

Figure 2.

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QUALITY OF LIFE AT DIAGNOSIS IN ELDERLY PATIENTS WITH ACUTE MYELOID LEUKEMIA CONSIDERED FIT FOR INDUCTION OF REMISSION CHEMOTHERAPY

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Aims: In elderly patients with acute myeloid leukemia (AML), complete remission (CR) rate following intensive chemotherapy is approximately 45% with a shorter duration of remission and high treatment-related mortality (30-50%). Median survival is about 12 months. Intensive chemotherapy is indicated in a small proportion of “fit” elderly patients. In a phase III, prospective, randomized, open-label, multicenter trial designed to assess the efficacy of post-remission treatment with 5-Aza *versus* best supportive care (BSC) in patients >60 years of age with AML in CR after conventional induction “3+7” and consolidation chemotherapy, QoL was assessed in patients at diagnosis and in the 2 years post-remission. We present interim results of QoL assessment at diagnosis.

Methods: Patients with newly diagnosed AML with >30% bone marrow blasts, “*de novo*” or evolving from myelodysplastic syndrome without contraindications for intensive chemotherapy and with an ECOG performance status <3 are included. Induction chemotherapy consists of two courses of “3+7”: daunorubicin 40 mg/m² daily days 1-3 and cytarabine 100 mg/m² daily continuous IV infusion days 1-7. Patients in CR receive consolidation (cytarabine 800 mg/m² 3 hour infusion bid days 1-3) and are randomized 1:1 to receive BSC or 5-Aza maintenance therapy until AML recurrence for 4 years and six months. QoL assessment was performed at baseline and during the follow-up period using the EORTC QLQ-C30 and the QOL-E v.3 questionnaires. Higher scores reflect better quality of life, except for symptom scores of the EORTC QLQ-C30. **Results:** Ninety-eight patients (male/female 49/49) of median age 70 (IQR 65-74) years have been enrolled. At diagnosis median hemoglobin was 9.1 (8.4-9.9) g/L, leukocytes 7.9 (2.3-29.7)/μL, platelets 54 (29-85) Gi/L and bone marrow blasts 70 (50-86)%. Seventy-five patients had “*de novo*” AML and 23 had comorbidities. Thirty-eight patients obtained a CR following chemotherapy. Median QOL-E scores were poor (<60) in all dimensions, except for fatigue (76, IQR 52-86) and did not distinguish prognosis. Median EORTC QLQ-C30 scores were good in all domains except for global health status (50, IQR 33-67). Role Function was better in patients obtaining CR (Figure 1). **Conclusions:** Elderly patients with AML at diagnosis identified as fit for chemotherapy generally do not present fatigue. Global health status is poor and perception of role function may be associated with response to induction chemotherapy.

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QUALITY OF LIFE AND LATE EFFECTS IN 44 LONG-SURVIVING NON M3 ACUTE MYELOID LEUKEMIA PATIENTS

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Acute Myeloid Leukemia (AML) outcome had improved in last decades, conversely late effects and quality of life studies are still lacking. We have administered two questionnaires, EORTC QLQ-C30 and FACT-AN, in 44 cured AML patients (31 <60 years and 13 >60 years) treated at our department between 1997 and 2010 (7 Allogeneic, 16 Autologous Transplant, 21 chemotherapy alone). We stratified QoL scores by age at diagnosis, performance status (PS), Sorrow Index, kind of leukemia treatment, comorbidity at diagnosis. Multivariate analysis showed that older patients had worse EORTC QLQ-C30 physical and emotional scale scores and higher values of pain symptoms in comparison to younger counterpart, with RR of 20.1 (p=0.001), 22.7 (p<0.04) and 18.4 (p=0.03) respectively. Elderly patients also had lower Total Outcome Index and FACT-An subscale scores (RR: 11.9, p=0.02; and 8.77, p=0.04 respectively). Sorrow index >2 was related to lower EORTC QLQ-C30 social scale and dyspnea scores (RR: 32.5; p=0.001 and 21.7; p=0.001 respectively) and FACT-An functional well being values (RR=3.9; p=0.001). Late effects, occurring 3 months after the end of treatment, evaluated in 44 patients, included 12 cases of grade II-IV cardiotoxicity (3 arrhythmia, 9 cardiomyopathy) with 89% incidence in patients with cardiac comorbidities at diagnosis, 0%, 20% and 55.5% in patients receiving respectively Daunorubicin, Idarubicin and at least two different anthracyclines. Sorrow Index>2 was the only factor significantly predicting cardiotoxicity at the multivariate analysis with a RR of 82.7 (p=0.001). We also observed 15 cases of metabolic toxicities (2 hyperglycemia, 12 iron overload and 1 electrolytic alteration), 6 case of gastrointestinal toxicity (gastric ulcer, 2 irritable bowel, 1 parodontopathy, 1 severe and persistent mucositis, 1 esophagitis). 3 patients (2 males and 1 female) had been fertile; all female patients developed menopause after Transplant. 3 patients had secondary neoplasia consisting of Multiple Myeloma, breast cancer and axillary sarcoma. Our study underlines the importance of Sorrow Index at diagnosis in defining patients eligibility to cardio-prophylactic therapy. We also suggest the use of psycho-somatic strategies, also based on physical activities or autogenic training, in long term AML survivors. The analysis of larger series of cured AML patients are strongly needed in order to define guidelines for reducing long term treatment AML toxicity.

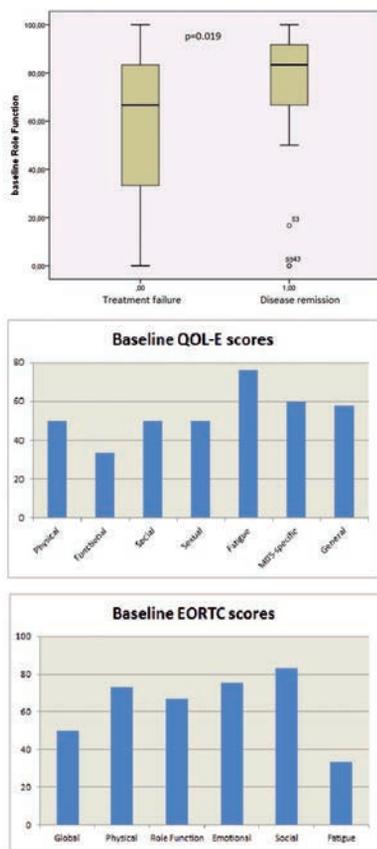


Figure 1. EORTC QLQ-C30 Role function scores at diagnosis in elderly AML patients failing chemotherapy induction treatment versus those obtaining complete remission.