MPN-993

Clinical Outcomes in Patients With Myelofibrosis Treated With Ruxolitinib and Anemia-Supporting Medications

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Introduction

- Patients with myelofibrosis often present with anemia[1]
- Transient dose-dependent anemia is a known consequence of treatment with ruxolitinib (a potent, selective Janus kinase [JAK]1/JAK2 inhibitor), which can influence decisions regarding initiation, dosing, and discontinuation of therapy[2]
- Erythropoiesis-stimulating agents (ESAs) and danazol are recommended options to manage anemia in this population[3]
  - –However, there is a lack of data on clinical outcomes of patients with myelofibrosis who are treated with ruxolitinib and these agents

Objective

- To evaluate the treatment patterns and clinical outcomes of patients with myelofibrosis treated with ruxolitinib and ESAs or danazol in the large phase 3b JUMP trial

Methods

Study Design and Patients

- JUMP was a large (N=2233), global, single-arm, open-label, phase 3b expanded-access study that evaluated the safety and efficacy of ruxolitinib for patients with myelofibrosis in a setting similar to routine clinical practice[4]
  - –JUMP included adults with primary or secondary myelofibrosis and baseline platelet counts ≥50×10^9/L
  - –Ruxolitinib starting dose was 5–20 mg twice daily based on baseline platelet count
- This post hoc analysis included patients with baseline anemia (hemoglobin <12.0 g/dL [Hb<12] or the Hb<10.0 g/dL subset [Hb<10]) who were not receiving anemia medication at enrollment but initiated ESAs or danazol within 3 months of enrollment and remained on therapy for ≥3 months

Assessments

- Spleen length response: defined as ≥50% reduction from baseline in palpable spleen length
- Symptom response: defined as ≥6.5-point increase in Functional Assessment of Cancer Therapy–Lymphoma total score from baseline
- Transfusion dependence was defined as ≥3 units of red blood cells in the previous 12 weeks (either before baseline or Week 24)
- Transfusion independence was defined as 0 red blood cell transfusions in the previous 12 weeks (either before baseline or Week 24)

Statistical Analyses

- Data were summarized using descriptive statistics

Results

Patients

- Of the 1384 patients with Hb<12 and 755 in the Hb<10 subset who did not receive supportive care for anemia at enrollment, 101 (7.3%) and 52 (6.9%), respectively, initiated an ESA or danazol within 3 months of enrollment and were included in this analysis **(Table 1)**
- The median (range) time from enrollment to first dose of an ESA or danazol was 43 (2–91) days in the Hb<12 group and 34 (2–90) days in the Hb<10 subset
  - –In the Hb<12 group, 98 patients received an ESA, and 3 received danazol
  - –In the Hb<10 subset, 50 patients received an ESA, and 2 received danazol

Table 1. Demographics and Clinical Characteristics at Enrollment

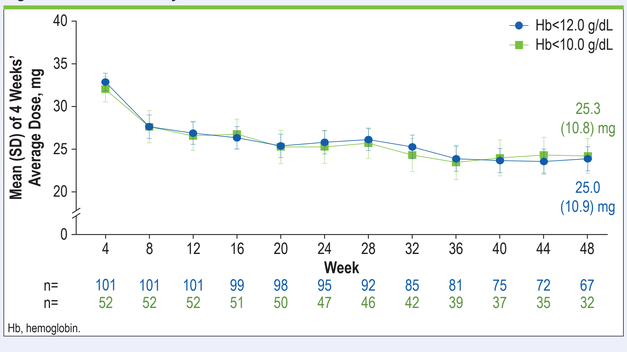
	Analysis Population*	
Parameter	Hb<12.0 g/dL (n=101)	Hb<10.0 g/dL (n=52)
Age, median (range), y	70.0 (45–86)	71.5 (45–84)
≥65 y, n (%)	74 (73.3)	36 (69.2)
Female, n (%)	46 (45.5)	25 (48.1)
BMI, mean (SD), kg/m^2	25.1 (4.2)	25.5 (4.5)
≥30 kg/m^2, n (%)	10 (9.9)	8 (15.4)
Time since initial diagnosis, median (range), mo	18.6 (0.3–312.0)	12.9 (0.3–157.7)
DIPSS risk, n (%)		
High risk	13 (12.9)	13 (25.0)
Intermediate-2	36 (35.6)	27 (51.9)
Intermediate-1	32 (31.7)	2 (3.8)
Low risk	1 (1.0)	0
Missing	19 (18.8)	10 (19.2)
Hb, mean (SD), g/dL	9.9 (1.1)	9.1 (0.8)
Platelet count, mean (SD), ×10^9/L	322.2 (250.4)	297.4 (223.2)
WBC count, mean (SD), ×10^9/L	14.5 (13.3)	15.6 (16.2)
Palpable spleen, n (%)	92 (91.1)	46 (88.5)
Length, mean (SD), cm below LCM	13.0 (6.6)	12.1 (6.1)
Transfusion dependent, n (%)	10 (9.9)	7 (13.5)
Median (range) follow-up duration, mo	17.5 (4.6–57.1)	16.7 (4.6–53.7)
Median (range) duration of ESA/danazol treatment, mo	10.2 (3.3–44.3)	9.2 (3.4–40.8)

BMI, body mass index; DIPSS, Dynamic International Prognostic Scoring System; ESA, erythropoiesis-stimulating agent; Hb, hemoglobin; LCM, left costal margin; WBC, white blood cell.
* Patients who had anemia at baseline (enrollment) but were not yet receiving supportive ESA or danazol. Patients were required to start ESA or danazol treatment within 3 months of baseline and remain on anemia-supporting therapy for ≥3 months.

Ruxolitinib Exposure

- 4-week average doses remained above 25 mg/d for most study visits **(Figure 1)**

Figure 1. Mean Total Daily Dose of Ruxolitinib

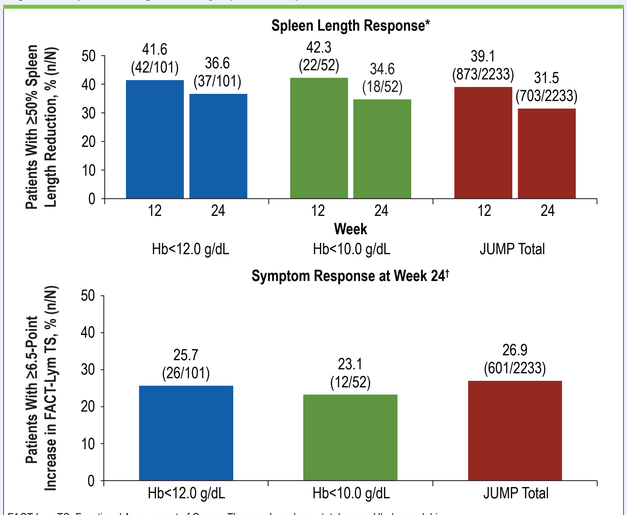


Hb, hemoglobin.

Spleen Length and Symptom Response

- Spleen length response and symptom response rates were comparable between the Hb<12 group and Hb<10 subset **(Figure 2)**
- The rates were consistent with those observed in the total JUMP population

Figure 2. Spleen Length and Symptom Response

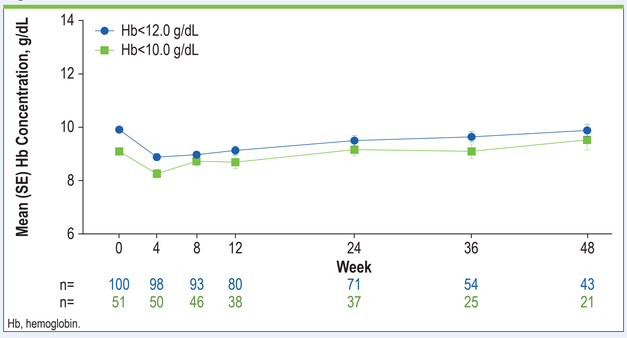


FACT-Lym TS, Functional Assessment of Cancer Therapy–Lymphoma total score; Hb, hemoglobin.
* For patients with Hb<12.0 g/dL, data were missing for 28 (27.7%) patients at Week 12 and for 42 (41.6%) at Week 24; for patients with Hb<10.0 g/dL, data were missing for 16 (30.8%) at Week 12 and 25 (48.1%) at Week 24; for the total JUMP population, data were missing for 590 (26.4%) at Week 12 and 953 (42.7%) at Week 24. Patients with missing data were considered non-responders.
† Symptom response was not assessed at Week 12. All patients provided a Week 24 symptom assessment.

Hb Levels and Transfusion Status

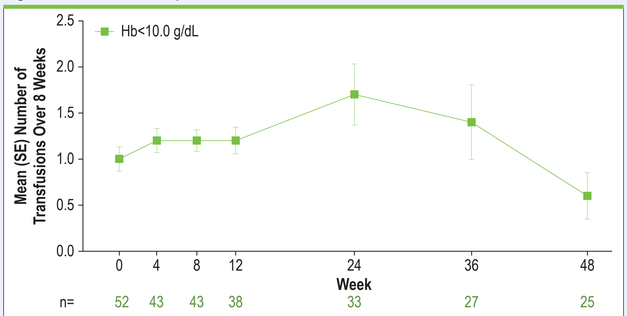
- For both the Hb<12 group and Hb<10 subset, mean Hb during the study reached a nadir at Week 4 and steadily increased thereafter to Week 48 **(Figure 3)**
  - –The mean percentage change from baseline to Week 48 was 1.5% in the Hb<12 group and 6.5% in the Hb<10 subset
- Transfusion requirements decreased between baseline and Week 48 **(Figure 4)**
- 4 patients (57%) with Hb<10 and transfusion dependence at baseline were no longer transfusion dependent at 24 weeks, including 3 who became transfusion independent

Figure 3. Hb Levels Over Time



Hb, hemoglobin.

Figure 4. Transfusion Requirement Over Time



Hb, hemoglobin.
Values for transfusions are the mean number of recorded transfusions per patient over a rolling 8-week period preceding each time point. Values were set to 0 for patients who did not have a transfusion.

Conclusions

- **For patients with anemia at myelofibrosis diagnosis who received ESAs or danazol in combination with ruxolitinib, spleen and symptom response rates were similar to those reported in the entire JUMP study population**
- **In addition, most patients tolerated doses of ruxolitinib >25 mg daily and post-enrollment maintained an Hb level within 1.0 g/dL of baseline throughout the study period**
- **These results support the use of an ESA or danazol as an option for anemia supportive care in combination with ruxolitinib and may allow for maintenance of ruxolitinib dose intensity in myelofibrosis patients with anemia**

Disclosures

PV reported consultancy, speakers bureau, and board of directors or advisory committee membership for Incyte; consultancy and/or advisory role for Blueprint Medicines, AbbVie, CTI BioPharma Corp, Novartis, Amgen, Pfizer, Genentech, Stemline, and MorphoSys; research funding from Seattle Genetics, Amgen, Astex Pharmaceuticals, Incyte, Blueprint Medicines, Kartos Therapeutics, Gilead/Forty Seven, Constellation Pharmaceuticals, AbbVie, CTI BioPharma Corp, and Takeda.

JR, **JEH-M**, **EB**, and **VB** are employees and stakeholders in Incyte.

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