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Detection of anti-asparaginase antibodies during therapy with *E.coli-asparaginase* in children with newly diagnosed acute lymphoblastic leukemia and lymphoma

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Background: Asparaginase is an effective antileukemic agent which is included in most front-line protocols for pediatric acute lymphoblastic leukemia (ALL) worldwide. Since asparaginase is a bacterial protein, it may induce formation of antibodies. The reported frequency of antiasparaginase antibodies is highly variable: antibodies have been reported in as many as 79% of adults and as many as 70% of children after intravenous or intramuscular administration of E.coli asparaginase.

Purpose: The aim of this study was to determine if the presence of antibodies during induction and continuation phases in newly diagnosed children with ALL and lymphoblastic lymphoma during therapy with E.coli asparaginase had any correlation with various factors such as: age, gender, hypersensitivity reactions, response to therapy and EFS.

Patients and Methods: Between the period from March 2005 to May 2007, sixty-four children who attended the Menia outpatient pediatric oncology clinic, or were admitted to the inpatient department of the Menia oncology center, were enrolled in the study. Forty children had newly diagnosed ALL and 24 had lymphoblastic lymphoma. Patients were 48 males (75%) and 16 females (25%) with a male:female ratio 3:1. Their ages ranged from 3.5 to 17 years with mean age of 9.6 years. All patients received asparaginase therapy according to the St. Jude Total XIII protocol, in a dose of 10,000 IU/m2/dose, intramuscularly for 6-9 doses during the induction phase and another 6-9 doses during continuation phase according to disease status.

Results: Forty one patients achieved complete remission, 9 had partial remission and 14 were lost to follow-up at different intervals of treatment. Antiasparaginase antibodies were detected in 36 patients (56%) out of 64 patients and 37 patients (60%) out of 62 patients who were treated with asparaginase at day 8 and day 27 of induction phase respectively. Moreover, 33 patients (61%) out of 54 patients and 41 patients (83%) out of 50 patients had positive antiasparaginase antibodies at week 10 and week 21 of continuation phase respectively. The 2-year EFS of the whole group was 50%. There was no statistical significance difference between positivity of antiasparaginase antibodies and the following: age, gender, hypersensitivity reaction, response to therapy and EFS.

Conclusion: The presence of antiasparaginase antibodies was unrelated to age, gender, hypersensitivity reaction, response to therapy and event free survival of newly diagnosed children with acute lymphoblastic leukemia and lymphoblastic lymphoma.

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