Original Article

Characteristics and Prognostic Factors of Myelodysplastic Syndrome Patients in Ramathibodi Hospital: A Retrospective Study

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Background : *Myelodysplastic syndrome (MDS) remains a challenging problem in hematology practice. Prognostic factors for disease outcome are well-defined in western population. However, whether or not these factors are valid in Thai patients is still to be evaluated.* ***Methods :*** *A retrospective study was performed examining patient and disease characteristics of 53 MDS patients in Ramathibodi Hospital. Various outcomes of each group of patients were measured and compared.* ***Results :*** *The median age was 74 years old and 45.3% were male. Thirteen of them had International prognostic scoring system (IPSS) intermediate-2 risk or above whereas 16 were classified as RAEB (refractory anemia with excess blasts)-1 or RAEB-2. The most frequent cytogenetic results were normal karyotype. The median overall survival was 78 months. On univariate analysis, older age (≥70 year), male gender, hemoglobin <9g/dL, pancytopenia, bone marrow blast ≥ 10%, intermediate-2 and high risk IPSS, very high risk WHO classification-based prognostic scoring system (WPSS) and no erythroid response after 12 week of treatment were significantly associated with worse overall survival (P < 0.05). Multivariate analysis showed only two prognostic factors, age more than 70 years old and pancytopenia, associated with poor overall survival.* ***Conclusion:*** *Findings in this study supported the previously reported prognostic factors in MDS and may provide initial information on outcomes of Thai patients with myelodysplastic syndrome.*

Key Words : ● *Myelodysplastic syndrome* ● *Prognosis* ● *Retrospective study*

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Introduction

Myelodysplastic syndrome (MDS) is a heterogenous group of clonal hematological disorders characterized by a profound defect in myeloid stem cell resulting in one or more lineages of cytopenia (anemia, neutropenia and thrombocytopenia).

As a result, patient with MDS are at risk for symptomatic anemia, infections and bleeding, as well as progression to acute leukemia[1]. Patients with MDS have been classified into subgroups based upon the percentage of bone marrow blasts, according to 1982 French, American and British (FAB) consensus conference and the WHO classification provided an extension and improvement of FAB classification[2,3].

An international myelodysplastic syndrome risk analysis workshop performed a global analysis of survival data related to numerous clinical variables from seven previously reported studies of patients with primary MDS. This resulted in an International prognostic scoring system (IPSS), which was published in 1997. In this system, percentage of marrow blasts, certain cytogenetic abnormalities and numbers of cytopenias were used in combination to define a risk group for both

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overall survival and acute myeloid leukemia evolution in a given patient. Patients with low, intermediate-1, intermediate-2 and high risk groups have overall survival of 5.7, 3.5, 1.2 and 0.4 years respectively[3].

In respect to survival, the MDS patients display a very diverse pattern. Some of them developed leukemia shortly after diagnosis, while others could be sustained for years. Various opinions have arisen regarding the prognostic factor in MDS patients, particularly International prognostic scoring system (IPSS)[4]. Other adverse prognostic factors and risk models, which have been reported to improve the prognostic value of IPSS include patients age[4], performance status[4], total white blood cell counts[4], severity of anemia[5], transfusion dependence[6], CD 34 positivity of bone marrow nucleated cell[7], red blood cell mean corpuscular volume[8], increase of Wilm's tumor gene[9], increase in serum beta-2 microglobulin concentration[10], mutation of the FLT3 gene[11], decrease in platelet mass[12], present of bone marrow fibrosis[13], low level of circulating endothelial cells[14], abnormal localization of immature precursor (ALIP).

The purpose of this study is to study the characteristics of patients with myelodysplastic syndrome in Ramathibodi hospital in relation to survival rates, prognostic factors for survival rates and analysis of treatments.

Patients and Methods

The data of all 53 adult, age $\geq$15 years, patients with primary MDS who attended hematology clinic at Ramathiodi hospital during January 2000 to October 2010 were analyzed. The diagnosis and classification of MDS were defined based on WHO classification 2008[15] and bone marrow smears were confirmed by at least two hematologists. Hematological improvement is based on International working group response criteria 2000 (IWG 2000)[16]. We excluded therapy-related MDS and patients who had prior malignancy before diagnosis of MDS.

Statistical analysis

Log rank test and the Kaplan-Meier analysis were used to evaluate and compare survival rate. Survival was measured from diagnosis to death or last date of follow up. The Cox regression model was applied for multivariate survival analysis and identification of the most significant independent prognostic factors related to survival. All analysis was performed using SPSS version 16. A p value less than 0.05 was considered statistically significant.

Results

The characteristics of patients are show in table 1. Patients included 24 men (45.3%) and 29 woman (54.7%) with a median age of 74 years (range 24-89 years). The mean white blood cell (WBC) count was 4.5 x 10^9/L, mean hemoglobin was 9.0 g/dL and mean platelet count was 150 x 10^9/L. Median follow up time was 19.9 months (range 1.4-119.6 months).

By IPSS criteria based on their initial presentation to our institution, 6 (13.2%) patients were considered low risk, 31 (58.5%) patients were considered intermediate-1 risk, 10 (18.9%) patients were considered intermediate-2 risk, and 3 (5.7%) patients were considered high risk.

The results of cytogenetic analysis were available in 50 patients, among whom 26 patients (49.1%) were normal and 24 patients (50.9%) were not. According to IPSS, 30 patients (56.6%) were classified as a good cytogentic risk, 11 patients (20.8%) were intermediate and 9 (16.9%) were poor cytogenetic risk groups.

Twenty-eight patients (52.8%) received erythropoietin, 10 (18.9%) patients received G-CSF, 3 (5.7%) patients received hypomethylating agent, 14 (26.7%) received anabolic hormone and 1 (1.9%) patients underwent stem cell transplantation. Other 13 (24.5%) patients did not receive any treatment due to mild degree of cytopenia and 4 (7.5%) patients received only transfusion.

Among the patients who received treatments, 19 patients (52.7%) met IWG 2000 for erythroid response after 12 weeks of the treatment and 17 patients did not respond.

In patients who received erythropoietin, 14 patients

Table 1 Initial characteristics of patients at diagnosis

Parameter	No of patients	%	Mean	Median
Age (years)			70.0	74.0
Gender				
Male	24	45.3		
Female	29	54.7		
Occupation				
Civil service	2	3.8		
Official clerk	2	3.8		
Agriculture	5	9.4		
Factory	3	5.7		
Business	5	9.4		
House wife	10	18.9		
Elderly/retire	26	49.1		
Co-morbid diseases				
Cardiovascular	11	20.8		
Cerebrovascular	3	5.7		
Diabetes	18	34		
Hypertension	29	54.7		
Renal disease	8	15.1		
Liver disease	3	5.7		
Other	24	45.3		
Performance status				
0	17	32.1		
1	30	56.6		
2	5	9.4		
3	1	1.9		
4	0	0		
Hemoglobin (g/dL)			9.0	8.6
< 10	33	62.3		
10-10.9	8	15.1		
11-11.9	7	15.1		
≥ 12	5	9.4		
White blood cell ($x10^9$/L)			4.55	3.92
< 4.0	27	50.9		
4.0-10.0	24	45.3		
≥ 10.0	2	3.8		

Table 1 Initial characteristics of patients at diagnosis (continued)

Parameter	No of patients	%	Mean	Median
Platelet (x10^9/L)			150	110
<20	5	9.4		
20-49	5	9.4		
50-99	10	18.9		
100-140	14	26.4		
>140	19	35.8		
Creatinine (mg/dL)				
<1.3	38	71.7		
≥1.3	15	28.3		
Albumin (g/L)				
2.0-2.9	11	20.8		
3.0-3.9	24	45.3		
≥4	18	34		
Erythropoietin levels (mIU/mL)				
<200				
≥200	14	26.4		
Not done	5	9.4		
	34	64.1		
antiHIV				
Not available	24	45.3		
Negative	29	54.7		
HBsAg				
Not available	24	45.3		
Negative	26	49.1		
Positive	3	5.7		
Anti-HCV				
Not available	24	45.3		
Negative	29	54.7		
Serum ferritin (ng/mL)				
Not available	31	30.2		
<500	16	30.2		
500-1,000	2	3.8		
>1,000	4	7.5		
Number of cytopenia				
1	15	28.3		
2	20	37.7		
3	18	34.0		

Table 1 Initial characteristics of patients at diagnosis (continued)

Parameter	No of patients	%	Mean	Median
Chromosome study				
Not available	3	5.7		
Normal	26	49.1		
-Y	3	5.7		
-X	0	0		
Del 5q	1	1.9		
Del 20q	0	0		
+8	0	0		
Chromosome 7 abnormality	2	3.8		
Complex chromosome	7	13.2		
Other*	11	20.8		
MDS subtype				
RCUD	9	17.0		
RARS	5	9.4		
RCMD	23	43.3		
RAEB-1	8	15.1		
RAEB-2	8	15.1		
5q-	0	0		
IPSS				
Low	6	11.3		
Intermediate-1	31	58.5		
Intermediate-2	10	18.9		
High	3	5.7		
WPSS				
Very low	8	15.1		
Low	17	32.1		
Intermediate	11	20.8		
High	11	20.8		
Very high	3	5.7		
Treatments				
Erythropoietin	28	52.8		
G-CSF	10	18.9		
Hypomethylating agent	3	5.7		
Chemotherapy	0	0		
Anabolic hormone	14	26.7		
Stem cell transplantation	1	1.9		
Miscellaneous	17	32.0		
Transfusion dependent**	13	24.5		

**Polyploidy, 46XX t(4;9), 46X inv(Y); ** A red cell transfusion every 8 weeks at least over a period of 4 months*

(50%) met IWG 2000 for erythroid response after 12 weeks of treatment (7 patients met major response and 7 patients met minor response criteria).

At the time of the last follow-up, 16 (30.1%) patients died with one patient progressed to acute myeloid leukemia and died. Causes of death are listed in Table 2. Nine patients (56.3%) died outside of our hospital, and mortality causes could not be retrieved.

The median overall survival was 78 months (Figure 1) and median overall survival by IPSS risk (low/intermediate-1 vs. intermediate-2/high risk) are shown in figure 2. The characteristics associated with overall survival are shown in Table 3.

Older age (≥70 year), male gender, hemoglobin < 9g/dL, pancytopenia, bone marrow blast ≥ 10%, intermediate-2 and high risk IPSS, very high risk World Health Organization (WHO) classification-based Prognostic Scoring System (WPSS)[17] and no erythroid response after 12 weeks of treatment were significantly associated with worse survival (P<0.05). Comorbid diseases, white blood cell counts, platelet counts, cytogenetic subgroup, treatment and red blood cell transfusion showed no association with survival.

The Cox proportional hazards model was applied to the multivariate survival analysis and identified age ≥ 70 years and pancytopenia as significant factors for poor survival (Table 4).

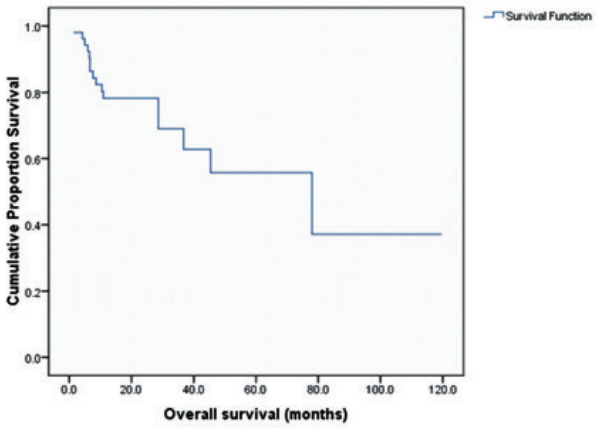

Figure 1 Overall survival (months)

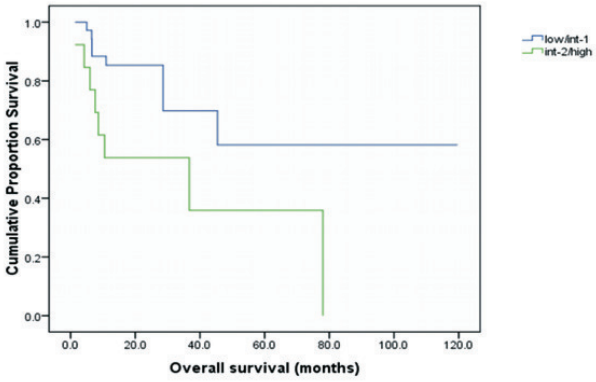

Figure 2 Overall survival by IPSS (months)

Discussion

Our study was done in a single center. We studied patient characteristics, survival rate and prognostic factors for survival rate and treatment outcome analysis in patients with MDS. Our data showed that our patients are in the old age group with median age at diagnosis of 74 years, with more number of women.

The majority of patients with MDS had cytopenia in 2 or 3 lineages and the most frequent cytogenetic was normal karyotype. Based on the IPSS score, the majority of our patients had low and intermediate-1 risk, which showed better clinical outcome and median overall survival was not reached. The median overall

Table 2 Causes of death

Causes of death	No of patients	%
Leukemia	1	6.25
Non-leukemic causes		
Cardiovascular	-	
Infection	6	37.5
Bleeding	-	
Unknown	9	56.25

Table 3 Characteristics associated with overall survival

Parameter	Category	No. of patients	P-value, RR (95%CI)
Age(years)	<70/≥70	18/35	0.04, 7.71(1.10-53.83)
Gender	Male/Female	24/29	0.006, 2.65(1.07-6.59)
Co-morbid disease	Cardiovascular	11	0.64, 0.54(0.14-2.05)
	Cerebrovascular	3	0.37, -
	Diabetes	18	0.60, 0.64(0.24-1.72)
	Hypertension	29	0.60, 1.37(0.58-3.24)
	Renal disease	8	0.73, 1.29(0.47-3.54)
	Liver disease	3	0.66, 1.11(0.21-5.81)
Hemoglobin (g/dL)	<9/≥9	29/24	0.01, 2.67(0.99-7.24)
WBC ($x10^9$/L)	<4.0/≥4.0	27/26	0.26, 1.60(0.68-3.78)
Platelet ($x10^9$/L)	<10.0/≥10.0	22/31	0.18, 1.81(0.79-4.12)
Creatinine (mg/dL)	<1.3/≥1.3	38/15	0.96, 1.18(0.45-3.09)
Albumin (g/L)	<3/≥3	11/42	0.41, 1.27(0.50-3.18)
Erythropoietin levels (ng/mL)	<200	14	0.11, 2.10(0.70-6.27)
	≥200	5	
Serum ferritin (ng/mL)	<1,000/≥1,000	18/4	0.40, -
Number of cytopenia	<3/≥3	35/18	0.04, 1.94(0.87-4.32)
%Bone marrow blasts	<10/≥10	46/7	0.01, 2.98(1.48-5.99)
IPSS score	Low/int-1	37	0.02, 0.35(0.16-0.74)
	Int-2/high	13	
WPSS	Very high	3	0.006, 0.44(0.17-1.11)
	Non very high	47	
Cytogenetics	Good/Int	41	0.30, 1.65(0.68-4.02)
	poor	9	
Transfusion	Dependent*	13	0.20, 1.84(0.83-4.09)
	Non-dependent	40	
Erythroid response at	Response	19	0.003, 0.08(0.01-0.56)
12 week	No response	17	

**A red cell transfusion every 8 weeks over a period of at least 4 months; RR: relative risk*

Table 4 Multivariate analysis of prognostic factors for overall survival

Characteristic	Hazard Ratio (95% CI)	P Value
Age ≥70 yr	16.94 (1.97-142.85)	0.01
Pancytopenia	3.84 (1.11-13.33)	0.03
High WPSS	7.58 (0.74-77.66)	0.08
Intermediate-2/high IPSS	2.10 (0.54-8.14)	0.28
Bone marrow blast ≥10%	1.12 (0.18-6.93)	0.89

survival of patients with intermediate-2 and high risk was 16.0 months. The median overall survival of the whole group was 78 months which was longer than the previous studies[3,23]. This may be explained by greater proportion of patients who were in low risk category as majority of patients in our study (69.8%) were classified as either low or intermediate-1 risk by IPSS, and 26 patients (49.1%) had normal karyotype. The longer survival rate may be contributed by some intrinsic or extrinsic pathobiological characteristics in Thai patients, which might be different from other ethnics. Further studies to identify these characteristics may provide more useful information to predict patients' outcome. However, survival rate in high risk group was comparable to other study[3].

In univariate analysis, we found prognostic indicators for survival included age ≥70 years, male gender, hemoglobin <9 g/dL, pancytopenia, bone marrow blast ≥10%, intermediate-2 and high risk IPSS, very high risk WPSS and no erythroid response after 12 weeks of treatment. Using multivariate analysis, only two significant independent prognostic indicators were age ≥70 years old and pancytopenia at presentation which resembled several previous studies[18-22]. The reason that IPSS was not identified as important prognostic factor in our study may be due to the fact that older people tend to have worse IPSS score, together with poor tolerance to aggressive treatments.

Summary

In our study, IPSS together with other patients' characteristics were useful to establish prognostic stratification for survival which could apply to Thai patients. These prognostic factors that we found may provide initial information to develop a prognostic scoring system unique for Thai MDS patients in the future. This limitation of the study is its retrospective design, small number of included patients from a single institute. Further prospective studies with multicenter collaboration may shed further light to the outcome of these patients.

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การศึกษาย้อนหลังถึงลักษณะและปัจจัยที่มีผลต่อ Myelodysplastic Syndrome (MDS) ในโรงพยาบาลรามาธิบดี

กิตติยา มณีเชษฐา, สุภร จันท์จารุณี, วิชัย อติชาตการ, แสงสุรีย์ จูฑา, ธีรยา พัววิไล, พิมพ์ใจ นิภารักษ์ และ อาทิตย์ อังกานนท์

หน่วยโลหิตวิทยา ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

ความเป็นมา *Myelodysplastic Syndrome (MDS) ยังคงเป็นปัญหาที่ท้าทายต่อเวชปฏิบัติทางโลหิตวิทยา ปัจจัยที่มีผลต่อการรักษาของโรคนี้มีผลการศึกษาอย่างชัดเจนในประชากรของประเทศตะวันตก อย่างไรก็ตาม ยังไม่มีข้อมูลที่ชัดเจนว่า ปัจจัยเหล่านี้จะใช้ได้กับผู้ป่วยชาวไทยหรือไม่* ***วิธีการ*** *ทำการศึกษาย้อนหลังเกี่ยวกับลักษณะของผู้ป่วยและลักษณะของโรคในผู้ป่วย 53 คนซึ่งได้รับการวินิจฉัยว่าเป็น MDS ในโรงพยาบาลรามาธิบดี และมีการวัดเพื่อเปรียบเทียบผลลัพธ์ที่ได้ภายในกลุ่มผู้ป่วยดังกล่าว* ***ผลการศึกษา*** *ค่ามัธยฐานอายุของผู้ป่วยเท่ากับ 74 ปี ร้อยละ 45.3 เป็นเพศชาย สิบสามคนในกลุ่มผู้ป่วยมีผลการประเมินด้วย International prognostic scoring system (IPSS) อยู่ในกลุ่มความเสี่ยงปานกลางระดับ 2 (intermediate -2) หรือมากกว่า ในขณะที่อีกสิบหกคนถูกจัดอยู่ในกลุ่ม RAEB (refractory anemia with excess blasts)-1 หรือ RAEB-2 เซลล์พันธุศาสตร์ที่พบมากที่สุดคือเซลล์พันธุศาสตร์แบบปกติ อัตรามัธยฐานของระยะเวลารอดชีวิตคือ 78 เดือน จากการวิเคราะห์โดยใช้ตัวแปรเดี่ยว ผู้ที่มีอายุมากกว่าหรือเท่ากับ 70 ปี เพศชาย ค่าฮีโมโกลบิน น้อยกว่า 9 กรัมต่อเดซิลิตร มีเม็ดเลือดต่ำทั้ง 3 ชนิด (pancytopenia) มีเซลล์ตัวอ่อนในไขกระดูก (bone marrow blast) มากกว่าหรือเท่ากับร้อยละ 10 มีค่าประเมินแบบ IPSS อยู่ในกลุ่มความเสี่ยงปานกลางระดับ 2 (intermediate -2) และกลุ่มความเสี่ยงสูง (high risk) มีค่าประเมินแบบ WHO classification-based prognostic scoring system (WPSS) อยู่ในกลุ่มความเสี่ยงสูงมาก (very high risk) และไม่มีการตอบสนองของเม็ดเลือดแดง (erythoid) หลังการรักษา 12 สัปดาห์ มีความสัมพันธ์กับระยะเวลาการรอดชีวิตที่น้อยกว่าอย่างมีนัยสำคัญที่สถิติที่ระดับ $P<0.05$ การวิเคราะห์แบบใช้ตัวแปรหลายตัวแสดงถึงปัจจัยที่มีผลต่อการรักษาเพียง 2 ปัจจัยคือ อายุที่มากกว่าหรือเท่ากับ 70 ปีและมีเม็ดเลือดต่ำทั้ง 3 ชนิด (pancytopenia) มีความสัมพันธ์กับระยะเวลาการรอดชีวิตน้อย* ***สรุป*** *ผลการศึกษานี้สนับสนุนปัจจัยที่มีผลต่อโรค MDS ที่มีมาก่อนหน้านี้ และอาจให้ข้อมูลเบื้องต้นเกี่ยวกับผลลัพธ์ของโรค MDS ในผู้ป่วยชาวไทยได้*

Key Words : ● *Myelodysplastic syndrome* ● *การพยากรณ์โรค* ● *การศึกษาย้อนหลัง*

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