

[2332] Front-Line Treatment of Low-Grade Non-Follicular Non-Hodgkin Lymphoma (Final Report of Gisl LL02 Trial). Session Type: Poster Session, Board #522-II

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Indolent Non-follicular non-Hodgkin Lymphoma (NFO-NHL) is a group of relatively frequent lymphoproliferative diseases, nevertheless extended clinical and prognostic studies are still lacking. In 2002 the Gruppo Italiano Studio Linfomi (GISL) initiated a LL02 prospective multicenter phase II trial, with the aim to evaluate the efficacy and safety of FC combination in the first-line therapy of NFO-NHL patients younger than 70 years. Between July 2002 and September 2006, 58 adult patients (35 males and 23 females, median age 64 yrs, range 40-75) affected by NFO-NHL in active disease phase, were consecutively enrolled in 12 GISL Hematological Centres. Patients were treated with a dose of 25 mg/m² Fludarabine plus 250 mg/m² Cyclophosphamide administered intravenously daily for 3 days; each cycle was repeated every 28 days for 6 courses. During the treatment patients received oral thrimethoprim-sulphametoxazole prophylaxis. After the intermediate evaluation, 48/58 patients (82.8%) had an objective response (ORR) with a 20.7% of complete remission (CR) plus 62.1% of partial remission (PR); at the final evaluation the ORR percentage was 84.5% with a 41.4% of CR (24 pts) and 43.1% of PR (25 pts); three patients were in progressive disease (5.2%) and one in stable disease (1.7%). The median overall survival (OS) was not reached with an 88% and 84% at 12 and 24 months; the progression free survival (PFS) was 89% and 77% and the event free survival (EFS) was 81% and 66% at 12 and 24 months respectively. About the toxicity profile, the major toxicity was hematological with a 18% cases of WHO grade III or IV anemia, 40% leucopenia, 33% neutropenia and 10% piastrinopenia. The 12% of patients had an infective episode with a 7.7% of WHO grade III-IV. In conclusion the FC chemotherapy is a useful chance for advanced untreated non follicular low-grade NHL, with an optimal ORR, CR and PFS. The crucial point of FC remains OS, that not seems to be significantly improved in comparison with fludarabine alone or with standard therapy, even though the better quality of responses; Rituximab plus FC association is growing in literature as the probably key to find a real improvement also in this aspect.

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Disclosure: Off Label Use: Fludarabine is used as off label product in this subset of patients affected by non-Hodgkin lymphomas, according to the single institutions policies.

Sunday, December 9, 2007 6:00 PM

Session Info: Poster Session: Lymphoma: Chemotherapy, excluding Pre-Clinical Models-Hodgkin Lymphoma and PET (6:00 p.m.-8:00 p.m.)