Published in final edited form as:

Vox Sang. 2012 May ; 102(4): 331–337. doi:10.1111/j.1423-0410.2011.01568.x.

Patterns of Blood Product Use among Patients with Myelodysplastic Syndrome

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Abstract

Background and Objectives—Most patients with myelodysplastic syndrome (MDS) require blood product support to manage the severe anemias which frequently accompany MDS. Our objective was to show the feasibility of linking the Surveillance, Epidemiology and End Results (SEER) database with records from Puget Sound Blood Center (PSBC) to characterize blood product use over time in successive cohorts of MDS patients.

Materials and Methods—We identified patients with MDS in the SEER registry. The cohort was then linked to PSBC records to discern blood product use.

Results—Included in the analysis were 783 patients with MDS entered in the SEER database from 2001 to 2007 for whom data were also available in the PSBC database. Among MDS patients who received transfusions, 97% received packed red blood cells; 52% received platelets. The proportion of MDS patients receiving blood products declined from 2001 to 2007.

Conclusion—These data show a recent decline in blood product use for patients with MDS. Future studies are needed to further evaluate the reasons for this finding, specifically exploring the impact of newer medications on blood product use in MDS patients.

Keywords

myelodysplastic syndrome; transfusion; red blood cells; platelets; survival

Introduction

Blood product support is an essential component of managing patients with myelodysplastic syndrome (MDS). Patients are frequently of advanced age with attendant comorbidities that can be exacerbated by severe anemia, which is the most frequent presentation of MDS.

Although packed red blood cell (RBC) transfusions can alleviate symptoms of anemia and maintain cardiovascular integrity for variable periods of time, long term transfusion support has a negative impact on quality of life, and transfusion dependence has been shown to be

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Competing Interests: The authors have no competing interests.

Authorship: All authors made substantial contributions to research design, the analysis/ interpretation of data, and drafting/revising the paper. Drs. Ramsey, McDermott, and López contributed to acquisition of the data. All authors have approved the submitted version of the paper.

associated with shortened overall survival.[1–4] Depending on age, performance status, and International Prognostic Scoring System (IPSS)-defined risk category, patients are treated with various medications in an attempt to reduce their dependence on RBC transfusions. Newer FDA approved treatment modalities such as azacitidine, decitabine, and lenalidomide have been shown in clinical trials to reduce transfusion dependence and blood product exposure in a proportion of patients.[5–7] To date, however, there has been no longitudinal study of blood product use and possible changes over time among patients with MDS.

We carried out a linkage of the Survival, Epidemiology, and End Results (SEER) population-based cancer registry with records of the regional blood bank that is the only supplier of blood products in the registry catchment area. The major goal was to determine the feasibility of linking the blood bank database with the SEER database. This linkage then allowed for characterization of blood product use in patients with newly diagnosed MDS registered in the SEER database. Specifically, we evaluated the time span from MDS diagnosis to transfusion dependence, the total volume of transfusions over time in terms of year of treatment (e.g., 2001 versus 2002) and time from MDS diagnosis.

In a secondary and exploratory analysis, we examined the relationship between volume of transfusions and cancer-specific and overall mortality.

Materials and Methods

Identification of Study Population

Patient-level data obtained from the SEER Seattle-Puget Sound registry were merged with blood product use data obtained from the Puget Sound Blood Center (PSBC). The SEER-Puget Sound registry provides high-quality data on the incidence, tumor characteristics, stage at diagnosis, initial treatment, and survival of all newly diagnosed cancers (except non-melanoma skin cancers) occurring in residents of 13 counties in western Washington State. [8] Data on cancer cases are obtained by SEER through hospitals, outpatient surgical centers, pathology laboratories, physician offices, and death certificate reviews. PSBC is the transfusion service for major medical centers in 15 Puget Sound area counties. All 15 counties covered by PSBC are also included in the SEER registry. Over 20,000 transfusion services are provided every month, making PSBC a rich source of transfusion data. The database includes information on patient identifiers, number of units sent and type of blood products received.

The SEER-Puget Sound registry was searched for confirmed MDS cases and subsequently cross-linked with the PSBC database by using person-level identifiers (i.e., full name, gender, date of birth, and zip code if available). Inclusion criteria were: age 21 years and older at the time of MDS diagnosis and MDS diagnosis date between January 1, 2001 and December 31, 2007. Patients were excluded if they had any other malignancy previously recorded in SEER. The follow-up period was to December 31, 2008 for all patients.

The appropriate Institutional Review Boards approved the study, and a waiver of consent was obtained for access to each database before performing the linkage.

Identification of Blood Product Use

The study focus was to determine blood product use following the SEER-defined date of diagnosis of MDS. Blood products were defined as platelets or RBCs. PSBC records were used to determine blood product use for each patient.

Data Analysis

Blood product use was characterized by time from diagnosis (0–12, 13–24, and 25–36 months from diagnosis) and by type of product (RBCs, platelets) and for trends in use over the years of observation. White blood cell, fresh frozen plasma and whole blood usage are not included due to the extremely limited patient use. We also examined blood product use during the last 6 months of life.

In our exploratory analysis evaluating the relationship between number of transfusions and mortality, we used a competing risk survival analysis, creating separate baseline hazard functions for each type of death (MDS-related, non-cancer related). Independent variables included age at diagnosis, race (white or non-white), sex and MDS subtype (refractory anemia (RA), RA with sideroblasts, RA with excess blasts, RA with excess blasts in transformation, refractory cytopenia with multilineage dysplasia, MDS with 5q deletion, MDS, not otherwise specified (NOS). We compared two separate models, one using time-varying covariate measuring the cumulative number of RBC or platelet units used by the patient, and a second with a categorical denoting a cumulative number of RBCs exceeding 20 units. The threshold value of 20 was chosen, because it is widely considered to represent a relevant level, above which the risk of serious transfusion-related problems, in particular iron overload, increases substantially (see Discussion). Separate models were used for patients receiving RBC transfusions and patients receiving platelet transfusions.

Results

Among 783 patients identified from the linkage between the PSBC and SEER databases, 781 patients met the age criterion (i.e., were 21 years of age or older). Of those patients, 546 were identified as having no prior malignancies and were included in the analysis (Table 1). The most common pathologically characterized diagnosis was refractory anemia with excess blasts (RAEB, n=125, 23% of all cases in the analysis), with RA being the next most frequent diagnosis (n=111, 20%). Approximately one-third of cases (n=188) was listed as MDS-NOS. Because these three categories comprised the majority of MDS cases, all tables describing blood product use characterize transfusion in these three subtypes along with the overall population.

Patterns of Blood Product Use

Almost all MDS patients received one or more blood products during the follow-up period, with 94% (n=515) receiving RBC transfusions (Table 1) and 48% (n=261) receiving platelets.

The proportion of patients receiving any blood product tended to decline over time following diagnosis (Table 2a), with the exception of MDS-NOS, where used varied from period to period. The average numbers of RBC and platelet units stratified by months following diagnosis are shown in Table 2b. Among those receiving at least one blood product, the average number of RBC units varied from 7.9 to 22.4 units (median 6, range 1 to 102). The average number of platelet units fluctuated during the follow-up period from 4.0 units to 21.4 units (median 5, range 1 to 213) (Table 2b).

Forty percent of MDS patients received a blood product during the last six months of life. Analysis of the three most commonly diagnosed subtypes of MDS showed that 44% of MDS-NOS patients, 39% of patients diagnosed with RAEB and 32% of RA patients received blood products in the last six months of life. RBCs were more commonly used than platelets; 43% of MDS-NOS patients received RBCs while 19% received platelets.

Among patients who received blood products, 34% received 20 or more units of RBCs from the date of diagnosis. Patients most likely to receive 20 or more RBC units were older, were male, and carried the diagnoses of RA [FAB classification], refractory cytopenia with multilineage dysplasia, and MDS with 5q deletion [WHO classification].

Trends in Blood Product Use over Time

Between 2001 and 2007 the overall *proportion of patients* who were transfused declined, but *among those receiving transfusions*, the numbers of transfusions varied greatly, with no clear trend over time (Table 1). Between 2001 and 2003, 39% of MDS patients received at least one RBC transfusion, and 42% received at least one platelet transfusion. Between 2005 and 2007, 30% of patients received at least one RBC transfusion and 28% received at least one platelet transfusion. Among patients who did receive RBC transfusions, the average number of RBC units transfused within 12 months of diagnosis varied over time, increasing from 11.7 units for those diagnosed in 2001 to a peak to 15.2 units for those diagnosed in 2003, then declining to 10.8 units for those diagnosed in 2007. During the last six months of life, the use of RBCs increased from 5.5 units in 2001 to 9.4 units in 2007. Platelet use in the last six months of life varied widely from year to year.

Overall Survival

According to cancer registry records, of the 354 patients in the analysis who died, 67% died from causes other than cancer, 30% from MDS or a related malignancy such as leukemia, and 3% from another type of cancer diagnosed following the MDS diagnosis.

Exploratory Evaluation of Total Blood Product Use and Survival

In the exploratory evaluation of transfusion volume and mortality risk, Cox proportional hazards models showed substantially higher risks of both cancer-related death (including those who died from MDS or MDS progression to leukemia) and non-cancer related death for patients who had received 20 or more units of RBC (cancer-related HR 6.71, 95% CI 4.22–10.66; non-cancer related HR 2.66 95% CI 1.95–3.62). Age at diagnosis was also significantly associated with mortality risk. Compared to the referent histological group of RA, the subtype RA with ring sideroblasts was associated with a 50% reduction in risk of death, RAEB had approximately twice the risk, and RAEB with transformation roughly four times the hazard of death (Table 3). The model evaluating individual platelet transfusions found that higher cumulative volumes of platelet transfusion were associated with a very modest but statistically significant increased risk of all-cause mortality (HR 1.02, 95% CI 1.01–1.02).

Discussion

To our knowledge, this is the first retrospective analysis to characterize blood product use by linking a population-based cancer registry and a regional blood center serving the same catchment area. Among 788 patients diagnosed with MDS in the western Washington State SEER region between 2001 and 2007, 765 received at least one blood product during the follow-up period. Compared to other MDS subtypes, a higher proportion of patients with refractory anemia with excess blasts (RAEB) received blood products, and persons with this subtype received more products during all time periods following diagnosis. Overall, blood product use decreased following the first 12 months after diagnosis, suggesting less aggressive hemoglobin and platelet support needs for patients surviving longer than 12 months. There was no clear trend in average blood product use per patient over the seven years of observation.

National Comprehensive Cancer Network guidelines suggest supportive care, including transfusions, along with erythropoiesis stimulating agents, as the standard of care for patients with low grade MDS.[9] Blood product support largely consists of RBC transfusions for symptomatic anemia or platelet transfusions for severe thrombocytopenia or thrombocytopenia with bleeding. Among patients with RA, a relatively low risk disease, the major problem over time is often failing marrow function, whereas in the other MDS categories, a major problem is progression to leukemia, requiring therapy beyond that of transfusions.

The past decade has seen an increasing awareness of MDS, as suggested by the findings of Goldberg et al. who, in a review of Medicare files, calculated an incidence of MDS of 45,000 cases in 2003, representing a four- to five-fold increase in diagnosed cases of those over 65 years of age in the US.[10] This increased awareness may be, in part, related to the development and FDA approval of three drugs (i.e., azacitidine, decitabine, lenalidomide) that offer therapeutic options for patients with MDS. The availability of these medications is leading to key changes in the clinical practice guidelines for management of patients with MDS.[11] The disease awareness is likely to have led to more aggressive diagnostic investigations, including bone marrow examination, even in patients in the eighth decade of life, rather than attributing peripheral blood findings to “anemia of old age”. With MDS being diagnosed more frequently, a greater demand for treatment such as chemotherapy and transfusions is likely. Possibly more important is the fact that a very common side effect the three approved new drugs is myelosuppression, which may necessitate at least temporarily increased transfusion support, even in patients who eventually show treatment responses. Testing these hypotheses in large claims-based database linked with medication information is feasible, as this analysis demonstrated the feasibility of linking the blood bank database with the SEER database. Such analyses can evaluate if increased use of blood products during the last six months of life occur because more blood product use is postponed until the latest stages of the disease, possibly as a consequence of the new medications,

Overall, however, new treatments for MDS (e.g., azacitidine, lenalidomide) and more intensive use of growth factors such as erythropoietin may have reduced the need for RBC transfusions, certainly in patients who respond to those treatment strategies.[12] Management of patients with moderate or poor prognosis MDS has become more aggressive over time, with the use of high intensity chemotherapy and, most notably, hematopoietic cell transplantation. Our data show that the use of RBC and platelet transfusions during the last six months of life is higher than during the first few years after a diagnosis (Tables 1, 2a, 2b). In many cases, however, the actual impact of specific treatments—including aggressive supportive care—on patient survival remains unclear.

Recent data suggest that dependency upon RBC transfusions is associated with shortened survival in MDS patients.[1,10,13,14] The underlying cause is a matter of debate. Transfusion dependence may be the expression of a more aggressive disease path physiology; it is likely, however, that transfusion effects, such as iron overload and secondary hemochromatosis, are contributing factors. Various sets of guidelines suggest that patients with MDS who have received at least 20 units of RBCs or show serum ferritin levels exceeding 1000 or 2000 µg/liter should be considered for chelation therapy.[15] Our study shows that an increasing number of patients exceed this threshold, even in the first 12 months following diagnosis. An exploratory evaluation showed increased cancer-related mortality among patients who received 20 or more units of RBCs. This result cannot be considered causative, however, since increasing RBC transfusion support may simply be a marker for worsening disease. The result of our analysis relating RBC transfusion volume and *non-cancer* related death lends support to previous retrospective studies that show an association of high volume RBC transfusion with poorer survival among MDS patients.[2–

4] Still, the conclusions remain tentative, since life-threatening conditions that are quite frequent in older individuals, such as coronary artery disease or congestive heart failure, may be exacerbated by anemia, and will lead to more aggressive blood product support, i.e. the underlying comorbid conditions rather than complications related to iron overload represent the cause of death.

There are several limitations to this analysis. Blood center data contain less detailed clinical information and are less accurate than medical charts in identifying patients with specific conditions.[10] Over- or under-reporting can result from the potential for coding errors. [10,16] For example, we were not able to calculate international prognostic scoring system (IPSS) scores, as SEER and PSBC records do not contain all the necessary parameters. Also, specific information on treatment in the immediate period following diagnosis, and information on treatments received in the later months of the disease was not consistently available. This is particularly true for the most recently included patients, i.e. those who were diagnosed 2005–7, because this group had a shorter observation period compared to the other two groups. Few patients in the 2005–7 group reached 36 months of observation, and thus cannot be compared directly to the two other groups. If transfusions are postponed until later disease stages, the consumption of the latter group will be falsely low. Also, some patients may have proceeded to hematopoietic stem cell transplantation with attendant need for RBC and platelet support. Such a clinical course would confound our interpretation; however this was likely to affect only a small proportion of patients, as we concentrated much of the analysis on the first 12 months (an interval during which few patients undergo hematopoietic cell transplantation). Also, 73% of patients were older than 65 years, and only few patients in that age group receive a hematopoietic cell transplant. It is also unknown if our patients remained in the geographic area following treatment; it is possible that patients left the area to move to another location with perhaps greater family support.

A relatively large proportion of our patient cohort was designated as MDS subtype not otherwise specified. This may reflect lack of information at diagnosis or uncertainty about subtype in the patient's medical record. A recent study of SEER data found that many patients with MDS are incorrectly classified.[17] Thus, the observed correlations of transfusion need with MDS category must be interpreted with caution.

In conclusion, the use of both RBC and platelet transfusions was highly variable in patients with MDS observed from 2001 to 2007. Future studies which incorporate the linkage of SEER records, blood product use and health care claims may be able to discern the impact of novel medications upon blood product use in patients with MDS.

Acknowledgments

Funding Source: This study was supported by research funding from the National Cancer Institute grant N01-PC-35142.

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Table 1

Patient characteristics.

Characteristic	Received RBC	Received Platelets	No Blood Products Received	Total
Number (%) ^a	515 (94%)	261 (48%)	18 (3%)	546 (100%)
Male	59%	65%	44%	59%
Female	41%	35%	56%	41%
Diagnosis year				
2001–2003	39%	42%	28%	38%
2003–2005	31%	31%	22%	31%
2005–2007	30%	28%	50%	31%
Age at diagnosis (years)				
25 and under	0%	1%	0%	0%
26–35	2%	3%	0%	2%
36–45	2%	4%	6%	2%
46–55	9%	12%	6%	8%
56–65	16%	21%	22%	15%
66–75	21%	23%	17%	20%
76–85	36%	28%	33%	37%
86 and older	14%	9%	17%	16%
MDS Subtype^b				
RA	21%	36%	6%	20%
RA with sideroblasts	13%	8%	17%	13%
RA with excess blasts	23%	16%	28%	23%
RA with excess blasts in transformation	1%	2%	0%	1%
Refractory cytopenia with multilineage dysplasia ^c	6%	9%	11%	7%
MDS with 5q deletion ^c	2%	0%	0%	1%
Therapy-related MDS	0%	0%	0%	0%
MDS, NOS-MDS, NOS	34%	30%	39%	34%

^aThe RBC column and platelet columns do not represent mutually exclusive groups of patients;^baccording to SEER registry.^cIn the FAB classification these categories (distinguished by WHO) are included within the RA group.

Abbreviations:

RBC - Red blood cells

MDS – Myelodysplastic syndrome

RA - Refractory anemia

NOS - Not otherwise specified

Table 2aBlood products received by patients with MDS.^a

Blood Product Received ^b	Diagnosis			
	MDS-NOS	RA	RA with excess blasts	All patients
Months 0–12 post diagnosis				
Number (N) at start of period ^b	188	111	125	546
N receiving at least 1 product	80 (43%)	72 (65%)	51 (41%)	249 (46%)
Platelets	42 (22%)	60 (54%)	19 (15%)	145 (27%)
RBC	78 (41%)	72 (65%)	49 (39%)	243 (45%)
Months 13–24 post diagnosis				
N at start of time period	127	58	92	372
N receiving at least 1 product	34 (27%)	23 (40%)	29 (32%)	107 (29%)
Platelets	12 (9%)	12 (21%)	9 (10%)	41 (11%)
RBC	32 (25%)	21 (36%)	28 (30%)	102 (27%)
Months 25–36 post diagnosis				
N at start of time period	87	28	61	242
N receiving at least 1 product	26 (30%)	7 (25%)	10 (16%)	61 (25%)
Platelets	7 (8%)	4 (14%)	4 (7%)	24 (10%)
RBC	25 (29%)	7 (25%)	9 (15%)	59 (24%)

^aNumber of MDS patients who received at least one unit of the specified blood product within the time period from the date of diagnosis for the three most common MDS subtypes and for all subtypes.

^bNumber of patients with diagnosis, regardless of receipt of blood products.

Abbreviations:

MDS – Myelodysplastic syndrome

NOS - Not otherwise specified

RA - Refractory anemia

RBC - Red blood cells

Table 2bBlood product use in MDS patients who received at least one blood product.^a

Blood Product Received	Diagnosis ^b			
	MDS-NOS	RA	RA with excess blasts	All patients
Month 0–12 post diagnosis				
Number at start of time period ^c	N=80	N=72	N=51	N=249
Platelets	14.7 (23.1)	20.8 (28.7)	5.7 (5.8)	16.1(24.5)
RBC	12.0 (14.9)	22.4(16.9)	9.7 (11.0)	15.6 (17.2)
Total Products	19.5 (30.6)	39.8 (40.8)	11.5 (13.5)	24.6 (34.5)
Month 13–24 post diagnosis				
Number at start of time period	N=34	N=23	N=29	N=107 ^a
Platelets	21.4 (29.2)	17. 7 (27.6)	10. 8 (9.4)	16.0 (22.3)
RBC	13.8 (17.5)	12.6 (12.2)	8.4 (9.0)	11.5 (13.1)
Total products	20.5 (31.1)	20.7 (30.62)	11.5 (14.9)	17.1 (24.9)
Month 26–36 post diagnosis				
Number at start of time period	N=26	N=7	N=10	N=61
Platelets	13.6 (11.8)	4.0 (1.4)	12.0 (16.4)	15.7 (36.9)
RBC	10.5 (14.5)	7.9 (4.1)	13.8 (16.5)	12.4 (16.3)
Total Products	13.8 (18.3)	10.1(5.4)	17.2 (26.3)	18.2 (37.0)

^a Among patients receiving at least 1 unit of the specified blood product during the specified period from diagnosis, the average number of units of blood products (SD) received by the three most common MDS subtype and for all subtypes.

^b Includes the 3 most common diagnosis and for all MDS patients.

^c Number of people receiving at least one RBC or platelet.

Abbreviations:

MDS – Myelodysplastic syndrome

SD – Standard deviation

NOS - Not otherwise specified

RA - Refractory anemia

RBC - Red blood cells

Table 3

Cox proportional hazards model evaluating the impact of receiving 20 or more RBC transfusions on likelihood of any cause of death. The referent histologic subgroup is refractory anemia (RA).

Parameter	P value	Hazard Ratio	95% Hazard Ratio Confidence Limits
Age at Diagnosis	<.0001	1.03	1.02 1.04
White	0.86	1.03	0.72 1.48
Female	0.57	0.93	0.73 1.19
MDS subtype (RA ^a as reference group)			
RA with sideroblasts	0.004	0.51	0.33 0.80
RA with excess blasts	0.0007	1.82	1.28 2.57
RA with excess blasts in transformation	0.02	3.92	1.20 12.79
Refractory cytopenia	0.38	0.79	0.46 1.34
MDS with 5q deletion	0.12	0.33	0.08 1.34
MDS-NOS	0.86	1.03	0.75 1.42

^aTherapy-related MDS does not appear in the analysis because cases=0.

Abbreviations:

RBC – Red blood cells

MDS – Myelodysplastic syndrome

RA - Refractory anemia

NOS - Not otherwise specified