Myelofibrosis Observational Real-World Experience in Community Oncology (MORE-CO): A Retrospective Analysis of Baseline Clinical Factors Impacting Overall Survival

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Anthony Michael Hunter[1], Alexander Coltoff[2], Lucio Gordan[3], Tom Liu[4], Amanda Warner[3], Aya Alajrash[3], Nicole Niehoff[4], Alin Kalayjian[4,*], Trevor Heritage[3], Shiyuan Zhang[4], Arsh Singh[3]

[1]Winship Cancer Institute of Emory University, Atlanta, GA, USA; [2]Hollings Cancer Center, MUSC, Charleston, SC, USA; [3]Florida Cancer Specialists & Research Institute, Tampa, FL, USA; [4]GSK, Collegeville, PA, USA

Introduction

- Myelofibrosis (MF) is a chronic myeloproliferative neoplasm characterized by overactivation of the Janus kinase (JAK)-signal transducer and activator of transcription pathway[1]
- Patients with MF may present with a range of constitutional symptoms (eg, fever, night sweats, pruritus, bone pain, and weight loss), enlarged spleen, and anemia[1,2]
  - The frequency and severity of these manifestations generally increase throughout the course of the disease, and all are associated with worse quality of life and shorter survival[1,2]
- An evidence gap exists in describing patient characteristics and survival outcomes based on anemia status and splenomegaly in patients with MF treated in a US community oncology setting
- Using data from the Florida Cancer Specialists & Research Institute (FCS) database and health records, the objective of this real-world study was to describe characteristics and overall survival (OS) of patients with MF, stratified by baseline splenomegaly assessment and anemia status, treated in US community practice

Methods

Study Design and Patients

- This retrospective, observational, longitudinal cohort study included adult patients presenting to FCS with a diagnosis of MF (index date) between January 1, 2017, and December 31, 2022
  - Patients were identified by *International Classification of Diseases, 10th Revision, Clinical Modification* codes for MF (D7581), osteomyelofibrosis (D474), and myeloproliferative disease (D471)
  - Patients were required to have ≥1 visit to FCS within 3 months prior to (baseline period) and after (study observation period) the index date
    - Demographic variables were collected within 6 months prior to or within 30 days after the index date
  - Follow-up continued until the end of the study observation period, last contact date, or date of death, whichever occurred first

Data Source

- Data were captured from the FCS database and electronic health records (structured data)
  - FCS is one of the largest independent, privately held medical oncology/hematology practices in Florida
- Manual chart review (unstructured data) was performed as needed to ensure completion of data elements and to obtain data elements that were not captured in structured data fields
- All data were stratified by baseline splenomegaly assessment and anemia status

Variable Definitions

- **Splenomegaly assessment:** per physician report, assessed by imaging or physical examination at baseline
  - Patients were grouped by no evidence of splenomegaly or presence of splenomegaly
- **Anemia status:** based on laboratory-assessed hemoglobin (Hb) level at baseline
  - Patients were grouped by moderate/severe anemia (Hb level of <10 g/dL) or no/mild anemia (Hb level of ≥10 g/dL)
- **Symptom assessment:** derived from clinical notes as either symptom improvement or no symptom improvement
- **OS:** time interval from the index date to date of death from any cause

Statistical Analyses

- Baseline characteristics and clinical outcomes were described as frequency count and percentage, mean and SD, or median and range
  - All values were stratified by baseline splenomegaly assessment (no evidence of splenomegaly vs splenomegaly) and/or anemia status (moderate/severe vs no/mild)
- Incidences of clinical outcomes were aggregated and described during the follow-up period
- For binary variables, *P* values were calculated using a χ^2 test
- For continuous variables, *P* values were calculated using a *t*-test
- OS was analyzed using the Kaplan-Meier method, pairwise log-rank testing, and a multivariate Cox proportional hazards model
  - Alignment of the Cox model with the proportional hazards assumption was assessed

Results

Baseline Patient Characteristics by Anemia Status

- Of 1699 patients with MF identified from the FCS database, 193 had baseline splenomegaly assessments and were included in this analysis (splenomegaly, n=116; no evidence of splenomegaly, n=77)
  - Of these 193 patients, 93 (48.2%) had baseline moderate/severe anemia and 100 (51.8%) had no/mild anemia
- Baseline patient demographic and clinical characteristics by anemia status are summarized in **Table 1**
  - In patients with moderate/severe vs no/mild anemia, mean Charlson Comorbidity Index (CCI) score was significantly higher (0.9 vs 0.5, *P*=.006) and median platelet count was significantly lower (235 vs 445×10⁹/L, *P*<.001)

Table 1: **Baseline Characteristics by Anemia Status**

	Baseline anemia status[a]		
	Moderate/severe anemia (n=93)	No/mild anemia (n=100)	*P* value
Age, mean (SD), years	73.7 (8.9)	71.3 (10)	.08
Male, n (%)	46 (49.5)	55 (55.0)	.53
Race, n (%)			.62
Asian	2 (2.2)	3 (3.0)	
Black or African American	3 (3.2)	3 (3.0)	
White	83 (89.2)	83 (83.0)	
Other or unknown	5 (5.4)	11 (11.0)	
CCI score			**.006**
Mean (SD)	0.9 (1.1)	0.5 (0.9)	
Median (range)	0.0 (0-3)	0.0 (0-3)	
MF subtype, n (%)			.47
PMF	49 (52.7)	56 (56.0)	
PET-MF	16 (17.2)	21 (21.0)	
PPV-MF	18 (19.4)	18 (18.0)	
Unknown MF type	10 (10.8)	5 (5.0)	
Transfusion status, n (%)			**<.001**
Transfusion dependent[b]	1 (1.1)	1 (1.0)	
Transfusion independent[c]	73 (78.5)	99 (99.0)	
Transfusion requiring[d]	19 (20.4)	0	
Hb level, median (range), g/dL	8.7 (4.8-9.9)	12.0 (10.0-17.2)	**<.001**
Platelet count, median (range), ×10⁹/L	235.0 (11-1596)	445.0 (41-1785)	**<.001**
Thrombocytopenia status, n (%)			**.002**
Mild (platelet counts >100×10⁹/L)	69 (74.2)	91 (91.0)	
Moderate (platelet counts 51-100×10⁹/L)	13 (14.0)	8 (8.0)	
Severe (platelet counts <51×10⁹/L)	11 (11.8)	1 (1.0)	
Positive *JAK* mutation, n (%)	53 (57.0)	63 (63.0)	.48
Positive *CALR* mutation, n (%)	11 (11.8)	15 (15.0)	.66
Positive *MPL* mutation, n (%)	6 (6.5)	7 (7.0)	1.0
Palpable spleen measurement at diagnosis			.41
n	48	58	
Mean (SD), cm	17.2 (4.2)	16.5 (4.5)	
Median (range), cm	16.6 (7-30)	15.8 (7.8-27.3)	
Length of follow-up, median (range), months	23.0 (2-87)	33.0 (5-87)	**.001**

P values in bold denote significance (P<.05).
CALR, calreticulin; CCI, Charlson Comorbidity Index; Hb, hemoglobin; JAK, Janus kinase; MF, myelofibrosis; MPL, myeloproliferative leukemia gene; PET, post-essential thrombocythemia; PMF, primary myelofibrosis; PPV, post-polycythemia vera.
[a] Moderate/severe anemia was defined as having an Hb level of <10 g/dL. No/mild anemia was defined as having an Hb level of ≥10 g/dL.
[b] Transfusion dependent was defined as requiring ≥4 units of packed red blood cells or having an Hb level of <8 g/dL in the prior 8 weeks.
[c] Transfusion independent was defined as receiving no packed red blood cell transfusions and having no Hb levels of <8 g/dL in the prior 8 weeks.
[d] Transfusion requiring was defined as not meeting the definitions of transfusion dependent or transfusion independent.

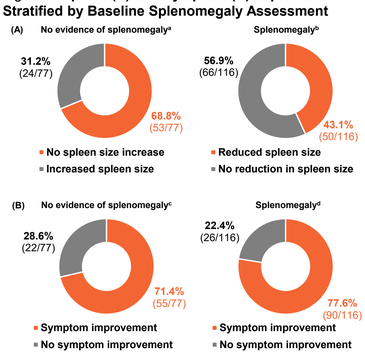
Baseline Patient Characteristics by Splenomegaly Assessment

- In patients with no evidence of splenomegaly vs splenomegaly:
  - Similar proportions of patients were White (85.7% vs 88.5%) and diagnosed with primary MF (57.1% vs 52.6%), but numerically fewer patients were male (44.2% vs 59.3%)
  - Median age at MF diagnosis (75 years [range, 52-94 years] vs 72 years [range, 41-88 years]) and mean (SD) CCI score (0.8 [1.1] vs 0.6 [0.9]) were numerically higher
  - Median Hb level (10.1 vs 10.0 g/dL) and the proportion of patients who were transfusion independent (90.9% vs 87.9%) were similar, but median platelet count was numerically higher (442 vs 275×10⁹/L)
  - Most patients had a positive *JAK* mutation (55.8% vs 62.9%); similar proportions had positive *CALR* (13.0% vs 13.8%) or *MPL* (7.8% vs 6.0%) mutations

Changes in Spleen and Symptom Assessment During Follow-Up

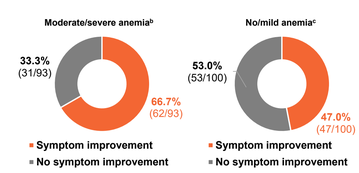
- Median duration of follow-up was similar for patients based on splenomegaly assessment (no evidence of splenomegaly, 31 months; splenomegaly, 30 months) but was significantly shorter for patients with moderate/severe vs no/mild anemia (23 vs 33 months, respectively; *P*=.001); duration range was 2 to 87 months for all patients
  - **Figure 1** shows change in spleen size and symptoms during the study period by baseline splenomegaly assessment
  - **Figure 2** shows change in symptoms from MF diagnosis to 24 weeks after JAK inhibitor initiation by baseline anemia status; patients with baseline moderate/severe vs no/mild anemia had a significantly higher rate of symptom improvement (*P*=.009)

Figure 1: **Spleen (A) and Symptom (B) Improvement Stratified by Baseline Splenomegaly Assessment**



[a] 3 Patients were not evaluable for spleen assessment and were categorized as having no change in spleen size.
[b] 1 Patient was not evaluable for spleen assessment and was categorized as having no change in spleen size.
[c] 5 Patients had no symptoms recorded and were categorized as having no improvement in symptoms.
[d] 2 Patients had no symptoms recorded and were categorized as having no improvement in symptoms.

Figure 2: **Symptom Improvement Stratified by Baseline Anemia Status[a]**



Hb, hemoglobin.
[a] Moderate/severe anemia was defined as having an Hb level of <10 g/dL. No/mild anemia was defined as having an Hb level of ≥10 g/dL.
[b] 27 Patients had no symptoms recorded and were categorized as having no improvement in symptoms.
[c] 48 Patients had no symptoms recorded and were categorized as having no improvement in symptoms.

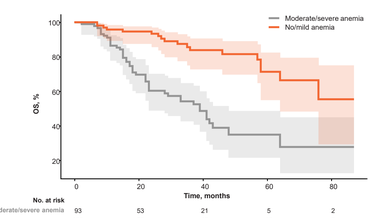
Treatment Use During Follow-Up

- Treatments received stratified by baseline anemia status are shown as **Supplemental Data** behind the **QR code**
  - A significantly higher percentage of patients with moderate/severe vs no/mild anemia received treatment with any JAK inhibitor (*P*=.01) or anemia supportive care (*P*<.001)
  - There were no significant differences in the individual use of ruxolitinib, pacritinib, and fedratinib

Overall Survival

- OS was similar in patients with no evidence of splenomegaly vs those with splenomegaly at baseline (*P*=.53) (**Supplemental Data** behind the **QR code** and **Table 2**)
- OS was significantly shorter in patients with baseline moderate/severe vs no/mild anemia (*P*<.001) (**Figure 3** and **Table 2**)
- Patients with both splenomegaly and moderate/severe anemia at baseline had the shortest median OS duration of 33 months, and this was significantly shorter than in patients with no/mild anemia with (*P*<.001) and without (*P*<.001) splenomegaly (**Figure 4** and **Table 2**)
- There was no significant difference in OS based on driver mutational status (*P*>.05)

Figure 3: **Kaplan-Meier Analysis of Survival by Baseline Anemia Status[a]**



No. at risk					
Moderate/severe anemia	93	53	21	5	2
No/mild anemia	100	73	43	18	2

Hb, hemoglobin; OS, overall survival.
[a] Moderate/severe anemia was defined as having an Hb level of <10 g/dL. No/mild anemia was defined as having an Hb level of ≥10 g/dL.

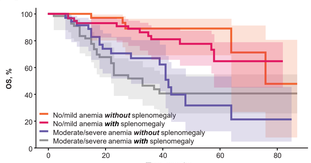
Conclusions

- Moderate to severe anemia significantly predicted shorter OS and remained a strong negative prognostic variable after controlling for potential baseline confounders; low platelet count was also a strong and significant predictor of shorter OS
  - These data show that patients with Hb levels of <10 g/dL and platelet counts of <100×10⁹/L are at the highest risk for early mortality
- Stratification by enlarged spleen size provided further OS differentiation among anemic patients; however, spleen size alone was not a significant predictor of shorter OS
- Overall, these findings highlight the importance of including anemia management alongside spleen and symptom improvement as treatment goals in the care of patients with MF in community settings

Limitations

- Baseline splenomegaly assessments were based on physician report, which may have introduced a risk of reporting bias and variability
  - However, as all patient data were obtained from the same institution and database, variability in reporting was likely reduced
- Only patients in the FCS database were included, limiting the generalizability of these results to patients in other databases across the US
- Data for treatment use were only collected for the 3 JAK inhibitors approved in the US prior to the index date of December 31, 2022, namely ruxolitinib (approved in 2011), fedratinib (approved in 2019), and pacritinib (approved in 2022)[3-5]
  - No patients in this analysis were treated with momelotinib (approved in September 2023)[6]
- Future analyses exploring the impact of different treatment options on OS in these MF patient populations could provide additional insights

Figure 4: **Kaplan-Meier Analysis of Survival by Baseline Splenomegaly Assessment Plus Anemia Status[a]**



No. at risk					
No/mild anemia *without* splenomegaly	40	28	15	5	1
No/mild anemia *with* splenomegaly	60	45	28	13	1
Moderate/severe anemia *without* splenomegaly	36	22	11	3	1
Moderate/severe anemia *with* splenomegaly	57	31	10	2	1

Hb, hemoglobin; OS, overall survival.
[a] Moderate/severe anemia was defined as having an Hb level of <10 g/dL. No/mild anemia was defined as having an Hb level of ≥10 g/dL.

Table 2: **OS by Baseline Splenomegaly Assessment and Anemia Status**

				OS estimate, %			
	n	Events, n (%)	Censored, n (%)	Time to event, median (95% CI), months[a]	Month 6	Month 12	Month 24	*P* value
Baseline splenomegaly assessment								
No evidence of splenomegaly	77	24 (31.2)	53 (68.8)	64 (43-NE)	98.7	96.0	83.7	.53[b]
Splenomegaly	116	40 (34.5)	76 (65.5)	NR (39-NR)	99.1	88.2	72.4	
Baseline anemia status[c]								
No/mild	100	18 (18.0)	82 (82.0)	NR (64-NR)	100	95.9	93.3	**<.001[d]**
Moderate/severe	93	46 (49.5)	47 (50.5)	39 (23-48)	97.8	86.7	60.6	
Baseline splenomegaly assessment and anemia status								
No/mild anemia ***without*** splenomegaly	40	5 (12.5)	35 (87.5)	76 (64-NE)	100	100	97.0	–
No/mild anemia ***with*** splenomegaly	60	13 (21.7)	47 (78.3)	NR (58-NR)	100	93.0	90.8	
Moderate/severe anemia ***without*** splenomegaly	36	18 (50.0)	18 (50.0)	42 (29-64)	97.1	91.4	70.4	
Moderate/severe anemia ***with*** splenomegaly	57	28 (49.1)	29 (50.9)	33 (22-NE)	98.2	83.5	54.0	
Genetic mutation								
CALR	26	4 (15.4)	22 (84.6)	NR (29-NR)	100	95.8	83.9	–
JAK	116	39 (33.6)	77 (66.4)	64 (43-NE)	100	92.9	76.5	
MPL	13	2 (15.4)	11 (84.6)	NR (NE-NR)	100	84.6	84.6	

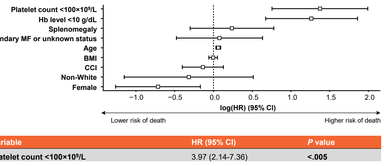
Condition 1 (shorter median OS duration)	Condition 2 (longer median OS duration)	*P* value (condition 1 vs 2)
Moderate/severe anemia ***with*** splenomegaly	Moderate/severe anemia ***without*** splenomegaly	.48
No/mild anemia ***without*** splenomegaly	Moderate/severe anemia ***without*** splenomegaly	**<.001**
Moderate/severe anemia ***without*** splenomegaly	No/mild anemia ***with*** splenomegaly	**.001**
Moderate/severe anemia ***with*** splenomegaly	No/mild anemia ***without*** splenomegaly	**<.001**
Moderate/severe anemia ***with*** splenomegaly	No/mild anemia ***with*** splenomegaly	**<.001**
No/mild anemia ***without*** splenomegaly	No/mild anemia ***with*** splenomegaly	.47

P values in bold denote significance (P<.05).
CALR, calreticulin; Hb, hemoglobin; JAK, Janus kinase; MPL, myeloproliferative leukemia gene; NE, not estimable; NR, not reached; OS, overall survival.
[a] NR indicates that the median value was not observed; NE indicates that the confidence limit could not be estimated within the observed data.
[b] P value is based on baseline splenomegaly vs no evidence of splenomegaly.
[c] Moderate/severe anemia was defined as having an Hb level of <10 g/dL. No/mild anemia was defined as having an Hb level of ≥10 g/dL.
[d] P value is based on baseline moderate/severe anemia vs no/mild anemia.

Multivariate Analyses for OS

- The Cox proportional hazards model for OS is shown in **Figure 5**
- In multivariate analyses, baseline moderate/severe anemia and low platelet count were the strongest predictors of shorter OS; older age and female sex were also significant OS predictors
  - Neither baseline splenomegaly (*P*=.38) nor CCI score (*P*=.32) had a significant impact on OS in this cohort

Figure 5: **Hazard Ratios for Cox Proportional Hazards Model**



Variable	HR (95% CI)	*P* value
Platelet count <100×10⁹/L	3.97 (2.14-7.36)	**<.005**
Hb level <10 g/dL	3.55 (1.96-6.42)	**<.005**
Splenomegaly	1.27 (0.74-2.18)	.38
Secondary MF or unknown status	1.08 (0.62-1.89)	.78
Age	1.07 (1.03-1.10)	**<.005**
BMI	1.00 (0.94-1.05)	.93
CCI	0.87 (0.67-1.14)	.32
Non-White	0.73 (0.32-1.67)	.45
Female	0.49 (0.28-0.84)	**.01**

P values in bold denote significance (P<.05).
HR or >1 indicates an increased risk, and HR of <1 indicates a decreased risk of death.
BMI, body mass index; CCI, Charlson Comorbidity Index; Hb, hemoglobin; HR, hazard ratio; MF, myelofibrosis.

Abbreviations

BMI, body mass index; CALR, calreticulin; CCI, Charlson Comorbidity Index; FCS, Florida Cancer Specialists & Research Institute; Hb, hemoglobin; HR, hazard ratio; JAK, Janus kinase; MF, myelofibrosis; MPL, myeloproliferative leukemia gene; OS, overall survival; PET, post-essential thrombocythemia; PMF, primary myelofibrosis; PPV, post-polycythemia vera.

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Corresponding author: Tom Liu, tom.x.liu@gsk.com