

S159 HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH CHRONIC MYELOID LEUKEMIA AFTER DISCONTINUATION OF TYROSINE KINASE INHIBITORS: RESULTS FROM THE EURO-SKI STUDY

Topic: Evolution of clinical management in CML

Fabio Efficace^{*1}, Francois-Xavier Mahon², Johan Richter³, Alfonso Piciocchi¹, Marta Cipriani^{1,4}, Franck Emmanuel Nicolini⁵, Henrik Hjorth-Hansen⁶, Antonio Almeida⁷, Jeroen J. W. M. Janssen⁸, Jiri Mayer⁹, Perttu Koskenvesa¹⁰, Panayiotis Panayiotidis¹¹, Ulla Olsson-Strömberg¹², Joaquín Martínez-López¹³, Philippe Rousselot¹⁴, Hanne Vestergaard¹⁵, Hans Ehrencrona¹⁶, Veli Kairisto¹⁷, Katerina Machova Polakova¹⁸, Satu Mustjoki¹⁹, Marc Berger²⁰, Andreas Hochhaus²¹, Markus Pffirmann²², Susanne Saussele²³

¹Data Center And Health Outcomes Research Unit, Italian Group For Adult Haematologic Diseases (Gimema), Rome, Italy; ²Service D'Hématologie Clinique, Institut Bergonié, Bordeaux, France; ³Department Of Hematology, Oncology And Radiation Physics, Skåne University Hospital, Lund, Sweden; ⁴Department Of Statistical Sciences, Sapienza University Of Rome, Rome, Italy; ⁵Service D'Hématologie Clinique & Inserm U1052 Crcl, Centre Léon Bérard, Lyon, France; ⁶Department Of Hematology, St Olavs Hospital, Trondheim, Norway; ⁷Department Of Hematology, Hospital Da Luz, Faculdade De Medicina, Universidade Católica Portuguesa, Lisbon, Portugal; ⁸Department Of Haematology, Radboud Umc, Nijmegen, Netherlands; ⁹Department Of Internal Medicine, Hematology And Oncology, Masaryk University Hospital, Brno, Czech Republic; ¹⁰Department Of Hematology, Hematology Research Unit Helsinki And Helsinki University Hospital Comprehensive Cancer Center, Helsinki, Finland; ¹¹First Propedeutic Department Of Internal Medicine, National And Kapodistrian University Of Athens, Athens, Greece; ¹²Department Of Medical Sciences, Uppsala University And Hematology Section, Uppsala University Hospital, Uppsala, Sweden; ¹³Hematology, Hospital Universitario 12 De Octubre, Cnio, Universidad Complutense De Madrid, Madrid, Spain; ¹⁴Department Of Haemato-Oncology, Ch Versailles, Versailles, France; ¹⁵Quality Of Life Research Center, Department Of Haematology, Odense University Hospital, Odense, Denmark; ¹⁶Department Of Clinical Genetics, Pathology And Molecular Diagnostics, Office For Medical Services, Region Skåne, Lund, Sweden; ¹⁷Division Of Clinical Genetics, Department Of Laboratory Medicine, Lund University, Lund, Sweden; ¹⁸Department Of Clinical Chemistry And Department Of Genetics, Turku University Central Hospital, Turku, Finland; ¹⁹Institute Of Haematology And Blood Transfusion, Prague, Czech Republic; ²⁰Hematology Research Unit Helsinki, University Of Helsinki And Helsinki University Hospital Comprehensive Cancer Center, Helsinki, Finland; ²¹Hématologie Biologique And Equipe D'Accueil 7453 Hemopaties Chroniques: Heterogeneite Intra-Clonale, Microenvironnement Et Resistance Therapeutique, Chu Estaing And Université Clermont Auvergne, Clermont-Ferrand, France; ²²Klinik Für Innere Medizin Ii, Universitätsklinikum Jena, Jena, Germany; ²³Institut Für Medizinische Informationsverarbeitung, Biometrie Und Epidemiologie, Ludwig-Maximilians-Universität, Munich, Germany

Background:

Stopping long-term therapy with tyrosine kinase inhibitors (TKIs) is now an option for an increasing number of patients with chronic phase chronic myeloid leukemia (CP-CML). However, there is paucity of evidence-based data on health-related quality of life (HRQoL) and symptom profile of these patients, once stopping therapy.

Aims:

We herein report HRQoL results of the EURO-SKI international study (Saussele S, et al. Lancet Oncol. 19:747-757, 2018) by examining HRQoL trajectories over time by age groups.

Methods:

The EURO-SKI was a prospective, open label, non-randomized trial enrolling adult patients with CP-CML across 11 countries in Europe. Patients had to be in treatment with any TKI for at least 3 years, and had to be in MR4 ($BCR::ABL1 < 0.01\%$ IS) for at least 1 year. HRQoL was a prespecified secondary endpoint of the study and was assessed with the EORTC QLQ-C30. A disease specific validated fatigue measure was also included: the FACIT-F.

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Evaluations were performed at baseline (at the time of treatment stop) and at month 1, 3, 6 and 12. As we hypothesized that benefits of TKI discontinuation would vary by age, the following four age group categories were considered: 18-39 (n=62 pts), 40-59 (n=272 pts), 60-69 (n=209 pts) and ≥ 70 (n=143 pts) years. A linear mixed effects model and growth curve analysis was used to analyze EORTC QLQ-C30 scores at baseline, month 1, month 3, month 6 and month 12 after TKI discontinuation. The longitudinal analysis for each age group modeled the different scores using fixed effects for the following variables: sex, Sokal-risk categories, MR4 duration in years, relapse, and times of visit. A random error was considered in the models to account for the within subjects' design variability. We also analyzed the proportion of patients experiencing improvement, stability or deterioration at 6 and 12 months by using previously established scale specific criteria for the EORTC QLQ-C30.

Results:

Of the 728 evaluable patients at baseline, 686 (94%) had a HRQoL assessment completed. Median age at the time of stopping TKIs was 60 (range 18-89) years and these patients had a median duration of therapy of 7.6 years. Investigation of the mixed model adjusted HRQoL trajectories over time, revealed a different pattern of changes within each age group category. Younger patients (ie., aged between 18-39 years and 40-59 years) typically reported the greatest benefits across several functional and symptom outcomes. For example, there was a statistically significant decrease of burden of fatigue (FACIT-F) over time in patients aged between 18-39 years ($p=.016$) and in those aged between 40-59 years ($p=.002$). No statistically significant improvements were observed in the other two older age groups. This finding was corroborated by results of the fatigue scale of the EORTC QLQ-C30 (Figure 1). Inspection of the proportion of patients with clinically relevant changes (deteriorated, improved, or stable) from baseline to 6 and 12 months, also indicated differences by age groups. For example, in the group of patients with no relapse, the percentage of patients who reported deterioration in physical functioning between baseline and 6 months was: 16%, 44%, 47% and 65%, in the groups aged 18-39, 40-59, 60-69 and ≥ 70 years, respectively.

Summary/Conclusion:

This large international study, suggests that HRQoL advantages of stopping long-term TKI therapy vary across different age groups, with younger patients benefiting the most. This information complements current knowledge in this area, and will help patients and physicians to make more informed decisions.

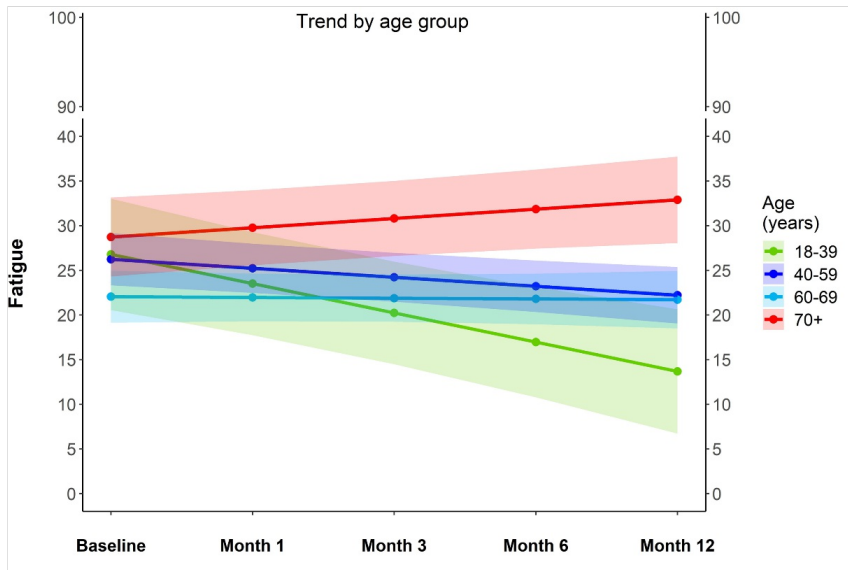
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Figure 1.
Fatigue by the EORTC QLQ-C30: mean score trajectories over time by age group categories
 (decreasing scores indicate decreasing severity)



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