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Phase 2 LYSA study of prednisone, vinblastine, doxorubicin, bendamustine for untreated older Hodgkin lymphoma patients

Clinical Trials & Observations

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Key Points

- The PVAB regimen yielded a complete metabolic response rate of 77.5% as first-line therapy for older HL patients, with acceptable toxicity.
- The 4-year cumulative risk of events was 35% for progression and relapse, 9% for death from lymphoma and 6% for nonlymphoma events.

Older classical Hodgkin lymphoma (cHL) patients require more effective and less toxic therapies. In this multicenter, prospective, phase 2 study, we investigated a new first-line therapy regimen comprising 6 cycles of prednisone (40 mg/m² Day 1-5), vinblastine (6 mg/m², Day 1), doxorubicin (40 mg/m², Day 1), bendamustine (120 mg/m², Day 1) (PVAB regimen) every 21 days for newly diagnosed classical HL patients aged 61 years or older with an advanced Ann Arbor stage. A Mini Nutritional Assessment (MNA) score ≥ 17 was the cutoff value for including patients ≥70 years old. The primary endpoint was the complete metabolic response (CMR) rate after 6 cycles. The median age of the 89 included patients was 68 years (range, 61-88), with 35 patients aged ≥70 years old (39%). Seventy-eight patients (88%) completed the 6 cycles. The toxicity rate was acceptable, with a 20% rate of related serious adverse events. CMR was achieved by 69 patients (77.5%; 95% CI, 67-86). After a median follow-up of 42 months, 31 patients progressed or relapsed (35%), and 24 died (27%) from HL (n=11), toxicity during treatment (n=4), secondary cancers (n=6), or other causes (n=3). The 4-year progression-free survival (PFS) and overall survival rates were 50% and 69%, respectively. Multivariate analysis showed that liver involvement (P =0.001), lymphopenia (P =0.001), CRP (P =0.0005), comedications (P =0.003) were independently associated with PFS. The PVAB regimen yielded a high CMR rate with acceptable toxicity. Over long-term follow-up, survival endpoints were influenced by unrelated lymphoma events. Registration at www.clinicaltrials.gov was NCT02414568.

Subjects: Clinical Trials and Observations