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# Overview of myelodysplastic syndrome in Baghdad, Iraq- clinical picture and outcome

## Abstract

**Background:** Myelodysplastic syndromes (MDS) can represent a challenge in diagnosis and treatment because of heterogeneous presentation, unpredictable response to variable measures with propensity for leukemic transformation.

**Aim of study:** To review MDS Iraqi patients in term of presentation, risk stratification and treatment options and to assess outcome of different treatment options in term of response criteria, quality of life and progression.

**Patients and method:** a hospital based study conducted over a period of 21 months from January 2018 till October 2019 in different hematology centers in Baghdad. Any patient with primary or therapy related MDS diagnosed were enrolled in this study. Each patient stratified into different risk groups when applying cytogenetic versus non cytogenetic scoring systems, the therapeutic options for every patient. They observed for their response to different therapeutic modalities and any evidence of progression.

**Results:** Mean age at diagnosis for MDS was 58.7±17. Anemia was the most common presenting symptom representing 68.4% of patients. MDS with excess blasts-II is forming 28.8%. Majority of patients categorized as intermediate risk group. Hypomethylating agents used for 50% of MDS patients while 32.1% received best available therapy.

Those on HMA achieve partial remission in 7.1%, 25.2% reached to stable disease, hematological improvement in 25.2%. Death outcome in 21.6 with a mean survival is 7.7 months. Disease progression in 10.8%, 7.2% showed leukemic transformation.

**Conclusion**: Iraqi MDS patients present at younger age with advanced manifestation that needs standard risk stratification. The non-cytogenetic score systems can't be of equivalent application even low resources circumstances.

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## Introduction

The myelodysplastic syndromes (MDSs) are a group of hematologic disorders often characterized by cytopenias in one or more hematopoietic lineages despite hypercellularity in bone marrow, with evidence for ineffective and dyspoietic hematopoiesis.[1] Patients with these disorders experience complications from cytopenias and may have propensity to progress to acute leukemia.[1]

Unfortunately; in Iraq, MDS has not been studied and little is known about its epidemiology, behavior and prevalence, but it is reported in other countries with overall, incidence is ranging between 3.2 to 4 per 100,000 annually.[2,3] Cytogenetic abnormalities present in 40–60% of patients with MDS , which are more frequent in higher grade MDS (i.e. MDS with an increase of blast cells and a worse prognosis) and in therapy related than de novo disease. Cytogenetic abnormalities are often unbalanced, e.g. trisomy 8, 19 or 21, monosomy 5 or 7, 1q+, 5q–, 7q–, 12p+, 17q– or 20q–. Certain balanced translocations and other chromosomal rearrangements also occur, e.g. inv(3)(q21q26.2) or t(3;3)(q21;q26.2).[4]

The current clinical management of MDS focuses on assessing disease risk at diagnosis by assaying clinical and patient characteristics and using prognostic scoring systems to estimate survival and risk of evolution to AML. This information is used to guide therapeutic recommendations for patients, which range from watchful waiting to palliation of symptomatic cytopenias to disease-altering treatments, such as chemotherapy and potentially curative allogeneic hematopoietic cell transplantation.[5]

In 1997, an International MDS Risk Analysis Workshop defined the International Prognostic Scoring System (IPSS) for primary, untreated MDS, based on bone marrow blast percentage, number of peripheral cytopenias, and karyotype.[6] Inappropriately, this system underestimates the clinical importance of severe neutropenia and thrombocytopenia in determining the need for therapeutic intervention, as well as it does not take into account the slope of any change in the critical parameters throughput disease course, such as the peripheral blood counts or blast percentage.[7]

WHO classification-based prognostic scoring system (WPSS) could predict survival and leukemia progression at any time during the course of disease, so it is a dynamic prognostic scoring system applied to reassess outcomes.[8] The Revised IPSS (R-IPSS) was developed to address some of limitations of IPSS system but it is only valid at diagnosis.[9]

In limited resources situations; when cytogenetic study are not accessible; an alternative scoring system may be required, such as the Spanish Sanz (Sanz et al, 1989) depending on percent of bone marrow blasts, platelets number and patient age or Bournemouth (Mufti et al, 1985) scores considering percent of bone marrow blasts, neutrophils, platelets count and hemoglobin level.[10–12]

## Objectives

To review MDS Iraqi patients in term of presentation, risk stratification and treatment options and to assess outcome of different treatment options in term of response criteria, quality of life and progression

## Patients and method

The study is a prospective study of MDS patients who were enrolled from different Hematology centers of Baghdad over a period between January 2018- October 2019. It includes any adult patient above 15 years old with a report of primary or therapy related myelodysplastic syndrome (MDS).

The diagnosis of every case was based on blood film with bone marrow examination according to at least interpretation by two hematopathologists for a morphological diagnosis proposed by WHO 2016 ,after an exclusion of secondary causes of dysplasia/cytopnia, like drug, alcohol, HIV and B12 deficiency. Cytogenetic study was done for only small number of patients as it is not available routinely. Every patient categorized according to WHO system.[13]

All patients were interviewed concerning demand for blood product supplement, erythropoiesis stimulating agent (ESA) or granulocyte colony stimulating factor (G-CSF), frequency of febrile illness, disease progression and specific therapy taken and any evidence of response and complications of treatment.

Response assessed according to International Working Group IWG 2006 criteria.[14]

All patients were informed about the study with a consent taken for agreement of participation of their records. MDS transformed to acute leukemia and even patient with uncontrolled advanced co morbidity had excluded.

- Selection of study sample:

Prognosis of patients with MDS can be calculated using a number of scoring systems included R-IPSS whenever it is available, but those who didn't perform a cytogenetic study assessed by Sanz score and Bournemouth score.[10–13]

- Data collection:

In addition to demographic, clinical data and laboratory data, risk stratification were all evaluated at time of presentation according to registration file as well as therapeutic option and response assessment after a period of follow up.

Treatment options for a given risk group were trucked for each patient, as lower risk patients and those of high risk but unable to tolerate high intensity therapy are dependent on supportive measures in form of blood products transfusion, erythropoesis stimulating agents, those with low risk, hypocellar marrow, non transfusion dependent are expected to respond to immune modulator/ immunosuppresent agents eg. Cyclosporine or ATG, high risk patients are candidate to high intensity chemotherapy and/ or allogenic stem cell transplant. Hypomethylating agents (Azacitidine or Decitabine) are good choices for high risk patients who are not candidate for intense therapy.

### Definition of responses and outcomes

The primary outcome was overall survival at the end of this study period means the length from either the date of diagnosis or the start of treatment for a disease, while secondary outcomes encompasses depth of response to variable measures and disease progression.

Depth of response in term of complete remission (CR) [< 5% bone marrow myeloblast with normal maturation of all cell lines with persistent dysplasia (should consider the normal range of dysplastic changes], partial remission (PR) [reduction of bone marrow blast by > 50% with other features of CR] and stable disease (SD) [failure to achieve PR in as a minimum response with no evidence of disease progression] is measured by applying IWG 2006 response criteria of MDS.[14]

Hematological improvement (HI) is a type of response evaluated according to IWG criteria for each cell line; namely HI-Erythroid [Hb increase by 1.5x109/L], HI-platelet [increase count modified according to baseline] and HI-neutrophil [increase count at least 100%]. Disease progression is defined as upgrading of MDS category, return to previous marrow state prior to intervention or AML transformation.

### Statistical analysis

All descriptive data were defined in terms of frequency , percentage, ratio, range and mean +SD like age groups, sex differences, risk groups, clinical manifestations and the hematological parameters using SPSS software Version 23. Statistical anyalsis using Student T test to define the most prevalent risk group with relationship to demographic data, clinical presentation, laboratory data, risk groups.

## Results

### Patients descriptions

It consists of 28 patients with MDS (including one patient with most likely therapy related MDS) with a follow up for 21 months. The mean age (± standard deviation) was 58.7(±17),with male representation of 57.1% (16/28) (M:F ratio of 1.3:1). Co-morbid disease (hypertension, diabetes mellitus, ischemic heart disease) is found in 57.1% (16/28) of patients (Table 1).

**Table 1** Demographic characteristics of patients.

| Variables | | MDS |
|---|---|---|
| Age | <60 years | 14(50%) |
| | ≥60 years | 14(50%) |
| | Mean ±SD | 58.7(±17) |
| Gender | Male | 16(57.1%) |
| | Female | 12(42.9%) |
| Co-morbid diseases | -ve | 12(42.9%) |
| | +ve | 16(57.1%) |
| Performance status | 0 | 10(35.7%) |
| | 1 | 10(35.7%) |
| | 2 | 8(28.6%) |
| | 3 | 0 |
| TOTAL | | 28 |

### Clinical manfestation

Features of anemia is the commonest manifestation in MDS patients forming 68.4% and the rest was distributed as such 25.2% of patients had fever in addition to anemia, 28.8% of patients had bleeding, 14.4% presented with splenomegaly and 10.8% of patient was accidentally finding in context of preparation for surgical procedure, other unusual presentation (sweet syndrome) was noticed in 3.6% of patients.

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## Hematological parameters

The initial hematological parameter showed that the mean white blood cell (WBC) is 5±4.7 x$10^9$/L (ranging between 1.1-34x$10^9$/L), the mean absolute neutrophil count (ANC) is 2.6±3.4 (ranging between 0.2-18 x$10^9$/L), the mean hemoglobin level (Hb) is 6.7±1.5 g/dl (ranging between 3-10 g/dl), the mean platelet is 118±133 x$10^9$/L (ranging between 5-510x$10^9$/L).

## Hematopathological classification

According to WHO classification (2016) , MDS with single lineage dysplasia (MDS-SLD) is found in 10.7% , MDS with multilineage dysplasia (MDS-MLD) is found in 14.3%, as well as MDS with excess blast-1 (MDS-EB-I) is found in 14.3%, MDS with excess blasts-II (MDS-EB-II) is found in 28.6%, but MDS with isolated del (5q) is found in 3.6% (Figure 1). The risk stratification for all patients was measured according different scoring systems, as showed in Table 2. Cytogenetic study was documented in 6 patients, 4 are with normal karyotype, 1 monosomy 7, 1with 5q deletion.

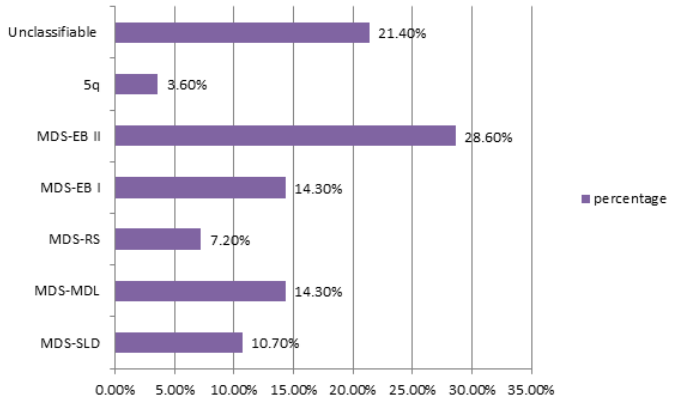


**Figure 1** WHO classification (2016) of MDS and unclassified cases.

**Table 2** Risk stratification of studied patients

| Risk stratification | | | NO(%) |
|---|---|---|---|
| MDS | IPSS-R | Very high | 2(7.1%) |
| | | High | 8(28.6%) |
| | | Intermediate | 12(42.9%) |
| | | Low | 5(17.9%) |
| | | Very low | 1(3.6%) |
| | Sanz | High | 3(10.7%) |
| | | Intermediate | 19(67.8%) |
| | | Low | 6(21.4%) |
| | Bournemouth | High | 4(14.3%) |
| | | Intermediate | 22(87.6%) |
| | | Low | 3(10.7%) |

## Treatment strategies

The treatment strategy are classified as supportive measures (blood products, hemopoietic growth factors), low intensity therapy (hypomethylating agents (HMA) and other best available therapy (BAT) that involved are low intensity chemotherapy (eg. Subcutaneous cytosine arabinoside), Immunomodulatory drug (IMiDs) and/or immune suppressants (eg. Cyclosporine) and/or anabolic steroids (danazole) and/or prednisolone and/or thrombopoietin receptor agonist as well as hydroxyurea and high intensity therapy (intensive chemotherapy and allogenic stem cell transplant (Allo-SCT). They are distributed as 10.7% are totally dependent on supportive measures, 50% received HMA with or without trying other best available therapies, 32.1% received variable low intensity therapies only, 7.1% performed Allo-SCT, while none received intensive chemotherapy among MDS patients.

## Response

For lower-risk MDS; the main goals of treatment are managing cytopenias and improving quality of life while for higher-risk MDS; it was for halting disease progression. Among all patients; 7.2% achieved complete remission (CR), both following Allo-SCT, 3.6% achieved partial remission (PR) on treatment by HMA, while 25.2% kept stable disease (SD) (5 of them on HMA). Hematological improvement is seen in 25.2% patients, 7.2% of them on HMA and the remaining 5 on BAT, 7.2% of them showed a relapse after HI. There were 21.6% who didn't achieve any response at all, 2 are lost, 1 is enrolled at end of study and it didn't followed. On focusing 14 MDS patients who are treated by HMA as a separate group; 7.1% (1) of them achieved PR, 35.5% (5) labelled as SD, 14.2% (2) got leukemic transformation, 14.2% (2) achieved hematological improvement alone (Table 3).

Regarding risk groups; higher risk groups: two MDS patients of very high risk group; 1 dead and another is lost. Among 8 MDS patients with high risk group; 2 patients achieved complete remission (CR), 4 stable, 1 transformed to acute myeloid leukemia, 1 isn't evaluated yet, while for intermediate and low risk groups; the unavailability of cytogenetic studies which may change the category preclude stratification. 17 (61.2%) patients showed improvement of QoL received variable therapeutic strategies.

The final outcome of MDS patients was Death in 21.6% (6) of patients (3 patients due to infection, 2 patients due to bleeding and one patient due to both infection and bleeding) with mean survival months was 7.7 months. 7.2% (2) of patients achieved CR on regular follow up. Progression of disease is seen in 10.8% (3) of patients (2 of them transformed to Acute myeloid leukemia), with mean period of 9.3 months(ranging from 6-12 mo.), all on HMA, the 2 leukemic transformation events seen with a mean time of 11 month. The rest are stable (25.2%) (Figure 2).

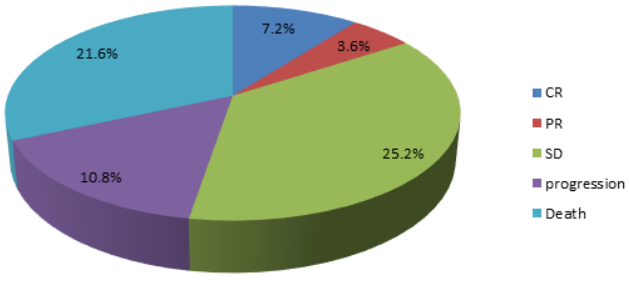


**Figure 2** Outcome of MDS patients.
*These percentages represented the patients who reached to final outcome (best response, progression and death), collectively 68.4% of total patients. The remainder 31.6% include those who got initial response (HI), those who didn't respond, lost patients and those who are not evaluated yet

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**Table 3** Response assessment for patient on HMA.

| Outcome | No. (%) | Risk group | |
|---|---|---|---|
| Complete remission | 0 | 0 | |
| Partial remission | 1 (7.1%) | Intermediate | |
| Stable disease | 5 (35.5%) | High | Intermediate |
| | | 2 | 3 |
| Hematological improvement | 2 (14.2%) | High | Intermediate |
| | | 1 | 1 |
| Failure 6 | | | |
| Progression | 2 (14.2%) | High | Intermediate |
| | | 1 | 1 |
| Death | 4 (28.4%) | Very high | Intermediate |
| | | 1 | 3 |
| Total No. | 14 | | |

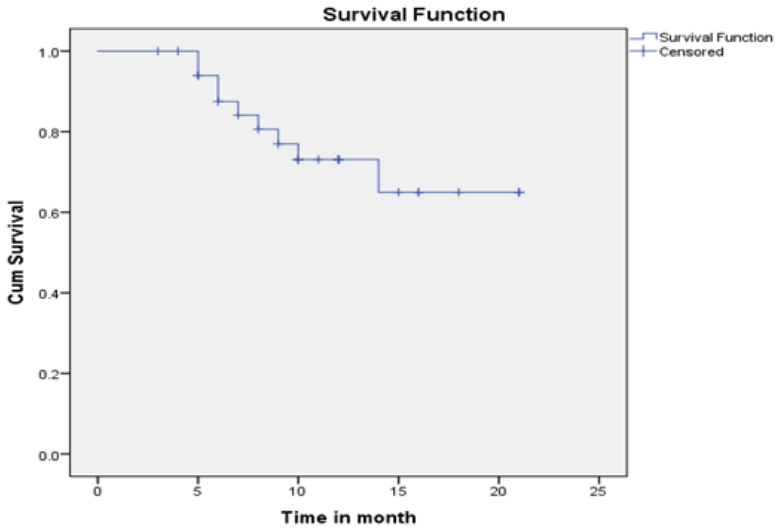


**Figure 3** KAPLEN MEIER overall survival analysis for MDS patients.

The overall survival (OS) was 64% and the mean months of survival was 16.7 months, the mean survival refers to the average number of months that people survive after being diagnosed with MDS (Figure 3). Test of equality of survival distributions for the different levels of risk stratification was no significant between different levels of risk stratification(p=0.5), the mean survival in high risk was 19.2 months, in intermediate was 14.1 months while in low risk 11.8 months (Table 4) (Figure 4).

**Table 4** Test of equality of survival distributions for the different levels of risk stratification

| Variable | | Number of death (%) | Mean survival (months ) | 95% confidence interval | | P value |
|---|---|---|---|---|---|---|
| | | | | Lower border | Upper border | |
| IPSS-R | High | 1(11.1%) | 19.2 | 16 | 22.4 | 0.4* |
| | Intermediate | 3(25%) | 14.1 | 10.9 | 17.4 | |
| | Low | 2(40%) | 11.8 | 7.5 | 16.1 | |

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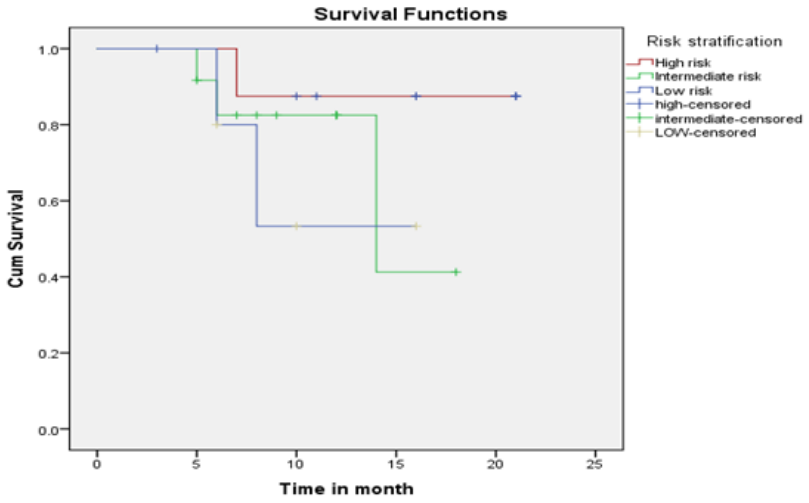


**Figure 4** KAPLEN MEIER overall survival [analysis] for different risk groups for MDS patients.

The death occurred in 40% (8) of patients with co-morbid disease and MDS while it occurred in 6.7%(1) of patients with without comorbidities and there were a significant association between history of co-morbid disease and death occurrences (p=0.048) (Table 5).

**Table 5** Relation of Death occurrence and some variable in MDS patients

| Variables | | Death | | P value |
|---|---|---|---|---|
| | | Occur | Not | |
| Age | <60 years | 2 (14.3%) | 12 (85.7%) | 0.36* |
| | ≥60 years | 4 (33.6%) | 8 (66.7%) | |
| Gender | Male | 4 (28.6%) | 10 (71.4%) | 0.64* |
| | Female | 2 (16.7%) | 10 (83.7%) | |
| Co-morbid diseases | -ve | 1 (9%) | 10 (90%) | 0.048* |
| | +ve | 5 (33.3%) | 10 (66.7%) | |
| Treatment strategy | BAT | 2 (18.2%) | 9 (81.8%) | 0.67* |
| | HMA | 4 (26.7%) | 11 (73.3%) | |

N.B: the total no. of patients calculated above is 26 + 2 lost with unknown fate

# Discussion

## Demographic and clinical data

In this study; the mean age of onset in MDS is similar to that of a study in Jordan 15, while others report a higher age 16,17,18 This may be indicate a younger onset in Iraq and adjoining countries, it's unknown if genetic or environmental factors being the cause behind this difference. Male to female ratio is 1.3:1, for MDS, which is comparable to that of Canadian study16, US 1.2:117, Sedighi et al as well reported similar percentage regarding the Iranian patients.[19]

The vast majority of the patients enrolled in this study presented with features of anemia followed by features of infection; which is compatible with others[14,15,20] that indicate an advanced presentation.

## Risk stratification

R-IPSS grouping, couldn't be applied exactly for all patients, but it is estimated that higher risk groups (7.1% very high + 28.6% high) constitute collectively 35.7% which is significantly lower than that estimated by Zaher et al. 13.8% (8.6% very high + 5.2% high).[20] Most patients in this study have the higher risk grouping at time of presentation even in absence of cytogenetics.

According to Bournemouth and Sanz score, it is found that the intermediate risk is the prominent group for both scores (67.8% for Sanz, 87.7% for Bournemouth).[10–13] However; the reliability of these scores is questionable ,as there are 10 patients estimated by R-IPSS as higher risk, while only 3 of them (10.7% ) are labeled as high risk by Sanz score and the remaining 6 patients as intermediate risk, the last one became of low risk. Similarly, regarding Bournemouth score

as 4 patients (14.3%) are considered as high risk while the rest are downgraded to intermediate risk group. Notably; Căzăceanu O has proved the importance of age and male gender when adopted non cytogenetic scores in his study.[21]

### Therapeutic strategies and response

Till now, the Allo-SCT is the only therapeutic strategy that could alter the nature of disease and achieved CR. HMA was adopted in 50%; the maximum response was PR in 3.6% which represents 7.1% of those treated with HMA and this is not much different from that demonstrated by Jabbor et al and Hussain but lower than Nazha et al finding of 12% PR to HMA.[22–25]

No CR seen among any of the studied patients; however, this is not the case in a study by Kantarjian et al when CR on Decitabine is 9% as well as Saba 2007 of 9%, apart from Nazha et al who demonstrated 17% CR in response to HMA.[23,25] This lower response rate may be a result of treatment interruption and small sample of this study.

Maintaining a stable disease reports in 35.5% similar to Nazha et al.[25] Hematological improvement only among patients on HMA estimated to be 14.2% which is highly comparable to Nazha et al finding of 15% and not far from 13% found by Jabbor et al and Kantarjian et al.[22,23,25]

QoL is the earliest and most evident response among patients received different therapeutic modalities, 61.2% MDS patients showed improved QoL, 21.6% of them on HMA, little is known about this term of response, although Kantarjian et al cited briefly to superior QoL in comparison supportive measures.[23]

### Survival and leukemic transformation

Leukemic transformation occurred in 7.2%; all on HMA, in a mean period of 11 months from starting therapy, this coincides with finding of Kantarjian et al 2006 of 12.1 months, and not much far from Nazha et al 14.6 months.[23,25] Both transformed patients are below 60 years old which is incompatible with Ofir Shukron et al of higher risk of leukemic transformation in patients older than 65 years old.[26]

The overall survival is 64%, showed significant p value with comorbidities (p=0.048) which is comparable to Naqvi et al who demonstrated a significant impact of comorbidities on survival in MDS.[27] Treatment strategy has no impact on mean overall survival of 16.7 months, and that is not different of Hagop Kantarjian et al.[23]

## Conclusion

Iraqi MDS patients present at younger age with advanced manifestation that needs standard risk stratification to justify a proper treatment decision. The non-cytogenetic score systems can't be of equivalent application even low resources circumstances. HMA with best supportive care can modify disease course partially but curative treatment could be obtained only for those who have underwent allo-SCT.

## Acknowledgments

None.

## Conflicts of interest

The authors declare no conflicts of interest.

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