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2775 48-Month Update On Survival and AML Transformation In a 600-Patient Registry Of Lower-Risk MDS Patients

Program: Oral and Poster Abstracts
Session: 633. Myelodysplastic Syndromes: Poster II

Sunday, December 8, 2013, 6:30 PM-8:30 PM
Hall E (Ernest N. Morial Convention Center)

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Introduction: Packed red blood cell transfusion is often required for the treatment of anemia in patients (pts) with myelodysplastic syndromes (MDS). Transfusion requirement is associated with poorer clinical outcomes and reduced overall survival (OS) in MDS. We prospectively collected data on clinical outcomes in chelated and non-chelated, transfused, lower-risk MDS pts. OS, leukemic transformation, and clinical events are reported for these groups at 48 mos on study.

Methods: This 5-year, non-interventional registry enrolled 599 pts from 107 US centers. Pts were ≥18 years old with lower-risk MDS (WHO, FAB classification, and/or IPSS) and transfusional iron overload (serum ferritin ≥1000 µg/L and/or ≥20 packed red blood cell units and/or ≥6 units every 12 weeks). The chelated group included all pts who had ever used iron chelation; sub-analysis was performed on pts with ≥6 mos chelation. Assessments were every 6 mos for 5 years or until death and included demographics, survival, disease status, comorbidities, causes of death, and MDS therapy.

Results: We present results for non-chelated pts and those chelated ≥6 mos. Baseline demographics and IPSS risk status were similar between groups, although transfusion burden appeared higher in chelated pts (Table 1). At 48 mos, 120 pts continued on registry and 479 had discontinued (379 died [63.3%]; 64 lost to follow-up [10.7%]; 25 other [4.2%]; and 11 completed the study [1.8%]). In all, 269 pts (44.9%) received chelation therapy; 202 had ≥6 mos lifetime chelation. The percentage of pts who had ever received MDS therapy was lower among non-chelated (88.2%) vs chelated ≥6 mos pts (93.6%; P=0.0425). At enrollment, cardiac and vascular comorbid conditions were higher and endocrine conditions trended higher in non-chelated vs chelated ≥6 mos pts (52.1% vs 30.7% [P<0.0001], 59.4% vs 45.0% [P=0.0013], and 43.9% vs 35.6% [P=0.0588], respectively). While on registry, cardiac, vascular, and endocrine comorbid conditions all trended higher in non-chelated vs chelated ≥6 mos pts (50.9% vs 44.1%, 56.4% vs 49.0%, and 40.3% vs 38.6%, respectively; P>0.05 all comparisons). Presence of cardiovascular comorbidities was associated with a significantly shorter mean (SE) OS (89.1 [5.83] mos vs 85.2 [4.43] mos; P<0.01); however this association was not seen with endocrine comorbidities. Median OS was longer in chelated ≥6 mos vs non-chelated pts (P<0.0001; Table 2). Most frequent causes of death were MDS/acute myeloid leukemia (AML), cardiac events, and infection. Time from diagnosis to leukemic transformation was longer in chelated ≥6 mos vs non-chelated pts (P<0.0001).

Conclusions: At 48 mos, chelated pts had significantly longer OS and time to AML transformation. At baseline, fewer chelated ≥6 mos vs non-chelated pts had cardiac and vascular comorbidities. Baseline characteristics and IPSS risk status were similar between groups. Additional assessments over the 5-year duration of this registry will provide further information on the association between chelation and clinical outcomes.

Table 1. Demographics, IPSS Risk Status, and Transfusion Burden

	Non-chelated	Chelated	Chelated ≥6 mos
	n=330	n=269	n=202
Age, years, median (range)	77 (47–99)	75 (21–94)	75 (21–94)
Males, %	58.8	56.5	52.5
Risk status, n (%)	56 (34.8)	57 (42.9)	40 (39.2)
IPSS – low			
IPSS – intermediate-1	105 (65.2)	76 (57.1)	62 (60.8)
Median baseline ferritin (range), ng/mL	1353 (3–7379)	1500 (33–16,422)	1486 (81–16,422)
Transfusions, median			
Lifetime units transfused at baseline	20.0	38.5	44.0
Units transfused/4 weeks while on registry	1.41	2.11	2.16

IPSS, International Prognostic Scoring System.

Table 2. Summary of Survival and AML Transformation at 48 Months

	Non-chelated	Chelated	Chelated ≥6 mos
	n=330	n=269	n=202
Median OS from Dx (range), mos	48.7 (1.8–289.4)*	96.8 (2.3–187.8)	102.5 (2.3–187.8)*
Deaths, n (%)	230 (69.7)*	149 (55.4)	105 (52.0)*
Median time to AML transformation from Dx (range), mos	45.6 (6.9–82.5)*	67.6 (16.4–176.6)	77.0 (16.4–176.6)*
AML transformations, n (%)	34 (10.3)	17 (6.3)	14 (6.9)

AML, acute myeloid leukemia; Dx, diagnosis; OS, overall survival.

*P<0.0001, non-chelated vs chelated ≥6 mos.

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