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Conference Abstract A14

Efficacy of PD-1 Inhibitor Maintenance Therapy After Autologous Transplantation in Patients With Relapsed/Refractory Classical Hodgkin Lymphoma: Interim Results of a Phase II Clinical Study (NCT06812858)

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Background

Maintenance therapy with PD-1 inhibitors after autologous hematopoietic stem cell transplantation (auto-HSCT) in patients with relapsed/refractory classical Hodgkin lymphoma (r/r cHL) has shown promising results in pilot studies, including improved progression-free survival rates and a favorable safety profile. The current study aims to evaluate the efficacy and safety of PD-1 inhibitor therapy as maintenance after auto-HSCT in r/r cHL using a prospective multicenter design.

Materials and Methods

This international, prospective, multicenter phase 2 clinical trial included adult patients with histologically confirmed r/r cHL who underwent auto-HSCT as consolidation after the 2nd or later lines of therapy (NCT06812858). Enrollment criteria: primary refractory disease or early relapse (within 12 months after first-line therapy), late relapse with unfavorable risk factors (extranodal involvement, bulky disease, B symptoms), PET/CT positive status at the time of auto-HSCT, more than one salvage regimen. According to the study protocol, patients received maintenance PD-1 inhibitor therapy (selected by the investigative center): 12 cycles of nivolumab (40 mg or full dose) every 14 days, or 8 cycles of pembrolizumab every 21 days, with subsequent response evaluation by PET/CT (LYRIC criteria).

Results

20 patients were enrolled across 3 centers. Median age at initiation of maintenance therapy was 31 years (range 19–59). Primary refractory disease and early relapse after the first line were observed in 11 (55%) and 4 (20%) patients, respectively. All patients received PD-1 inhibitors in salvage regimens prior to auto-HSCT: 5 (25%) received monotherapy, 4 (20%) combination with chemotherapy, 11 (55%) both monotherapy and combination. The best response to pre-transplant PD-1 inhibitor therapy was complete in 18 patients (90%) and partial in 2 (10%). Brentuximab vedotin was used in 7 (35%) patients before auto-HSCT at any line. Pre-transplant complete response: 18 (90%), partial: 2 (10%). Auto-HSCT as consolidation for 2nd line—7 (35%), 3rd line—8 (40%), 4th line—4 (20%), and 5th line—1 (5%). Median number of high-risk factors per modified AETHERA criteria: 2 (1–4). For maintenance, pembrolizumab was used in 6 (30%), nivolumab full dose—5 (25%), nivolumab fixed 40 mg—9 (45%). Median time from day 0 to maintenance initiation was 2.3 months. Median follow-up: 2 months (1–13). All patients alive at last restaging; 7 completed maintenance with no relapses.

Conclusions

Results demonstrate efficacy of PD-1 inhibitor maintenance therapy, including low-dose nivolumab (40 mg), in high-risk r/r cHL patients after auto-HSCT.