Anemia burden in patients with myelofibrosis treated with a JAK inhibitor: data from Optum Market Clarity Database

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Introduction

- Myelofibrosis (MF) is a hematologic malignancy characterized by splenomegaly, constitutional symptoms, thrombocytopenia, and anemia[1,2]
- Anemia is associated with fatigue, lower quality of life, excess morbidity, cardiovascular mortality, poor prognosis, and worse overall survival (OS)[3,4]
- Red blood cell (RBC) transfusions are often used to manage anemia, but this may lead to patients becoming transfusion dependent, which can worsen with time and carries the additional risk of iron overload[3]
- Ruxolitinib is a commonly used JAK 1/2 inhibitor (JAKi) that is indicated to treat intermediate and high-risk MF, but can cause or exacerbate anemia, demonstrating the need for effective anemia treatment[5]
- To date, there are limited data on the real-world management of anemia and clinical outcomes in patients with MF treated with a JAKi

Objective

- The aim of this study was to describe the real-world burden of anemia in patients with MF who receive a JAKi in the United States by describing their clinical characteristics, treatment patterns, and clinical outcomes

Methods

Data source and study design

- This retrospective observational study used Optum® Market Clarity electronic medical record (EMR) data from US payers
- Included patients were ≥ 18 years of age, had a diagnosis of MF with related anemia, received a JAKi, had continuous medical and pharmacy enrollment, and had ≥ 6 months of EMR data available before and after the index date
- The index date was the date of first JAKi initiation on or after MF diagnosis within the period of July 1, 2013 to December 31, 2023
- Data were extracted from January 1, 2013 to June 30, 2024
- Patients had a variable follow-up period, with the last date of follow-up being the end of data availability, end of continuous enrollment, last clinical date from EMR, death, or the first stem-cell therapy (SCT) date after the index date, whichever occurred first

Statistical analysis

- Descriptive statistics were used to describe demographic and clinical characteristics, treatment patterns, and OS
- Kaplan–Meier (KM) methodology was used to analyze OS, and the Spearman correlation method used to analyze the association between hemoglobin (Hb) level and OS

Results

Demographic and clinical characteristics

- 429 patients were included in this study
- The median age was 70.0 years, with 66% being 65 years or older (**Table 1**)
- The cohort was generally balanced in sex distribution (52.0% female, 48.0% male) and was predominantly Caucasian (80.4%)
- Most patients had secondary MF at initial diagnosis (79.0%) and a high comorbidity burden (71.3% had a Charlson Comorbidity Index [CCI] ≥ 3)
- Median (range) time from initial diagnosis to index was 40.3 (0–124.7) months

Treatment patterns

- Duration of treatment (DOT) was numerically shorter with each line of treatment (LOT; **Table 2**)
- Time between treatments were similar across LOT
- The most common 1L, 2L, and 3L treatments were hydroxyurea (n = 230), ruxolitinib (n = 178), and hydroxyurea (n = 11), respectively (**Table 3**)
- Pre-index date, 58.0% of patients received at least one form of supportive care, with the most common being erythropoiesis-stimulating agents (ESAs; 34.0%) and vitamins and minerals (24.2%; **Table 4**)
- Post-index date, 58.5% of patients received supportive care, with an increase from pre-index date in RBC transfusions (39.4%) and a slight decrease in ESAs (26.8%)

Clinical outcomes

- Among the 158 patients with Hb results, OS varied by Hb levels (**Figure 1**)
- There was a negative correlation between Hb grading at index and OS ($r = -0.17993$, $P = 0.0237$)

Table 1. Patient demographic and clinical characteristics at JAKi initiation

Characteristic	All patients (N = 429)	Patients with Hb results (n = 158)			
		Normal[a] (n = 51)	Grade 1 (mild)[b] (n = 58)	Grade 2 (moderate)[c] (n = 32)	Grade 3 (severe)[d] (n = 17)
Age at index, years					
Mean (SD)	68.5 (12.1)	66.3 (14.4)	66.2 (12.2)	72.5 (10.3)	74.1 (9.6)
Median (range)	70.0 (20.0-88.0)	69.0 (25.0-88.0)	68.0 (20.0-84.0)	76.5 (44.0-84.0)	77.0 (55.0-86.0)
< 65 years, n (%)	146 (34.0)	21 (41.2)	24 (41.4)	5 (15.6)	4 (23.5)
≥ 65 years, n (%)	283 (66.0)	30 (58.8)	34 (58.6)	27 (84.4)	13 (76.5)
Sex, n (%)					
Female	223 (52.0)	29 (56.9)	26 (44.8)	19 (59.4)	9 (52.9)
Male	206 (48.0)	22 (43.1)	32 (55.2)	13 (40.6)	8 (47.1)
Type of MF at initial diagnosis, n (%)					
Primary MF	67 (15.6)	9 (17.6)	8 (13.8)	10 (31.3)	4 (23.5)
Secondary MF	339 (79.0)	39 (76.5)	49 (84.5)	19 (59.4)	11 (64.7)
Unknown	23 (5.4)	3 (5.9)	1 (1.7)	3 (9.4)	2 (11.8)
Charlson Comorbidity Index, n (%)					
0	18 (4.2)	3 (5.9)	0	1 (3.1)	0
1	34 (7.9)	2 (3.9)	5 (8.6)	0	1 (5.9)
2	71 (16.6)	9 (17.6)	12 (20.7)	6 (18.8)	1 (5.9)
≥ 3	306 (71.3)	37 (72.5)	41 (70.7)	25 (78.1)	15 (88.2)
Race, n (%)					
Caucasian	345 (80.4)	41 (80.4)	44 (75.9)	26 (81.3)	13 (76.5)
African American	38 (8.9)	7 (13.7)	8 (13.8)	5 (15.6)	2 (11.8)
Asian	6 (1.4)	2 (3.9)	0	0	0
Other/unknown	40 (9.3)	1 (2.0)	6 (10.3)	1 (3.1)	2 (11.8)
Geographic region, n (%)					
Midwest	165 (38.5)	17 (33.3)	24 (41.4)	18 (56.3)	5 (29.4)
Northeast	107 (24.9)	17 (33.3)	18 (31.0)	4 (12.5)	2 (11.8)
South	89 (20.7)	8 (15.7)	7 (12.1)	4 (12.5)	7 (41.2)
West	54 (12.6)	7 (13.7)	9 (15.5)	5 (15.6)	3 (17.6)
Other/unknown	14 (3.3)	2 (3.9)	0	1 (3.1)	0
Insurance, n (%)					
Commercial	139 (32.4)	17 (33.3)	19 (32.8)	8 (25.0)	4 (23.5)
Medicare	266 (62.0)	29 (56.9)	35 (60.3)	22 (68.8)	13 (76.5)
Medicaid	23 (5.4)	4 (7.8)	4 (6.9)	2 (6.3)	0
Unknown/other/missing	1 (0.2)	1 (2.0)	0	0	0
MF-related anemia diagnosis prior to index, n (%)					
Yes	336 (78.3)	34 (66.7)	48 (82.8)	31 (96.9)	17 (100)
No	93 (21.7)	17 (33.3)	10 (17.2)	1 (3.1)	0
Hb at index (g/dL)[e]					
Mean (SD)	11.4 (2.6)	14.4 (1.4)	11.4 (0.9)	9.1 (0.6)	7.2 (0.4)
Median (range)	11.4 (6.5-17.4)	14.3 (12.2-17.4)	11.3 (10.0-13.3)	9.3 (8.0-9.9)	7.3 (6.5-7.8)
Length of follow-up from index (months)					
Mean (SD)	26.7 (20.2)	32.3 (19.5)	22.1 (13.9)	30.2 (23.7)	18.3 (17.2)
Median (range)	21.3 (1.4-100.5)	28.8 (1.5-74.3)	17.0 (2.2-49.7)	25.4 (2.1-82.4)	10.4 (1.4-57.8)
Time from initial MF diagnosis to index (months)					
Mean (SD)	42.4 (32.0)	42.4 (32.6)	41.8 (31.4)	28.9 (28.7)	42.2 (35.0)
Median (range)	40.3 (0-124.7)	39.7 (0.6-119.9)	38.7 (0.1-121.0)	12.2 (1.1-103.6)	48.4 (0-97.8)

[a]Defined as ≥ 12 g/dL for women and ≥ 13.5 g/dL for men; [b]Defined as ≥ 10 - < 12 g/dL for women, ≥ 10 - < 13.5 g/dL for men; [c]Defined as ≥ 8 - < 10 g/dL; [d]Defined as ≥ 6.5 - < 8 g/dL; [e]In patients with available data.
SD, standard deviation.

Table 2. Duration of treatment

	1L treatment	Time from 1L discontinuation to 2L initiation	2L treatment	Time from 2L discontinuation to 3L initiation	3L treatment
Number of evaluable patients, n	429	287	287	42	42
Median (range) duration of treatment (or treatment gap), months	18.0 (0.03-119)	0.4 (0.03-71.2)	12.1 (0.03-90)	0.6 (0.03-21.0)	5.7 (0.03-84)
Mean (SD) duration of treatment (or treatment gap), months	27.1 (25.9)	5.4 (11.3)	17.9 (17.9)	2.9 (5.0)	12.4 (16.9)

1L, first-line; 2L, second-line; 3L, third-line.

Table 3. Lines of MF treatment regimens

	All patients (N = 429)
Median number of LOT (range)	2 (1-6)
1L treatments received,[a] n (%)	429 (100.0)
Hydroxyurea	230 (53.6)
Ruxolitinib	178 (41.5)
Ruxolitinib, hydroxyurea	9 (2.1)
Lenalidomide	4 (0.9)
SCT	3 (0.7)
Fedratinib	3 (0.7)
Pacritinib	2 (0.5)
2L treatments received, n (%)	287 (66.9)
Ruxolitinib	178 (62.0)
Ruxolitinib, hydroxyurea	64 (22.3)
SCT	15 (5.2)
Hydroxyurea	14 (4.9)
Pacritinib	5 (1.7)
Lenalidomide	4 (1.4)
Fedratinib	4 (1.4)
Momelotinib	3 (1.0)
3L+ treatments received, n (%)	42 (9.8)
Hydroxyurea	11 (26.2)
SCT	10 (23.8)
Ruxolitinib, hydroxyurea	9 (21.4)
Ruxolitinib[b]	8 (19.0)
Fedratinib[c]	5 (11.9)
Pacritinib[d]	5 (11.9)
Momelotinib[e]	4 (9.5)
Lenalidomide, hydroxyurea	1 (2.4)

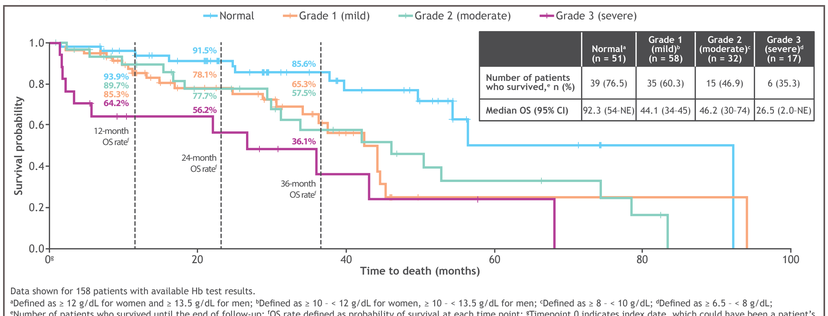
[a]Index date was the date of first JAKi initiation, therefore some patients had other treatments as their 1L therapy; [b]Patients with following drug combination were considered under ruxolitinib: ruxolitinib monotherapy (n = 7); ruxolitinib, pacritinib (n = 1); [c]Patients with following drug combination were considered under fedratinib: fedratinib monotherapy (n = 3); fedratinib, ruxolitinib (n = 2); [d]Patients with following drug combination were considered under pacritinib: pacritinib monotherapy (n = 11); pacritinib, hydroxyurea (n = 1); [e]Patients with following drug combination were considered under momelotinib: momelotinib monotherapy (n = 2); momelotinib, hydroxyurea (n = 1); momelotinib, pacritinib (n = 1).

Table 4. Supportive care

	All patients (N = 429)
Pre-index supportive care, n (%)	249 (58.0)
ESAs	146 (34.0)
Vitamins and minerals	104 (24.2)
RBC transfusion	93 (21.7)
G-CSFs	7 (1.6)
HMAs	6 (1.4)
Steroids	5 (1.2)
Iron chelating therapies	3 (0.7)
GM-CSFs	0
Erythroid maturation agents	0
Post-index supportive care, n (%)	251 (58.5)
RBC transfusion	169 (39.4)
ESAs	115 (26.8)
Vitamins and minerals	98 (22.8)
HMAs	25 (5.8)
Steroids	17 (4.0)
G-CSFs	9 (2.1)
Iron chelating therapies	6 (1.4)
Erythroid maturation agents	3 (0.7)
GM-CSFs	0

G-CSF, granulocyte colony-stimulating factor; GM-CSF, granulocyte-macrophage colony-stimulating factor; HMA, hypomethylating agent.

Figure 1. OS in patients stratified by Hb level



	Normal[a] (n = 51)	Grade 1 (mild)[b] (n = 58)	Grade 2 (moderate)[c] (n = 32)	Grade 3 (severe)[d] (n = 17)
Number of patients who survived,[e] n (%)	39 (76.5)	35 (60.3)	15 (46.9)	6 (35.3)
Median OS (95% CI)	92.3 (54-NE)	44.1 (34-45)	46.2 (30-74)	26.5 (2.0-NE)

Data shown for 158 patients with available Hb test results.
[a]Defined as ≥ 12 g/dL for women and ≥ 13.5 g/dL for men; [b]Defined as ≥ 10 - < 12 g/dL for women, ≥ 10 - < 13.5 g/dL for men; [c]Defined as ≥ 8 - < 10 g/dL; [d]Defined as ≥ 6.5 - < 8 g/dL; [e]Number of patients who survived until the end of follow-up; [f]OS rate defined as probability of survival at each time point; [g]Timepoint 0 indicates index date, which could have been a patient's first, second, or third LOT.
CI, confidence interval; NE, not evaluable.

Conclusions

- Treatment patterns in this real-world study showed that patients with MF and anemia experience delays between diagnosis and JAKi treatment initiation
- Approximately half of the patients received supportive care both before and after index and RBC transfusion rate increased after index, indicating a need for more targeted interventions
- Among patients with Hb level measurements at baseline, survival worsened as baseline Hb levels decreased
- These findings highlight that there is an unmet need for targeted treatments for patients with MF-associated anemia, as well as the importance of targeted interventions to manage Hb levels for improving overall patient prognosis

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