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GDPT versus CHOP in newly diagnosed peripheral T-cell lymphoma: A prospective randomized controlled, open-label study (No.NCT01664975)

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Background & Aim: Peripheral T-cell lymphoma is a distinct lymphoid neoplasm with aggressive course and poor outcome. Optimal treatment strategies for peripheral T-cell lymphoma have not been well defined. We compared the efficacy and safety of GDPT and CHOP regimens for patients with newly diagnosed peripheral T-cell lymphoma in a prospective randomized controlled and open-label clinical trial (No.NCT01664975).

Methods: All eligible patients with newly diagnosed peripheral T-cell lymphoma had measurable disease with an ECOG performance status ≤2 and adequate organ function. GDPT or CHOP chemotherapy was randomly assigned to patients. Patients in arm GDPT received intravenous gemcitabine (0.8 g/m^2) in 30 min on days 1 and 8, cisplatin (25 mg/m^2) on days 1-3, and oral prednisone (60 mg/m^2) on days 1-5, thalidomide (200 mg) until the end of the whole chemotherapy. Patients in group CHOP received intravenous cyclophosphamide (750 mg/m^2), doxorubicin (50 mg/m^2) and vincristine (1.4 mg/m^2, maximum 2 mg) on day 1, and oral prednisone (60 mg/m^2) on days 1-5. Each cycle was repeated six times every three weeks. Efficacy was evaluated every two cycles. The primary endpoint was to evaluate the efficacy assessed by progression-free survival. Secondary end points included response rate and overall survival.

Results: Between July 2010 and June 2016, 103 patients allocated into two groups randomly, of whom 52 were treated with GDPT therapy and 51 were treated with CHOP therapy. Patient characteristics were well balanced within the two arms of treatment at enrollment. The 2-year progression-free survival (PFS) and overall survival (OS) rates were better in GDPT group than that in CHOP group (57% versus 35% for 2-year PFS, P=0.0035; 71% versus 50% for 2-year OS, P =0.0001). Complete remission (CR) rate and overall response rate (ORR) of GDPT group were higher than that in CHOP group (52% versus 33%, P=0.044 for CR rate; 67% versus 49%, P=0.046 for ORR). Adverse effects of chemotherapy were hemocytopenia predominantly in both arms. No differences were observed between the two arms in terms of grade 3/4 myelosuppression, digestive tract, hepatic, renal, cardiac or neurological toxicity. Acute toxicity was moderate, tolerable and well managed in both arms.

Conclusions: GDPT chemotherapy resulted in significant improvement in PFS and OS compared with CHOP chemotherapy and side effects of chemotherapy was well tolerated for newly diagnosed peripheral T-cell lymphoma patients. Therefore, GDPT is a promising new regimen as potential first-line therapy against peripheral T-cell lymphoma.

Biography

Hui Yu is an Associate Professor in Department of Oncology at First Affiliated Hospital of Zhengzhou University. She completed her Medical studies at Xiangya School of Medicine, Central South University, and obtained her PhD degree in Cancer Research at University of Texas Health Science Center, San Antonio. Her research during PhD focused on "The signaling mechanisms responsible for the bystander responses induced by radiation therapy in non-targeted cells, which could result in clonal selection and tumor recurrence at the treatment site". After Residency training and Clinical fellowships at First Affiliated Hospital of Zhengzhou University, she has now expertise in the Diagnosis as well as Chemotherapy and Auto/Allo Stem Cell Transplantation for patients with lymphoma. As a Physician-Scientist who conducts laboratory and clinical research in hematological malignancies, her current research interests include "Molecular pathogenesis stratified treatment of T-cell lymphoblastic lymphoma".