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A 36-month analysis of treatment patterns and outcomes in patients with lower-risk myelodysplastic syndromes from a prospective observational study.

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Background: Many patients (pts) with lower-risk myelodysplastic syndromes (MDS) require chronic red blood cell transfusions for symptomatic anemia, which can result in iron overload. We present a 36-month interim analysis of a 5-year US registry that prospectively collected data on clinical events and survival in chelated vs non-chelated, transfused, lower-risk MDS pts. **Methods:** This multicenter, non-interventional registry enrolled 600 pts ≥18 yr old with lower-risk MDS (WHO, FAB, and/or IPSS risk stratification criteria) and transfusional iron overload (serum ferritin ≥1,000 ng/mL and/or ≥20 packed red blood cell units and/or ≥6 units every 12 wks). The chelated group included pts who had received any chelation. **Results:** Median age was 76 yr (range, 21–99), 57.8% were male, and risk status was 38.6% IPSS low risk and 61.4% IPSS INT-1 risk. Baseline demographics and IPSS risk status were similar between groups, although transfusion burden trended higher in chelated pts. As of April 30, 2012, 169 pts continued on the registry, and 431 discontinued (345 died, 57.5%; 61 lost to follow-up, 10.2%; and 25 other, 4.2%). In all, 264 pts (44%) received chelation therapy; 200 had ≥6 mos chelation. Overall survival (OS) and time to acute myeloid leukemia (AML) transformation were significantly longer, and the percentage of deaths was significantly lower, in chelated ≥6 mos vs non-chelated pts ($P<0.0001$, $P=0.011$ [median not reached in either group], $P=0.0002$, respectively. AML transformations appeared to be lower in chelated ≥6 mos pts (not significant [NS]). At baseline in non-chelated vs chelated ≥6 mos pts, there was a higher prevalence of vascular, cardiac, endocrine, and ophthalmologic disorders; this trend continued at 36 mos. Most frequent causes of death were

MDS/AML, cardiac events, and infection. Use of MDS therapy was lower among non-chelated pts (non-chelated, 88.4%; ≥6 mos chelation, 93.5%; NS). **Conclusions:** At 36 mos,chelated pts had significantly longer OS and time to AML, as well as significantly fewer deaths. Trends toward fewer AML transformations and fewer vascular, cardiac, endocrine, and ophthalmologic disorders were observed in chelated pts.
