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Methods: The present trial randomized 500 newly diagnosed multiple myeloma (MM) patients ≥ 65 years to either VMPT or VMP. Patients were treated with nine 5-week cycles of VMPT (bortezomib [Velcade] 1.3 mg/m2 days 1, 8, 15, 22; melphalan 9 mg/m2 days 1-4; prednisone 60 mg/m2 days 1-4, and thalidomide 50 mg days 1-35) or VMP (bortezomib, melphalan, and prednisone at the same doses and schedules previously described). The primary end point was progression-free survival (PFS).

Results: Among 354 evaluable patients (median age 71) receiving at least 1 cycle, PFS at 3 years was 71% in the VMPT group and 56% in the VMP group (P = .13). Overall survival at 3 years was 90% in the VMPT group and 89% in the VMP group (P = .81). Complete responses were reported in 35% of patients in the VMPT group and 21% in the VMP group, which was a highly significant difference (P < .0001).

Grade 3/4 peripheral neuropathy (among patients who received weekly infusion of bortezomib) was 2%/3% in the VMPT/VMP groups, respectively. Also, discontinuations for peripheral neuropathy were similar at 3%/4% for VMPT/VMP. Rates of peripheral neuropathy and discontinuation were both markedly lower with the weekly infusion than for twice-weekly infusion.

Conclusions: The four-drug combination as compared with the three-drug combination increased the CR rate significantly. There was a numerical increase in PFS but this was not statistically significant. Longer follow-up is needed to assess the effects on PFS and OS.

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