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[6574] Transfusion independence assessed using three alternative dosing schedules of azacitidine in patients with myelodysplastic syndromes

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The dosing schedule of azacitidine (75 mg/m²/day subcutaneous [SC] × 7 days, every 28 days) decreased transfusion requirements in myelodysplastic syndrome (MDS) patients in a CALGB trial by Silverman et al (JCO 2002;20:2429). Our study assessed effects on transfusion requirements in MDS patients receiving 3 alternative azacitidine dosing regimens not requiring weekend injections. Methods: This phase II, multicenter study enrolled MDS patients with any FAB subtype, life expectancy ≥7 months, and ECOG performance grade of 0-3. RA/RARS patients had to have ≥1 of the following: hemoglobin <110 g/L with transfusion need, platelet counts <100 × 10⁹/L, or ANC <1.5 × 10⁹/L. Patients were randomized to 1 of 3 SC regimens: AZA 5-2-2 (75 mg/m²/day × 5 days, followed by 2 days no treatment, followed by 75 mg/m²/day × 2 days), AZA 5-2-5 (50 mg/m²/day × 5 days, followed by 2 days no treatment, followed by 50 mg/m²/day × 5 days), or a 3rd regimen added later by protocol amendment: AZA 5 (75 mg/m²/day × 5 days). After 6 cycles, patients meeting International Working Group MDS response/improvement criteria (Blood 2000;96: 3671) of ≥ stable disease could continue in study for 12 more cycles. Results: In all, 75 patients (median age, 74.5 years; 61% male) are currently enrolled with 49 evaluable (completed ≥ 2 treatment cycles). To date, 12, 9, and 1 patient(s) have received ≥6 cycles of AZA 5-2-2, AZA 5-2-5, or AZA 5, respectively. RA + RARS, defined by FAB (60%) or WHO (47%), are the most common MDS subtypes. Of 24 patients, RBC transfusion dependent at baseline, 13 (54%) became independent (Table). Only 2 patients were platelet transfusion dependent at baseline; both became independent. After a median followup of 24 weeks, median duration of transfusion independence has not been reached. Conclusions: Treatment with azacitidine yields transfusion independence rates of 40%-60%. These preliminary results are similar across the 3 alternative doses and consistent with previous azacitidine data.

Proportion of Patients (≥56 days on treatment) with Transfusion Independence	Baseline Transfusion Status	Treatment Arm	All Patients, % (n/N)	RA+RARS Patients, % (n/N)
Blood Lineage				
RBC	Dependent	AZA 5-2-2	57 (8/14)	60 (6/10)
		AZA 5-2-5	60 (3/5)	33 (1/3)
		AZA 5	40 (2/5)	40 (2/5)
	Independent	AZA 5-2-2	75 (6/8)	75 (3/4)
		AZA 5-2-5	57 (4/7)	75 (3/4)
		AZA 5	60 (6/10)	60 (3/5)

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