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Disease and Clinical Characteristics of Patients With Myelofibrosis Enrolled in the MOST Study

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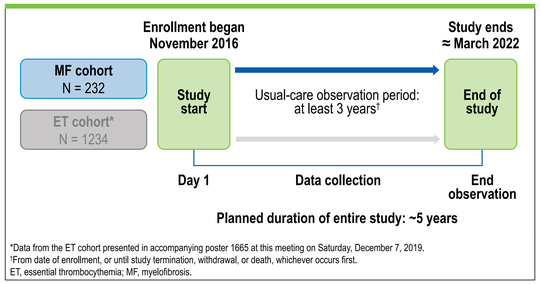
Background/Objective

- The Myelofibrosis and Essential Thrombocythemia Observational STudy (MOST; NCT02953704) is an ongoing multicenter, prospective, observational, noninterventional, nonrandomized, open-label study in patients with myelofibrosis (MF) or essential thrombocythemia in community and academic study sites in the United States **(Figure 1)**
- The objective of this analysis is to describe the demographic and clinical characteristics of patients with low- or intermediate-1 (INT-1)–risk (by age alone) MF enrolled in MOST

Figure 1. MOST Study Design



*Data from the ET cohort presented in accompanying poster 1665 at this meeting on Saturday, December 7, 2019.
†From date of enrollment, or until study termination, withdrawal, or death, whichever occurs first.
ET, essential thrombocythemia; MF, myelofibrosis.

Methods

- Eligible patients with MF were at least 18 years old and had low-risk or INT-1–risk by age alone according to the Dynamic International Prognostic Scoring System (DIPSS)
- Key exclusion criteria were participation in blinded investigational drug trials, life expectancy ≤6 months, or diagnosis of other concurrent myeloid malignancies
- Data regarding disease and clinical characteristics documented during usual-care visits were entered into an electronic case report form
- Data were analyzed with descriptive statistics

Results

- 232 patients with MF were enrolled between November 29, 2016 and March 29, 2019 at 124 sites
- 200 patients with low-risk (n = 77) or INT-1–risk by age alone (n = 123) MF were included in this analysis (data cutoff date: June 17, 2019) **(Table 1)**
  - 32 patients were excluded due to incorrect risk categorization (n = 27) or missing prognostic factors (n = 5) at the time of enrollment

Table 1. Demographics and MF Disease Characteristics at Enrollment

Variable	N = 200
Age, median (range), years	68 (35–88)
Sex, n (%)	
Male	103 (52)
Race, n (%)	
White	177 (89)
Black	12 (6)
Other*	11 (6)
Family history of MF/ET/PV, n (%)	13 (7)
Spleen palpation (manual)	
Spleen palpation performed, n/N (%)	157/200 (79)
Patients with palpable spleen, n/N (%)	55/157 (35)
Patients with palpable spleen measurements, n/N (%)	35/55 (64)
Spleen length, median (range), cm	7 (1–22)
Median time from MF diagnosis to enrollment, years	1.7 (0–37.7)
Time from MF diagnosis to enrollment, n (%)	
<1 year	88 (44)
1–<5 years	62 (31)
5–<10 years	33 (17)
≥10 years	17 (9)

*Other includes Asian (n = 1), American Indian/Alaska Native (n = 1), and other (n = 9).
ET, essential thrombocythemia; MF, myelofibrosis; PV, polycythemia vera.

Data from MOST promise to reveal important insights about the clinical features, progression, and treatment of patients with lower-risk MF

Results (continued)

- 93% (185/200) of patients were reported to have undergone bone marrow biopsy/aspiration. 82% of patients were reported to have mutation testing at the time of diagnosis
- Mutation test results were available for 142 of 200 patients (71%) before or within 30 days of diagnosis **(Table 2)**
  - 134 patients (94%) were tested for a *JAK2* mutation, of whom 71% were positive
- Results of complete blood counts reported at enrollment are shown in **Table 3**

Table 2. Mutation Test Results*

Patients with ≥1 mutation test result, n/N (%)	142/200 (71)
Mutation test, n/N (%)†	
JAK2-positive	95/134 (71)
CALR-positive	26/36 (72)
MPL-positive	3/23 (13)
JAK2 V617F, *CALR*, and *MPL* triple negative	3/12 (25)

*Mutation testing completed before or within 30 days of diagnosis.
†Numerator = patients positive for mutation; denominator = patients tested for mutation.

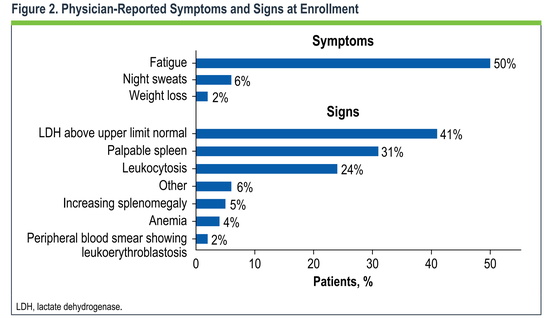
Table 3. Hematologic Laboratory Values Reported at Enrollment

Laboratory Value	Hemoglobin, g/dL	Platelets, × 10^9/L	Leukocytes, × 10^9/L
n	190	188	186
Median (Q1–Q3)	12.3 (11.1–13.6)	323.0 (175.5–488.0)	8.22 (5.8–11.5)
Patients above normal range,* n (%)	2 (1)	68 (36)	58 (31)
Patients below normal range,* n (%)	97 (51)	30 (16)	19 (10)

*Normal ranges (when not specified by the study sites): hemoglobin, women: 11.0–15.5 g/dL, men: 12.5–17.0 g/dL; platelets, 125–375 × 10^9/L; leukocytes, 3.7–11.0 × 10^9/L.

- According to physician-reported data, most patients (62%; n = 124) had ≥1 MF-related symptom or sign **(Figure 2)**
  - The most commonly reported symptom was fatigue (50%) and the most commonly reported sign was elevated lactate dehydrogenase (41%)

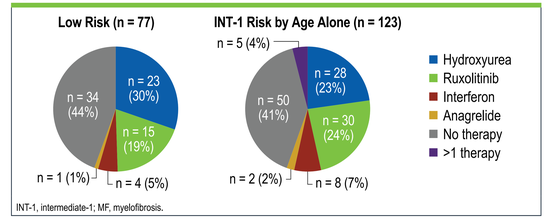
Figure 2. Physician-Reported Symptoms and Signs at Enrollment



LDH, lactate dehydrogenase.

- Across both risk groups, 111 patients (56%) were receiving MF-directed monotherapy at enrollment **(Figure 3)**
- Five patients (3%) were receiving >1 MF-directed therapy
- 44% of low-risk (34/77) and 41% of INT-1–risk (50/123) patients were receiving no MF-directed therapy at enrollment

Figure 3. Current MF-Directed Therapy at Enrollment



INT-1, intermediate-1; MF, myelofibrosis.

Disclosures

Gerds: Consulting or advisory role – *Apexx Oncology, Celgene, CTI Biopharma, Incyte Corporation*. **Lyons:** Leadership – *McKesson*; stock and other ownership interests – *Texas Oncology*; consulting or advisory role – *Amgen*. **Colucci, Kalafut, Paranagama:** Employment and stock ownership – *Incyte Corporation*. **Verstovsek:** Consulting or advisory role – *Incyte Corporation*.

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