

# An Evaluation of Treatment Patterns and Outcomes in Elderly Patients Newly Diagnosed With Acute Myeloid Leukemia: A Retrospective Analysis of Electronic Medical Records From US Community Oncology Practices

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## Abstract

**This retrospective observational study of data from the US community oncology setting evaluates real-world treatment patterns and outcomes for newly diagnosed, elderly patients with acute myeloid leukemia. The analysis focuses on those patients who did not receive standard induction therapy (“3 + 7”-type regimens). Background:** Many elderly patients with acute myeloid leukemia (AML) are considered ineligible for standard intensive induction therapy due to performance status and comorbidities. We analyzed treatment patterns and outcomes among elderly patients newly diagnosed with AML in the US community oncology setting. **Methods:** A retrospective observational study was conducted using patient-level data from a network of US community oncology practices provided by Altos Solutions. Patients aged  $\geq 60$  years, diagnosed with AML between November 2005 and February 2014, with  $\geq 1$  recorded visit and  $\geq 6$  months between diagnosis and data cutoff, were included. Only patients who received active treatment or best supportive care (BSC) per National Comprehensive Cancer Network (NCCN) AML Guidelines were analyzed. **Results:** Of 1139 patients meeting the inclusion criteria, 922 (median age 76 years) received NCCN-recommended treatments: standard induction ( $n = 5$ ), low-intensity therapy ( $n = 425$ ), BSC with hydroxyurea (HU) ( $n = 36$ ), or BSC without HU ( $n = 455$ ). For the low-intensity therapy cohort, median time from diagnosis to treatment initiation was 17 days; median duration of therapy was 5.1 months. Median overall survival (OS) from diagnosis in the low-intensity, BSC with HU, and BSC without HU groups was 12.3, 7.0, and 49.4 months, respectively. Median time to next therapy/death was 10.1 months in patients receiving low-intensity therapy. A higher proportion of patients receiving low-intensity therapy required transfusion or other supportive care versus those receiving BSC. **Conclusions:** As expected, OS in patients receiving low-intensity therapy or BSC with HU is poor for elderly patients with AML. Remarkably, intensive induction strategies are rarely used for older patients in community oncology practice.

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**Keywords:** Acute myeloid leukemia (AML), Electronic medical records (EMR), Observational study, Oncology, Treatment guidelines

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# Treatment Patterns in Elderly Patients With AML

## Introduction

Acute myeloid leukemia (AML) is the second most common form of leukemia, accounting for approximately 25% of adult leukemia cases in the Western world.<sup>1</sup> In 2015, it was projected to represent 1.3% of new cancer cases and 1.8% of deaths from cancer in the US.<sup>2</sup> The median age at AML diagnosis is 67 years, with 54% of patients diagnosed at  $\geq 65$  years; there is a higher incidence of AML in men than women.<sup>2-4</sup> The 5-year relative survival rate (adjusting for normal life expectancy) is estimated to be approximately 24%.<sup>5,6</sup>

Complete remission (CR) rates and overall survival (OS) in elderly patients with AML have improved over time, largely owing to advances in supportive care and the more widespread use of azanucleosides.<sup>7-11</sup> Recommendations for the management of AML vary according to age, comorbidities, and performance status. However, despite specific guidance for elderly patients with AML, these patients are less likely to achieve CR and remain relapse-free, due to a higher frequency of unfavorable cytogenetics, myelodysplastic syndromes (MDS), and other adverse biological factors, which are more commonly found in older patients.<sup>12,13</sup> The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Acute Myeloid Leukemia, V1.2015,<sup>3</sup> current at the time of this study (referenced with permission from the NCCN Clinical Practice Guidelines in Oncology for Acute Myeloid Leukemia V1.2015. © National Comprehensive Cancer Network, Inc 2015. All rights reserved. To view the most recent and complete version of the guideline, go online to [NCCN.org](http://NCCN.org)), recommend the following options for the management of AML in elderly patients aged  $\geq 60$  years: investigational therapy, standard induction therapy (with “3 + 7”-type regimens), or low-intensity chemotherapy for those patients considered “fit” (Eastern Cooperative Oncology Group Performance Status [ECOG PS] 0-2). For “unfit” patients (ECOG PS  $> 2$ , or 0-3 with significant comorbidities) the NCCN Guidelines recommend the use of either investigational therapy, low-intensity chemotherapy, or best supportive care (BSC); BSC includes management with hydroxyurea (HU), blood transfusions, growth factors, and anti-infectives.<sup>3</sup> The combined impact of the disease and its therapy on red blood cell (RBC) counts mandate the use of semi-regular transfusion support, which imposes a significant health cost during the routine care of patients with AML, irrespective of age.<sup>14</sup>

A number of studies have investigated real-world health care resource utilization and treatment outcomes in patients with AML by using US-based Surveillance, Epidemiology, and End Results (SEER) program data linked to Medicare claims or administrative claims data alone.<sup>7,8,15-18</sup> These studies support the view that older patients with AML do badly, with low survival rates (median 1.5-2.0 months when “untreated”) and incursion of high health care costs (mean \$41,594-\$96,078 per patient).<sup>15-17</sup> Younger patients with fewer comorbidities are more likely to receive chemotherapy, whereas older patients have fewer options available to them.<sup>16,17</sup> The criteria for defining patients characterized as “elderly” remains arbitrary; these studies used thresholds ranging from 65 to 75 years of age. In contrast, the NCCN Guidelines define elderly patients with AML as those  $\geq 60$  years of age.<sup>3</sup>

The primary objective of this study was to use aggregated patient-level clinical data from electronic medical records in US community

practices to characterize real-world treatment patterns among elderly ( $\geq 60$  years) patients newly diagnosed with AML, looking particularly at the use of the recommended treatment options of the NCCN Guidelines.<sup>3</sup> Secondary objectives included analysis of real-world outcomes and utilization of supportive therapies (including blood transfusions and growth factors).

## Methods

This retrospective, observational study was conducted using a dataset provided by Altos Solutions (Los Altos, CA), which includes oncology-specific electronic medical records representing 225,000 patients with cancer treated across 150 US community oncology practices. We studied older patients ( $\geq 60$  years) who had at least 1 recorded visit and a first diagnosis of AML  $\geq 6$  months before data cutoff (February 24, 2014). The rationale for this selection criterion was to allow patients to be observed for a minimum of 6 months; however, deaths occurring within 6 months of first diagnosis of AML were included in the survival analyses. Patients who satisfied these inclusion criteria who began therapy (inclusive of BSC approaches) during the observational period (November 1, 2005, to February 24, 2014) were included in the analysis. Patients were followed from date of initial diagnosis to the earliest date of loss to follow-up, death, or end of data collection. Patients were excluded from the study if insufficient data were available to document baseline characteristics or initial treatment.

For this analysis, patients were allocated to groups based on the NCCN Guideline recommendations for elderly patients with AML.<sup>3</sup> Patients receiving active treatment were grouped according to whether they had received standard induction therapy (defined as 7 days cytarabine 100-200 mg/m<sup>2</sup> plus 3 days of idarubicin 12 mg/m<sup>2</sup>, daunorubicin 45-90 mg/m<sup>2</sup>, or mitoxantrone 12 mg/m<sup>2</sup>), or low-intensity therapy (azacitidine, decitabine, or cytarabine at doses of  $< 50$  mg/m<sup>2</sup>). Patients receiving other treatments were excluded. Although some of these excluded patients may have received potentially active investigational agents, which is a recommended treatment approach in the NCCN Guidelines,<sup>3</sup> it was not possible to determine if this was the case from the dataset; hence, all patients receiving therapies not explicitly recommended in the NCCN Guidelines were excluded. Patients who received only supportive therapies (HU, platelet and RBC transfusions, granulocyte/granulocyte-macrophage colony-stimulating factors, azole antifungals, erythropoiesis-stimulating agents, and pain medications), were analyzed within 2 BSC groups: (1) BSC with HU, and (2) BSC without HU.

Treatment regimens were identified based on the recommendation of the treating physician during the first 28 days after the initiation of therapy. Treatment discontinuation was defined as the beginning of a new therapy (not part of the initial treatment regimen) or at the onset of kinetic failure ( $> 90$  days between successive cycles or between the last administration of treatment and the end of follow-up).

## Statistical Analyses

We conducted descriptive analyses of retrospective data; no statistical comparisons were made between study groups. Descriptive analyses were conducted to quantify patient baseline demographic and clinical characteristics, treatment patterns, and use of supportive

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