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### THE EFFECT OF AZACITIDINE ON HEALTH-RELATED QUALITY OF LIFE (HRQL) IN OLDER PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML): RESULTS FROM THE AZA-AML-001 TRIAL

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**Mark D. Minden**

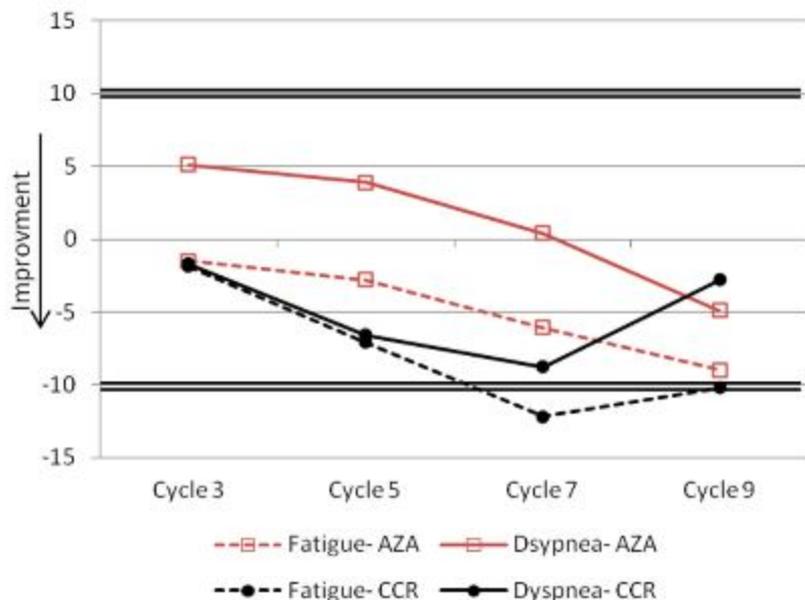
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*EHA Learning Center. D.Minden M. Jun 12, 2015; 100440*

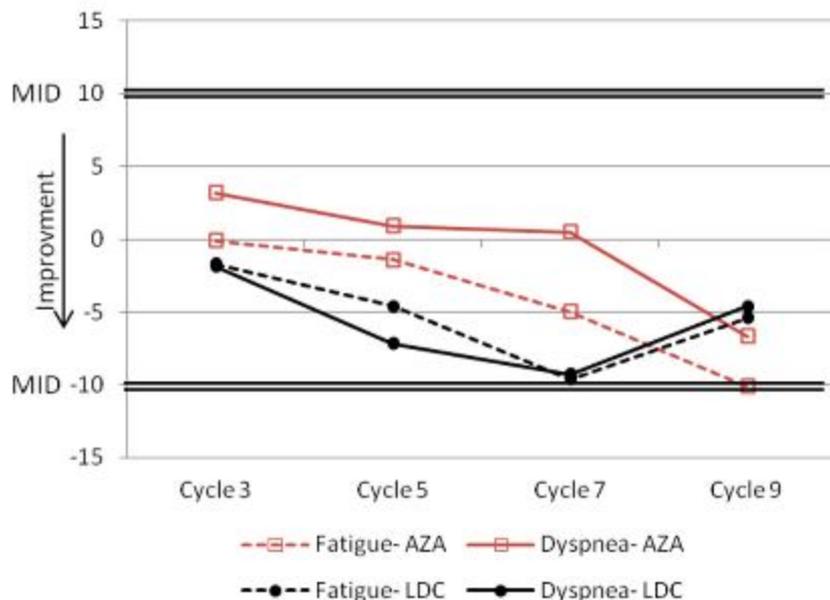
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<p><b>Abstract: P184</b></p> <p><b>Type:</b> Poster Presentation</p> <p><b>Presentation during EHA20:</b> From 12.06.2015 17:15 to 12.06.2015 18:45</p> <p><b>Location:</b> Poster area (Hall C)</p> <p><b>Background</b> Older patients (pts) with AML generally have a poor prognosis. While treatment (Tx) may extend overall survival (OS) for pts with AML, it may also cause significant toxicity and impairment of HRQL (Cheng, <i>Leukemia</i>, 2014). In the large, international, phase 3 AZA-AML-001 study, median OS for older pts with AML treated with azacitidine (AZA) was 10.4 months vs. 6.5 months for pts who received conventional care regimens (CCR; HR=0.85; p=0.1009) (Dombret, EHA, 2014). HRQL was a prespecified secondary endpoint of the study.</p> <p><b>Aims</b> To evaluate changes in HRQL during Tx among pts in AZA-AML-001.</p> <p><b>Methods</b> Pts were aged ≥65 years with newly diagnosed <i>de novo</i> or secondary AML (&gt;30% bone marrow blasts). Before randomization, pts were preselected to receive 1 of 3 CCR per investigator choice: induction chemotherapy, low-dose cytarabine (LDC), or best supportive care only. Pts were then randomized to AZA or CCR, in which case, they received their preselected Tx. Most pts (n=312, 64%) were preselected to receive LDC. HRQL was assessed by EORTC QLQ-C30 questionnaire at baseline, day 1 of every other Tx cycle, and at the end-of-study visit, which occurred at different time points for individual pts. Analyses included only pts who completed the baseline and at least 1 post-baseline HRQL assessment. An HRQL-specific statistical analysis plan (SAP) was finalized before database lock. HRQL changes were evaluated prospectively for the AZA and CCR cohorts, and <i>post hoc</i> for the pt subgroup preselected to LDC who received AZA or LDC. Four of the 15 QLQ-30 domains were prespecified in the SAP as most relevant: Fatigue (primary), Global Health Status/QoL, Physical Functioning, and Dyspnea (secondary). HRQL was evaluated through cycle 9 (~32 to 34 weeks) due to subsequent small cohort sizes. A prespecified 10-point minimally important difference (MID) threshold represents meaningful change.</p>	

# Mean Changes from Baseline EORTC QLQ-30 Domain Scores

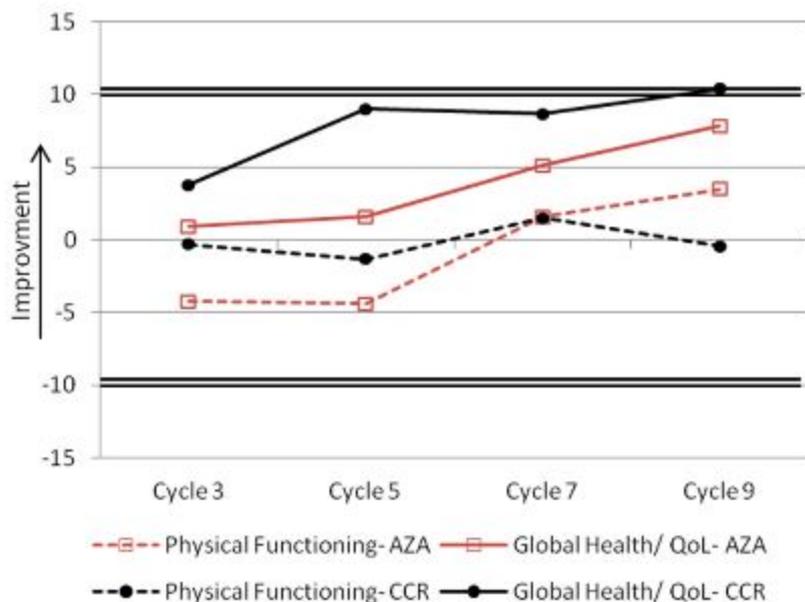
Mean Change v. Baseline AZA vs. CCR  
Fatigue & Dyspnea



Mean Change v. Baseline AZA vs. LDC  
Post-Hoc Analysis of Patients Pre-Selected to LDC



Mean Change v. Baseline AZA vs. CCR  
Physical Functioning & Global Health/QoL



Mean Change v. Baseline AZA vs. LDC  
Post-Hoc Analysis of Patients Pre-Selected to LDC

