients. This group was subdivided into 3 subgroups: patients from child Class A (23), child Class B (22), and child Class C (5 patients).

Egy-Score was calculated pre- and post-treatment for all patients.

2.1. Exclusion criteria

Malignancy, and HCC.

All patients underwent the following:

Through taking a history comprising age, gender, duration of illness, history of previous therapy, history of bilharziasis, and associated diseases, e.g., diabetes mellitus.

Drug history stressing on Regimen of treatment, adherence of the patient to the optimum dose and timing of antiviral drugs, as well as the history of adverse effects to antiviral drugs and their impact on dose reduction or interruption of therapy.

Full clinical evaluation emphasizing, in particular, body weight, body mass index (BMI), jaundice, extra-hepatic manifestations of chronic HCV infection, organomegaly.

2.2. Investigations

2.2.1. Laboratory investigations

(a) Whole blood picture, tests for kidney function {blood urea, Serum creatinine} and fasting blood sugar. (b) Liver test profile: alanine and aspartate aminotransferases (ALT, AST), serum albumin, prothrombine activity, serum billirubin, CA19-9 and alpha-2-macroglobulin. (c) Viral markers: HCV antibody and hepatitis B surface antigen by ELISA Technique. Quantitative PCR for HCV RNA before starting antiviral therapy, during therapy (within 4 weeks of initiating treatment) and at the end of therapy (within 3 or 6 months of initiating treatment). (d) Follow up of adverse events to therapy and its effect on dose and duration of treatment.

2.2.2. Imaging study

Abdominal ultrasound for assessment of the tissue echo pattern of the liver, portal vein diameter, liver size and to exclude the presence of cirrhosis. Also, the tissue echo pattern and the size of the spleen was assessed.

Child-Turcotte-Pugh (CTP) was calculated for cirrhotic patients.

2.2.3. Detection of degree of fibrosis

These markers were calculated pre-treatment:

The formula used to calculate Egy-Score was as follows: Egy-Score = 3.52 + 0.0063 × CA 19−9 (U/ml) + 0.0203 × age (year) + 0.4485 × alpha-2-macroglobulin (g/l) + 0.0303 × bilirubin (umol/l) − 0.0048 × platelet (109/l) − 0.0462 × albumin (g/l).

The FIB-4 score: This score is determined by age, platelet count, AST, as well as ALT. The HCV and HBV monoinfections can be detected using the Fib-4 score. For isolated HCV, it displayed an AUC of 0.85 for detecting severe fibrosis.

2.3. Statistical analysis

The data was loaded onto the computer and analysed with the IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). To describe qualitative data, numbers and percentages have been used. The Kolmogorov-Smirnov test has been employed to confirm the distribution's normality. The range (min and max), mean, median, standard deviation and interquartile range (IQR) have been employed to describe quantitative data. The obtained findings' significance has been established at the 5% level. To compare different groups, use the Chi-square test for categorical data. Whenever more than 20% of the cells get an anticipated count below 5, Fisher's exact correction for chi-square is used. Use the student t-test for normally distributed quantitative data for comparing two groups under study. The paired *t*-test is used for comparing two periods of normally distributed quantitative data. For comparison between the two study groups, use the Mann-Whitney test for quantitative variables with abnormal distributions. Sensitivity (TP) on the Y axis and 1-specificity (FP) on the X axis are plotted at various cutoff values to generate the receiver operating characteristic curve (ROC). The ROC curve enables performance comparisons among two tests. *P* values < 0.05 have been regarded as significant.

3. Results

Group I: Chronic hepatitis, and Group II: Cirrhosis.

There have been significant age differences between the two groups (Table 1).

Regarding the baseline EGY score, there were significant differences across both groups (Table 2).

There has been a highly significant difference between the baseline EGY score before treatment and the EGY score after treatment in both chronic hepatitis patients and child class A and child class B patients. There has been no significant difference in child class C patients (Table 3).

In terms of PV, spleen, liver texture, and liver size, there have been significant differences between both groups (Table 4).

There have been significant differences between both groups as regard EGY score components (Table 5).

There has been a significant relationship between EGY score baseline treatment with response in group I, in group Child A and in the Child B group (Table 6).

Cut off for baseline EGY score to predict responder patients ($n = 89$) from nonresponder was ≤2.92, Sensitivity was 77.53, Specificity 90.91, PPV was 98.6, NPV was 33.3 (Table 7).

Cut off for baseline EGY score to predict responder patients was <4, sensitivity was 92.68, Specificity 66.67, PPV was 92.7, NPV was 66.7 (Table 8).

4. Discussion

According to this research, there have been significant age differences between both groups.

Cavalcante and Lyra[6] reported in their study that predictive indicators of sustained therapeutic response in the "age" of based-interferon treatment have become less significant with the entrance of direct-acting antivirals, although viral genotype, cirrhosis, as well as viral kinetics could still influence treatment results with the novel accessible medicines.

Table 1. A demographic data comparison of the two study groups.

	Group I ($n = 50$) No. (%)	Group II ($n = 50$) No. (%)	Test of Sig.	*P*
Sex			$\chi^2 = 1.440$	0.230
Male	22 (44.0)	28 (56.0)		
Female	28 (56.0)	22 (44.0)		
Age (years)			$t = 3.240$[a]	0.002[a]
Min. − Max.	28.0−60.0	32.0−60.0		
Mean ± SD.	43.32 ± 8.91	48.30 ± 6.22		
Median (IQR)	44.50 (36.0−50.0)	49.50 (43.0−53.0		

IQR, Inter quartile range; SD, Standard deviation; t, Student t-test; χ^2, Chi square test.

p: the *P* value for comparing the groups under study.

[a] At $P \leq 0.05$, it is statistically significant.

Table 2. Comparison of the baseline EGY scores between the four study groups.

Baseline EGY score	Group I ($n = 50$)	Group II ($n = 50$)			F	*P*
		Child A ($n = 23$)	Child B ($n = 22$)	Child C ($n = 5$)		
Min.–Max.	1.56–3.01	2.09–3.19	3.0–5.0	4.80–5.30	156.663[a]	<0.001[a]
Mean ± SD.	2.22 ± 0.36	2.66 ± 0.24	3.71 ± 0.47	5.10 ± 0.21		
Median (IQR)	2.22 (1.95–2.50)	2.69 (2.51–2.82)	3.72 (3.38–3.93)	5.10 (5.0–5.30)		
P_0		<0.001[a]	<0.001[a]	<0.001[a]		
Sig. bet. grps.		$P_1 < 0.001$[a],$P_2 < 0.001$[a],$P_3 < 0.001$[a]				

F: F for One way ANOVA test, the Post Hoc Test was used for the pairwise comparison of each two groups (Tukey).
P: the *P* value for comparing the groups under study.
P_0: the *P* value used to compare Group I to all other groups.
P_1: the *P* value used to compare children A and B.
P_2: the *P* value used to compare children A and C.
P_3: the *P* value used to compare children B and C.
[a] At P ≤ 0.05, it is statistically significant.

According to this study, the baseline EGY score between both groups indicated a highly significant difference.

Alboraie et al.[7] showed that egyScore accurately differentiated between significant liver cirrhosis, severe hepatic fibrosis, and cirrhosis.

For the purposes of predicting cirrhosis (F4), severe LF (≥F3), and significant LF (≥F2), various Eyesore cutoff values were investigated. Their study provides a summary of the sensitivity, specificity, and values of positive and negative predictive of various EgyScore cutoff values for detecting cirrhosis (F4), severe LF (≥F3), and significant LF (≥F2). The most important cutoff values for significant LF (≥F2), severe LF (≥F3), and cirrhosis (F4) were 2.91850, 3.28624, and 3.67570, respectively. The EgyScore's diagnostic value has been evaluated using ROC curve analysis that yielded AUROCs of 0.776, 0.875, and 0.874 for the diagnosis of significant LF, severe LF, and cirrhosis, respectively.

The Egy-Score panel of surrogate biomarkers is a useful noninvasive tool for predicting the various stages of LF in people with CHC.

This research revealed that there were highly significant differences between baseline EGY score before treatment and EGY score after treatment in both chronic hepatitis patients and child class A patients and child class B patients, but no significant difference in child class C patients.

This demonstrates a clear enhancement in HCV patients who have advanced, compensated hepatic diseases following a prolonged virological responsiveness to direct-acting antivirals.

Similar to findings, Giannini et al.[8] reported that in patients who have advanced, compensated chronic hepatic diseases, SVR significantly improves

Table 3. Comparison of the baseline and after treatment based on EGY score in each group and subgroup.

EGY score	Baseline treatment	After treatment	t	*P*
Group I	($n = 50$)	($n = 50$)	8.356[a]	<0.001[a]
Min. − Max.	1.56–3.01	0.60–2.80		
Mean ± SD.	2.22 ± 0.36	1.78 ± 0.43		
Median (IQR)	2.22 (1.95–2.50)	1.80 (1.50–2.10)		
Child A	($n = 23$)	($n = 23$)	12.961[a]	<0.001[a]
Min. − Max.	2.09–3.19	1.11–3.0		
Mean ± SD.	2.66 ± 0.24	1.70 ± 0.49		
Median (IQR)	2.69 (2.51–2.82)	1.54 (1.34–1.92)		
Child B	($n = 22$)	($n = 22$)	10.738[a]	<0.001[a]
Min. − Max.	3.0–5.0	1.60–4.60		
Mean ± SD.	3.71 ± 0.47	2.47 ± 0.80		
Median (IQR)	3.72 (3.38–3.93)	2.17 (2.0–2.70)		
Child C	($n = 5$)	($n = 5$)	1.771	0.151
Min. − Max.	4.80–5.30	3.67–5.40		
Mean ± SD.	5.10 ± 0.21	4.57 ± 0.83		
Median (IQR)	5.10 (5.0–5.30)	4.90 (3.70–5.20)		

IQR, Inter quartile range; SD, Standard deviation; t, Paired *t*-test.
p: the *P* value comparing the basal treatment and after treatment.
[a] At P ≤ 0.05, it is statistically significant.

Table 4. Comparison of the two study groups based on various parameters.

	Group I ($n = 50$) No. (%)	Group II ($n = 50$) No. (%)	$\chi 2$	P
Liver Size			6.613[a]	0.022[a]
Normal	36 (72.0)	24 (48.0)		
Enlarged	14 (28.0)	24 (48.0)		
Shrunken	0 (0.0)	2 (4.0)		
Liver Texture			100.0[a]	<0.001[a]
Normal	50 (100.0)	0 (0.0)		
Coarse	0 (0.0)	50 (100.0)		
Spleen			14.943[a]	<0.001[a]
Normal	50 (100.0)	37 (74.0)		
Enlarged	0 (0.0)	13 (26.0)		
PV			14.943[a]	<0.001[a]
Normal	50 (100.0)	37 (74.0)		
Dilated	0 (0.0)	13 (26.0)		
Ascites			1.010	$FE_p = 1.000$
Absent	50 (100.0)	49 (98.0)		
Present	0 (0.0)	1 (2.0)		

FE, Fisher Exact; χ^2, Chi square test.
P: the *P* value for comparing the groups under study.
[a] At $P \leq 0.05$, it is statistically significant.

liver stiffness in the long run, and this enhancement is followed by an improvement in indirect markers of hepatic fibrosis and function, as well as a drop in portal hypertension parameters.

Table 6. Relation between EGY score baseline treatment with response in each group and each subgroup.

EGY score baseline treatment	Response		t	*P*
	Non-Responder	Responder		
Group I ($n = 50$)	($n = 2$)	($n = 48$)	2.104[a]	0.041[a]
Min.–Max.	2.47–3.01	1.56–2.92		
Mean ± SD.	2.74 ± 0.39	2.20 ± 0.35		
Median	2.74	2.18		
Child A ($n = 23$)	($n = 2$)	($n = 21$)	2.945[a]	0.008[a]
Min. – Max.	2.96–3.19	2.09–2.92		
Mean ± SD.	3.07 ± 0.16	2.62 ± 0.21		
Median	3.07	2.67		
Child B ($n = 22$)	($n = 4$)	($n = 18$)	2.607[a]	0.017[a]
Min.–Max.	3.38–5.0	3.0–4.23		
Mean ± SD.	4.20 ± 0.67	3.60 ± 0.35		
Median	4.20	3.59		
Child C ($n = 5$)	($n = 3$)	($n = 2$)	2.928	0.061
Min. – Max.	5.10–5.30	4.80–5.0		
Mean ± SD.	5.23 ± 0.12	4.90 ± 0.14		
Median	5.30	4.90		

SD, Standard deviation; t, Student t-test.
p: the *P* value for comparing non-responders to responders.
[a] At *P* 0.05, it is statistically significant.

Also, Abdelsameea et al.[9] concluded that DAA regimens are a breakthrough of the century. DAAs have shown true significant effects on all HCV-related health risks, which were initially derived from hepatic fibrosis regression, which would be

Table 5. Comparison of the two study groups based on EGY score components.

	Group I ($n = 50$)	Group II ($n = 50$)	U	*P*
Alpha 2 Macro globulin			U = 791.50[a]	0.001[a]
Min.–Max.	0.54–3.84	0.53–3.89		
Mean ± SD.	1.27 ± 0.76	1.75 ± 0.83		
Median (IQR)	1.05 (0.60–1.7)	1.49 (1.1–2.3)		
CA 19.9			U = 828.50[a]	0.004[a]
Min. – Max.	0.30–228.0	0.70–228.0		
Mean ± SD.	25.10 ± 33.28	46.74 ± 48.60		
Median (IQR)	18.0 (9.8–30.0)	29.50 (17.9–62.0)		
INR			T = 2.416[a]	0.018[a]
Min.–Max.	1.03–1.30	1.01–1.51		
Mean ± SD.	1.07 ± 0.06	1.11 ± 0.09		
Median (IQR)	1.03 (1.03–1.09)	1.06 (1.04–1.14)		
Bilirubin			U = 705.50[a]	<0.001[a]
Min. – Max.	0.10–1.24	0.40–1.80		
Mean ± SD.	0.48 ± 0.36	0.80 ± 0.34		
Median (IQR)	0.53 (0.10–0.70)	0.70 (0.60–0.90)		
Platelets ($\times 10^3$)			t = 5.351[a]	<0.001[a]
Min. – Max.	144.0–350.0	72.0–304.0		
Mean ± SD.	228.8 ± 45.33	174.5 ± 55.62		
Median (IQR)	226.0 (195.0–256.0)	170.0 (135.0–201.0)		
Albumin			t = 5.087[a]	<0.001[a]
Min. – Max.	3.40–5.50	2.60–4.90		
Mean ± SD.	4.05 ± 0.42	3.54 ± 0.56		
Median (IQR)	4.0 (3.80–4.30)	3.50 (3.0–4.0)		

IQR, Inter quartile range; SD, Standard deviation; U: Mann Whitney test.
p: the *P* value for comparing the studied groups.
[a] At $P \leq 0.05$, it is statistically significant.

Table 7. Validity (AUC, sensitivity, specificity) for baseline EGY score to predict responder patients (n = 89) from non-responder (n = 11).

	AUC	*P*	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
Baseline EGY score	0.873	<0.001[a]	0.770–0.976	≤2.92[b]	77.53	90.91	98.6	33.3

AUC, Area Under a Curve; CI, Confidence Intervals; NPV, Negative predictive value; *P* value, Probability value; PPV, Positive predictive value.

[a] At P ≤ 0.05, it is statistically significant.

[b] According to the Youden index, a cutoff was chosen.

regarded as the milestone of chronic hepatic diseases with associated complications.

This study found highly significant differences between both groups as regards albumin.

This is similar to Mak et al.,[10] who reported that the loss of liver cell mass results in a reduction in albumin synthesis in cirrhotic patients. Furthermore, portal blood flow is frequently reduced and poorly distributed, resulting in nutrient and oxygen maldistribution.

Also, Hoffman,[11] reported that albumin and globulin are the two primary proteins produced by the liver. Low levels could indicate disease or damage.

This study demonstrated that there have been highly significant differences between both groups as regards platelets.

This is consistent with the findings of Peck-Radosavljevic,[12] who reported that thrombocytopenia is a prevalent haematological condition in people who have the chronic hepatic disease. It has multiple contributing factors, with liver disease severity being the most significant one.

This study revealed highly significant differences in INR between both groups.

This is similar to Hoffman,[11] who reported that the Prothrombin Time (PT) test measures the length of time it takes for your clotting blood to occur. It could be a symptom of liver damage if it takes a lengthy period of time.

This study revealed a highly significant difference in bilirubin levels between both groups.

This is similar to the result of Hoffman,[11] who showed that the liver removes bilirubin from the body. Blood with high bilirubin levels might mean damage or disease.

This study reported a significant difference between both groups concerning PV, spleen, liver texture, and liver size.

In a retrospective review by Zhang et al.,[13] individuals with CHB who had percutaneous liver biopsies have been examined. A statistical analysis has been performed on the correlation between age, ALT, and hepatitis B e-antigen, as well as the thickness of the spleen, and the spleen's prognostic value has been assessed. We verified a tight and statistically significant relationship between splenomegaly and significant LF.

This study reported a highly significant difference in Alpha 2 Macroglobulin levels between both groups.

Alboraie et al.[7] showed that the mean Alpha 2 Macro globulin was 2.57 ± 0.54.

This study found a highly significant difference in CA 19.9 between both groups. Alboraie et al.[7] showed that the mean CA was 15.07 ± 16.64.

This study demonstrated highly significant differences between responders and nonresponders according to the baseline EGY scores in both chronic hepatitis patients and children's class A and B patients. In the children's class C patients, there have been no significant differences between responders and nonresponders.

In addition, Kinoshita et al.[14] reported that liver stiffness measurements predict responsiveness to sofosbuvir-based therapy regimens I and concluded that baseline liver stiffness (LS) measured with transient elastography (TE) and FIB-4 could be beneficial to predict therapy outcomes in the new era of DAAs and may be incorporated into the pre-therapy evaluation of chronic HCV patients for better patient therapy.

Table 8. Validity (AUC, sensitivity, specificity) for baseline EGY score to predict responder patients (n = 41) from non-responder (n = 9) in cirrhosis group.

	AUC	*P*	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
Baseline EGY score	0.844	0.001[a]	0.704–0.984	≤4[b]	92.68	66.67	92.7	66.7

AUC, Area Under a Curve; CI, Confidence Intervals; NPV, Negative predictive value; p value, Probability value; PPV, Positive predictive value.

[a] At P ≤ 0.05, it is statistically significant.

[b] According to the Youden index, a cutoff was chosen.

Our study reported that cut off for baseline EGY score to predict responder patients from non-responder was ≤2.92, sensitivity was 77.53, Specificity 90.91, PPV was 98.6, NPV was 33.3. Cut off for baseline EGY score to predict responder patients from nonresponder in cirrhosis group was <4, sensitivity was 92.68, Specificity 66.67, PPV was 92.7, NPV was 66.7.

4.1. Conclusion

EgyScore showed good sensitivity, specificity, positive and negative predictive values of HCV response to sofosbuvir-based therapy, and overall accuracy for detecting different stages of hepatic fibrosis and cirrhosis in patients with chronic hepatitis C.

Conflicts of interest

None declared.

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