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Comorbidities and Survival in a Large Cohort of Patients with Newly Diagnosed Myelodysplastic Syndromes

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Abstract

Comorbid conditions have rarely been systematically studied among patients with myelodysplastic syndromes (MDS). We conducted a large population-based study to assess the role of comorbidity in the survival of newly diagnosed MDS patients. This study included 1,708 MDS patients (age $\geq$ 66 years) diagnosed in the US during 2001–2002, with follow-up through the end of 2004. Hazard ratios (HRs) were estimated using multivariate Cox proportional hazard models. The median survival time was approximately 18 months. Fifty one percent of MDS patients had comorbid conditions. Patients with comorbid conditions had significantly greater risk of death than those without comorbidities. The HR was 1.19 (95% confidence interval [CI]: 1.05–1.36) and 1.77 (95% CI: 1.50–2.08) for those with a Charlson index of 1–2 and $\geq$ 3, respectively. The risk of death increases with Charlson index. MDS patients who have congestive heart failure or chronic obstructive pulmonary disease had significantly shorter survival than patients without those conditions, whereas diabetes did not appear to have an impact on survival. This study confirms comorbidity as a significant and independent determinant of MDS survival, and the findings underscore the importance to take comorbid conditions into account when assessing the prognosis of MDS.

Myelodysplastic syndromes (MDS) are a group of clonal disorders characterized by ineffective hematopoiesis, cytopenia and frequent progression to acute myeloid leukemia (AML). MDS is most common among the elderly; the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) data show that approximately 80% of incident MDS patients are diagnosed at 65 years or older ¹. A few characteristics, such as age, gender, blast percentage, number of cytopenias, transfusion dependence and cytogenetics, have been linked to the survival of MDS patients ^{2,3}.

Comorbidities, one or more diseases or disorders existed in addition to an index disease, are a significant concern among the elderly. In the U.S., 45% of the general population and 88% of the population aged 65 years or older have at least one chronic condition ⁴. It has been reported that cancer patients 70 years or older have an average of three comorbidities ⁵. Comorbidities may impact survival or treatment among cancer patients ⁶. Studies have shown that comorbidities affect the prognosis of female breast cancer ⁷, head and neck cancer ⁸, and lung

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cancer⁹. In addition, comorbidities have been identified as significant determinants of response to therapy and survival in older patients with AML¹⁰, a disease closely related to MDS.

Existing data on the role of comorbidities in the survival of MDS are scarce. Findings from two studies conducted in selected MDS patients suggest that comorbidities are useful in predicting survival of MDS patients after allogeneic stem cell transplantation¹¹ and MDS patients with supportive care only¹². Another hospital-based study found that non-hematological comorbidities, such as cardiac diseases, liver or pulmonary disease and solid tumors, negatively affect the survival of MDS patients^{13,14}.

There is a paucity of large population-based studies on the prognostic role of comorbidities in MDS. A database linking records of the SEER program (which has included MDS since 2001) with Medicare claims (which can be used to assess comorbidities) provided a valuable framework for population-based studies to take place. Utilizing the unique SEER-Medicare database, we conducted this study to evaluate the prognostic role of comorbidities among a large cohort of newly diagnosed MDS patients.

Materials and Methods

Data Sources

The SEER program consists of population-based tumor registries in 17 geographic areas, which cover approximately 26.2% of the US population and include the states of California, Connecticut, Hawaii, Iowa, Kentucky, Louisiana, New Jersey, New Mexico, and Utah, the metropolitan areas of Atlanta, Detroit and Seattle (Puget Sound), as well as rural Georgia and American Indians/Alaska Natives residing in the state of Alaska. Having long been viewed as pre-leukemic disorders, MDS are now considered malignancies due to the clonal nature. In the *International Classification of Diseases for Oncology, 3rd edition* (ICD-O-3) published in 2000, the behavior code for MDS was changed from “1” (uncertain whether benign or malignant) to “3” (malignant)¹⁵. In 2001, MDS became reportable to SEER.

The MDS histology types recorded in SEER are based on the ICD-O-3 codes, which overlap with both the French-American-British classification¹⁶ and the World Health Organization recommendation^{17,18}. Below is a list of the eight ICD-O-3 codes included in SEER for MDS: (1) 9980: refractory anemia (RA); (2) 9982: RA with ringed sideroblasts (RARS); (3) 9983: RA with excess blasts (RAEB, including RAEB under the FAB classification and both RAEB-1 and RAEB-2 under the WHO recommendation); (4) 9984: RAEB in transformation (RAEB-t); (5) 9985: refractory cytopenia with multilineage dysplasia (RCMD); (6) 9986: MDS associated with 5q deletion; (7) 9987: therapy-related MDS; and (8) 9989: MDS, not otherwise specified. Since the morphological feature of RAEB-t is considered more in line with that of AML, we conducted our analyses with and without the inclusion of patients with RAEB-t.

The linkage of the SEER data with the Medicare records is the collaborative effort of the NCI, the SEER registries, and the Center for Medicare and Medicaid Services (CMS). Among individuals who were included in SEER files and 65 years or older at the time of 1995 and 1999 linkages, 93% were found in the Medicare enrollment file¹⁹. In this study, we accessed Medicare claims from three sources: 1) the physician/supplier file, which contains claims for physician and other professional services; 2) the outpatient standard analytic file, which contains claims for outpatient facility services; and 3) the Medicare provider analysis and review file, which contains claims for hospital inpatient services.

Study Population

All individuals with MDS between 2001 and 2002 were identified from the most recent linked database; their Medicare claims through the end of 2004 were also obtained. The subjects

eligible to be included were (1) 66 years or older at the time of diagnosis; (2) had Medicare Part A and Part B coverage and no health maintenance organization (HMO) enrollment during the period of interest, which begins 12 months before diagnosis and ends at the time of death or in December 2004, whichever was earlier; and (3) did not have other malignancies prior to the diagnosis of MDS. The rationale to limit the age of diagnosis to 66 years or older is to ensure a minimum of 12 months of Medicare claims prior to MDS diagnosis so comorbidities can be assessed^{20,21}. We excluded patients who are enrolled in HMOs because their claims are not routinely reported to CMS²². Patients who had other malignancies prior to the diagnosis of MDS were excluded due to concern that their previous malignancies would affect survival and complicate the analysis. We also excluded patients who were identified from death certificates only and patients whose months of diagnosis were not specified. A total of 1,708 incident MDS patients who were diagnosed during 2001–2002 and fulfilled the eligibility criteria were included in the analysis.

Study Variables

Using claims record on inpatient, outpatient and carrier files from one year prior to the diagnosis of MDS through one month after the diagnosis, we calculated a summary measure of comorbid conditions known as the Charlson index²³. First developed in 1987, the Charlson index is a summary measure of 19 comorbid conditions, each of which is assigned a weight from 1 to 6 corresponding to disease severity^{19,23}. The weights are then summed to provide an overall score. To calculate this index, we used the Deyo adaptation with several procedure codes that reflect the Romano adaptation²⁴

(<http://healthservices.cancer.gov/seermedicare/program/charlson.comorbidity.macro.txt>). A total of 18 different conditions were included in this calculation, while cancer was not included (none of the patients included in our analysis had cancer prior to the diagnosis of MDS). We further grouped Charlson index into three categories, 0, 1–2 and 3+.

In addition to comorbid conditions, we obtained information on demographic characteristics and neighborhood socioeconomic status (SES) from the database. The database includes aggregate socioeconomic measures from the US Census Bureau that reflect the characteristics of neighborhoods in which patients resided²⁵. As all patients included in our analysis were diagnosed during 2001–2002, median household income at the census tract level from the 2000 US Census should be a reasonable reflection of their neighborhood SES at or shortly after diagnosis. Median household income was categorized into quartiles, with the first quartile representing the lowest income and the fourth representing the highest.

Date of death is included in the linked database. MDS patients who were still alive at the end of 2004 were considered censored. Survival time was defined as the duration between the date of MDS diagnosis and the date of death due to any cause or December 31, 2004, whichever was earlier.

Statistical analysis

Frequencies and percentages were used to describe various characteristics of the study population. For different subgroups of patients, the Kaplan-Meier method was utilized to draw survival curves, and the log-rank test was used to compare curves between subgroups. Unadjusted and adjusted Cox regression proportional hazard regression models were utilized to assess the impact of various characteristics on survival. We conducted linear trend tests across categories by using original values as the continuous term in the regression model. All analyses were conducted using SAS version 9.1 (SAS Institute, Inc., Cary, NC). All significance tests were two-sided with $\alpha = 0.05$.

Results

A majority of patients were male (52.5%), white (89.4%), and lived in big metropolitan areas (58.7%) (Table 1). Approximately 51% of patients had at least one comorbid condition. Of the 1,708 patients, 1,149 (67.3%) had died by the end of 2004. The median survival time was 18.0 [95% confidence interval (CI) 16.6 – 19.2] months, 23.5 (95% CI: 19.7 – 27.7) months and 9.7 (95% CI: 7.5 – 11.4) months for overall MDS, RA, and RAEB, respectively (Figure 1). More than half patients with RARS survived through the end of 2004, so the median survival time could not be estimated for RARS using the current data. The most frequently reported cause of death was neoplasm, accounting for 888 (56.6%) deaths. Among patients who died from neoplasms, 42.5% were reported to have died from MDS and 38.4% to have died from leukemia. Diseases of the circulatory system, the respiratory system, the digestive system and other diseases were reported to be the causes of death for 323 (20.6%), 88 (5.6%), 50 (3.2%), and 220 (14.0%) patients, respectively.

At any time point, MDS patients with more comorbidities had worse survival (Figure 2). The median survival time of MDS patients without comorbid conditions was significantly longer than that of patients with comorbid conditions (p value from log-rank test $< .0001$). Of interest, the same pattern held true when looking at major subtypes of MDS, RA, RARS and RAEB, respectively (detailed data not presented).

Analyses with unadjusted Cox proportional hazard models suggested that older age, male gender, the presence of comorbid conditions, and residence in low SES neighborhoods were associated with a greater risk of death (i.e. worse survival), whereas race and residence in an urban or rural area did not appear to affect survival (Table 1). The findings persisted in the multivariate analysis, when multiple factors were included in the same model simultaneously and adjusted for each other. Compared with MDS patients diagnosed at the age of 66–69 years, those who were 80 or older had significantly shorter survival; moreover, there was a significant inverse trend between age and survival. Male patients had significantly worse survival than female patients (HR = 1.16, 95% CI: 1.03–1.30). Compared with patients whose neighborhood income was in the lowest quartile, patients whose neighborhood income was in the highest quartile had significantly better survival (HR = 0.84, 95% CI: 0.71–0.99). Compared with patients without comorbid conditions (i.e. had a Charlson index of 0), those with a Charlson index of 1 – 2 or ≥ 3 had hazard ratios of 1.19 (95% CI: 1.05–1.36) and 1.77 (95% CI: 1.50–2.08), respectively; the test of trend was also statistically significant ($p < 0.01$). Compared with RA patients, RAEB patients had significantly shorter survival. These analyses were conducted for all MDS patients as one group, but the same pattern held among patients with RA, RARS or RAEB (detailed data not presented).

We also evaluated the impact of specific types of comorbid conditions on the survival of MDS. As shown in Table 2, diabetes (21.8%), congestive heart failure (CHF) (20.8%) and chronic obstructive pulmonary disease (COPD) (17.9%) were the most common comorbidities. MDS patients with CHF, COPD, dementia, acute ulcers or mild liver diseases had significantly shorter survival than patients who did not have these conditions, whereas having other comorbid conditions such as diabetes did not appear to affect survival (Table 2).

All analyses described above were repeated after excluding MDS patients whose subtypes were not specified, and the results derived from those analyses were extremely similar. In addition, the analyses were also carried out after excluding patients with RAEB-t, and the results were essentially the same.

Discussion

In this large population-based study of older persons with MDS, the presence of comorbidities at the time of MDS diagnosis is associated with poor survival. However, not all comorbidities appear to have the same impact on survival.

Comorbidity is the coexistence of various chronic illnesses in addition to the index disease. The prevalence of chronic diseases increases with age²⁶. Aging is a complex process, which usually facilitates promotion and progression of carcinogenesis²⁷. In this study, even after adjusting for age and other patient characteristics, comorbidity still significantly correlates with survival and appears to be an independent prognostic factor for MDS. This finding underscores the importance of taking comorbidities into account when evaluating the prognosis of MDS.

Different chronic diseases may have different impact on the survival of MDS patients. In previous studies, presence of cardiac failure, liver or pulmonary disease or solid tumors has increased risk of non-leukemic death among MDS patients^{13,14}. In this study, we observed a significant impact of CHF and COPD on survival, but not diabetes. While the relatively small number of patients with any single comorbidity may preclude definitive conclusions regarding the clinical significance of these findings, CHF and COPD can be severely exacerbated by anemia and infection, hallmarks of MDS. In the case of transformation to AML, CHF limits administration of anthracyclines (because of the cardiac toxicity), one of the two key chemotherapeutic agents in the treatment of leukemia. It may be of interest in the future to investigate how certain conditions affect MDS outcomes, in particular as it pertains to the administration of available therapies.

There are a variety of mechanisms which may mediate the effect of comorbidities. Comorbidities may influence clinical decision making concerning treatment. In studies of other types of cancer, comorbidities have been shown to not only affect cancer risk, but also affect cancer survival by limiting choices of treatment, particularly in the elderly patients^{28,29}. Several studies have found that comorbidities are prognostic predictors among patients receiving hematopoietic cell transplantation^{30–35}. Sorror *et al.* recommended that clinical trials comparing nonmyeloablative and myeloablative conditioning recruit patients with low comorbidities, whereas patients with high comorbidity scores and advanced diseases could be candidates for clinical trials using novel antitumor agents combined with nonmyeloablative hematopoietic cell transplantation³⁶. On the other hand, MDS may also affect the health impact of the comorbid illnesses (e.g. anemia exacerbating CHF) and limit the aggressiveness of treatment for the comorbid illnesses (e.g. thrombocytopenia limiting invasive cardiac procedures).

In this study, we focused on all-cause mortality rather than MDS-specific mortality. The rationale was two-fold. First, the cause of death reporting may not have been reliable and deaths due to MDS may have been miscoded, especially when considering that MDS patients usually die from infections and/or bleeding, which are not very specific. Second, common comorbid conditions such as CHF and COPD can be severely exacerbated by anemia and infection, which are likely to occur secondary to MDS. Thus, while MDS may be the principal factor leading to a patient's death, it may not be reported as such.

Forty eight percent of the patients did not have the exact MDS subtype specified. We analyzed the survival of these patients separately. The survival curve of MDS patients with unspecified subtypes and that of the overall group were nearly identical (Figure 1), suggesting that these two groups are comparable. We also observed a similar impact of comorbidities on survival among MDS patients with unspecified subtypes.

The median survival for MDS patients included in this analysis was somewhat shorter than what was previously reported^{1,3,37,38}. This may be due to the fact that all patients included in this analysis were 66 or older, while previous studies included younger patients, who have been consistently shown to have better survival^{1,3,37,38}.

In conclusion, we identified comorbidities as an independent predictor of survival in a large cohort of patients with newly diagnosed MDS. Treatment strategies for MDS should be designed to be applicable to a population of elderly patients with comorbidities to be clinically relevant. When assessing the prognosis of MDS, it would be critical to incorporate comorbidities of patients.

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Figure 1.
Survival of MDS Patients by Subtype, SEER-Medicare, 2001 – 2002

Figure 2.
Survivals of MDS Patients by Charlson Index, SEER-Medicare, 2001 – 2002

Table 1
Unadjusted and Adjusted Hazard Ratios (and 95% Confidence Intervals) for Selected Demographic and Clinical Characteristics, SEER-Medicare, 2001–2002

Characteristic	Total			Univariate model				Multivariate model ^a		
	N	%	Censored	Dead	HR	95% CI	P for trend	HR	95% CI	P for trend
Age (years)										
66–69	160	9.37	65	95	1.00		<0.01	1.00		<0.01
70–74	341	20.00	138	203	1.05	(0.82–1.34)		0.97	0.76–1.24	
75–79	406	23.80	148	258	1.15	(0.91–1.45)		1.17	0.93–1.49	
80–84	447	26.20	136	311	1.34	(1.06–1.68)		1.35	1.07–1.70	
85+	354	20.70	72	282	1.87	(1.48–2.37)		2.05	1.62–2.59	
Gender										
Female	812	47.50	294	518	1.00			1.00		
Male	896	52.50	265	631	1.17	(1.05–1.32)		1.16	1.03–1.30	
Race										
White	1527	89.40	495	1032	1.00					
Black	114	6.67	41	73	0.88	(0.70–1.12)				
Other	67	3.92	23	44	1.05	(0.77–1.42)				
Median Household Income										
1 st Quartile	423	24.80	121	302	1.00		<0.01	1.00		<0.01
2 nd Quartile	424	24.80	124	300	0.96	(0.82–1.13)		1.04	0.89–1.22	
3 rd Quartile	421	24.70	141	280	0.85	(0.72–1.00)		0.92	0.78–1.08	
4 th Quartile	422	24.70	166	256	0.74	(0.63–0.88)		0.84	0.71–0.99	
Charlson Index										
0	840	49.20	314	526	1.00		<0.01	1.00		<0.01
1–2	619	36.20	201	418	1.19	(1.04–1.35)		1.19	1.05–1.36	
3+	249	14.60	44	205	1.73	(1.47–2.03)		1.77	1.50–2.08	
Urban/Rural										
Big Metro	1002	58.70	333	669	1.00					
Metro	428	25.10	145	283	1.04	(0.90–1.19)				
Urban	88	5.15	29	59	1.01	(0.77–1.32)				
Less Urban	155	9.07	44	111	1.13	(0.92–1.38)				

Characteristic	Total		Censored	Dead	Univariate model			Multivariate model ^d		
	N	%			HR	95% CI	P for trend	HR	95% CI	P for trend
Rural	35	2.05	8	27	1.25	(0.85–1.84)				
Subtype ^b (ICD-O-3 Code)										
RA (9980)	314	18.40	120	194	1.00			1.00		
RARS (9982)	203	11.90	113	90	0.63	(0.49–0.82)		0.66	0.51–0.84	
RAEB (9983)	237	13.90	25	212	2.26	(1.86–2.76)		2.47	2.02–3.01	
RCMD (9985)	54	3.16	24	30	1.00	(0.68–1.47)		1.07	0.73–1.58	
MDS, not otherwise specified (9989)	829	48.50	259	570	1.23	(1.05–1.45)		1.24	1.06–1.46	

^a Age, gender, median household income, Charlson index and MDS subtypes are included in the model simultaneously.

^b Results are not shown for subtypes with fewer than 50 patients.

Table 2
Adjusted Hazard Ratios and 95% Confidence Intervals For Selected Comorbid Conditions, SEER-Medicare, 2001–2002

Comorbid Conditions ^a	Total			Dead ^b	HR ^c	95% CI
	N	%	Censored ^b			
Myocardial infarction	47	2.8	11	36	1.14	0.81–1.62
Old myocardial infarction	75	4.4	17	58	0.99	0.75–1.32
Congestive heart failure (CHF)	355	20.8	68	287	1.35	1.16–1.57
Peripheral vascular disease (diagnosis)	118	6.9	25	93	1.21	0.96–1.51
Peripheral vascular disease (surgical)	13	0.8	<5	Not shown	1.04	0.52–2.09
Cerebrovascular disease	136	8.0	39	97	1.02	0.82–1.27
Chronic obstructive pulmonary disease (COPD)	305	17.9	70	235	1.36	1.16–1.58
Dementia	32	1.9	<5	Not shown	1.49	1.02–2.18
Paralysis	12	0.7	<5	Not shown	0.84	0.42–1.67
Diabetes	372	21.8	111	261	1.09	0.93–1.28
Diabetes with sequelae	101	5.9	27	74	0.87	0.66–1.14
Chronic renal failure	99	5.8	24	75	1.05	0.82–1.34
Mild liver disease	24	1.4	<5	Not shown	1.96	1.18–3.26
Moderate-severe liver disease	11	0.6	<5	Not shown	0.95	0.44–2.05
Acute ulcers	45	2.6	6	39	1.80	1.27–2.55
Chronic ulcers	21	1.2	6	15	0.75	0.43–1.29
Rheumatoid diseases	68	4.0	25	43	0.93	0.68–1.26

^aComorbid conditions are not mutually exclusive - percentages do not add up to 100%. No patients had AIDS.

^bFollowing SEER-Medicare confidentiality rules, cells sizes fewer than 5 are not presented.

^cAdjusted for age, gender, median household income, MDS subtypes and other conditions in the table.