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Treatment Choices: A Quality of Life Comparison in Acute Myeloid Leukemia and High-risk Myelodysplastic Syndrome

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Abstract

The results of the present pilot study can be used to counsel older patients with acute myeloid leukemia and high-risk myelodysplastic syndrome regarding treatment choices that will align with their goals for their quality of life. Future studies are needed with a larger and more diverse patient sample to address whether the more intensive treatment approach improves patients' quality of life.

Background: In the present exploratory, observational study, we compared the effect of intensive versus nonintensive treatment on quality of life for patients aged ≥ 60 years diagnosed with acute myeloid leukemia or high-risk myelodysplastic syndrome at 1 month after treatment.

Patients and Methods: A total of 73 patients with acute myeloid leukemia or high-risk myelodysplastic syndrome who had been treated at the inpatient and outpatient malignant hematology at Moffitt Cancer Center, a National Cancer Institute-designated comprehensive cancer center, were included. Two paired measurements of self-reported quality of life were used, 1 before treatment and 1 at 1 month after treatment to compare intensive versus nonintensive treatment. Patients completed the Functional Assessment of Cancer Therapy–Leukemia version for the quality-of-life measurement. Repeated measures analysis of variance was used to compare the effect of treatment and time and the interaction of treatment and time. The main research variables were intensive versus nonintensive treatment as the independent variable and quality of life measured using the Functional Assessment of Cancer Therapy–Leukemia version as the dependent variable.

Results: Physical function and leukemia symptoms improved for patients treated with intensive chemotherapy. A trend was found for improved quality of life for the intensive treatment compared with nonintensive treatment, for which the quality of life was stable at 1 month.

Conclusion: The study participants treated with inpatient, induction chemotherapy experienced statistically significant improvement in their quality of life at 1 month. The outpatient, nonintensive study participants had stable quality of life at 1 month.

Keywords

AML; Decision making; Geriatric; MDS; QOL

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Disclosure

The authors declare that they have no competing interests.

Introduction

Patients diagnosed with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) face the difficult decision of choosing the best treatment with the knowledge of a life-threatening illness. However, few studies are available to guide health care professionals and patients in choosing the best treatment according to quality of life (QOL). Both AML and MDS are bone marrow malignancies that occur commonly in older individuals, for whom the optimal treatment remains controversial.[1] Treatment can range from supportive care to hematopoietic stem cell transplantation. The diseases are often studied together because they have similar disease characteristics, life expectancy (for high-risk MDS), age at diagnosis, comorbidities, and treatment options.[1–3] The most common form of adult acute leukemia is AML, with approximately 18,860 cases diagnosed and 10,460 deaths in 2014.[4] The median age at diagnosis in the United States is 67 years, according to the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) data.[4] The incidence of MDS using a claims-based algorithm in conjunction with SEER data project approximately 50,000 cases annually in the Unites States, with a median age of 76 years.[5] Approximately 20,000 cases of MDS are high risk.[6] High-risk MDS is determined by calculating an individual score, the International Prognostic System Score, from unique patient characteristics, including the number of cytopenias, percentage of marrow blasts, and cytogenetic abnormalities present.[7] The choice of treatment is determined by patient age, performance status, comorbidities, and preference.[8] High-risk MDS and AML are treated using the same methods, have a similar prognosis, and were grouped for comparison in the present study.

Treatment

The standard AML treatment for patients aged ≥ 60 years is determined by the performance status, previous hematologic disorders, the presence of unfavorable cytogenetic or molecular abnormalities, and whether AML is related to previous chemotherapy or radiation therapy.[9] The treatment recommendations for patients with an Eastern Cooperative Oncology Group performance status of 0 to 2 include a clinical trial, intense chemotherapy with induction chemotherapy, and nonintensive chemotherapy with azacitidine or decitabine. A clinical trial, non-intensive chemotherapy, and best supportive care are recommended for patients with a performance status > 2 or significant comorbidities and for those aged > 75 years. Intense chemotherapy includes cytosine arabinoside and an anthracycline administered in the hospital, with an anticipated length of hospitalization of 4 to 6 weeks, and a cure rate of 35%.[10] Most AML and high-risk MDS patients are not able to tolerate hematopoietic stem cell transplantation, which is the standard of care for many younger patients.[11] According to the SEER data, the 5-year relative survival rate from 2007 to 2012 was 25.9% for adults.[4] In contrast, the 5-year disease-free survival rates for AML patients aged ≥ 65 years was only 5%. The survival rates for older AML patients have not changed in the past 3 decades.[12] Studies are ongoing to try to improve the overall survival and cure rates for this distinct population of patients.[13,14] In contrast, few studies have focused on the quality of their survival with different treatment approaches.[15]

The goal of treatment with high-risk MDS is to maintain the best QOL and improve survival. Cure is impossible without allogeneic stem cell transplantation. The National Comprehensive Cancer Network has recommended that age, performance status, and comorbidities determine the appropriate therapy.[8] Patients should receive supportive care, which includes QOL evaluation, psychosocial support, transfusions with blood products when needed, and infection management.[8] The treatment recommendations for high-risk MDS include low-intensity therapy with a hypomethylating agent such as azacitidine or decitabine. Hypomethylating agents are administered in the outpatient setting monthly, for as long as the patient responds or until the development of adverse side effects. Allogeneic stem cell transplantation is considered if the patient is healthy and has a human leukocyte antigen-identical donor.[8,16,17]

Most AML and high-risk MDS patients die within 5 years with or without standard treatment.[18,19] To prevent unnecessary suffering, it is important to understand how treatment influences QOL for these patients, because cure is improbable. Aggressive cancer care near the end of life has been reviewed.[20] Patients with various malignancies continued to receive intensive chemotherapy within 14 days of death in 17.1% of patients, and approximately 10% of patients remained hospitalized in the last month of life. The hematologic malignancies, such as AML and MDS, were most strongly associated with aggressive care. Additional findings included underusage of hospice services. The 1999 National Cancer Policy Board defines this as poor quality of care, when practices of known effectiveness are infrequently used.[21] Studies are needed that compare patient QOL with different treatment approaches, intense versus nonintense, and the variables that can predict patient QOL with different treatment approaches.

The purpose of the present observational study was to evaluate the effect of different treatments on QOL for older AML and high-risk MDS patients. The independent variable was the 2 approaches to treatment, intensive and nonintensive. The dependent variable was QOL. We compared the difference in QOL scores measured using the Functional Assessment of Cancer Therapy–Leukemia version for intensive chemotherapy and nonintensive therapy within 7 days of new treatment and 1 month after initiation of treatment in older patients with AML or high-risk MDS.

Patients and Methods

The scientific review committee ofMoffitt Cancer Center approved the present study, followed by approval from the institutional review board of the University of South Florida. Patients were approached by the principal investigator at their scheduled appointment or during the first week of their admission to obtain informed consent and administer the questionnaires. Eligibility was confirmed using a checklist. A quiet, comfortable room was provided for the patients to complete the questionnaires. A copy of the consent form was provided to participants to keep for future reference, with contact information provided within the consent form. It was emphasized that participation was voluntary and that their care would not be altered, regardless of study participation. Demographic data were captured using a 2-page sheet completed by each patient. The Functional Assessment of Cancer Therapy–Leukemia version (FACT-Leu) and Brief Fatigue Inventory were administered

within the first week of treatment. The second FACT-Leu was administered ≥ 4 weeks later. The data were stored in a locked filing cabinet in a locked office in the hematology clinic. All data were extrapolated to Excel spreadsheets coded only by the patient identification number to ensure patient confidentiality. The FACT-Leu scores were designated as FACT-Leu 1 and FACT-Leu 2 to identify the first and second measurements.

Study Design

We used an exploratory observational study design to compare the QOL between the 2 treatment approaches in patients aged ≥ 60 years with high-risk MDS and AML at 2 measurement points. The plan was to compare 3 treatment groups; however, low accrual for the supportive care group limited the evaluation to 2 groups. A randomized controlled trial was not possible because treatment decisions are based on prognostic indicators and patient preference and because of ethical concerns for randomization to specific treatment versus supportive care, given the diagnosis.

The setting was the Department of Malignant Hematology at Moffitt Cancer Center, a National Cancer Institute-designated Comprehensive Cancer Center that sees > 100 new leukemia and high-risk MDS patients annually. Recruitment occurred at the patients' appointments in the hematology clinic or during admission to the Moffitt Cancer Center for treatment evaluation of AML or high-risk MDS.

The eligible participants were patients aged ≥ 60 years with a high-risk MDS or AML confirmed from the bone marrow pathology reports. High-risk MDS and AML were treated as 1 group. All included patients were able to read, write, and speak English, were oriented to person, place, and time, and were willing to participate. The collection of data occurred in both outpatient and inpatient environments.

Measures

QOL was assessed at enrollment and within ≥ 1 month of enrollment using the FACT-Leu. The FACT-Leu is divided into sections that measure physical well-being, social well-being, emotional well-being, and functional well-being.[21] Each area has 6 to 7 questions that measure the QOL in the 7 preceding days for physical, social, emotional, and functional well-being. A total of 27 Likert-type items are included, with patients asked to respond to each item with a score of 0 to 4, with 0 indicating "not at all" and 4, "very much." The summed scores range from 0 to 112, with higher scores indicating better QOL. A subscale specific for leukemia was added to the general scale, which consists of 17 items. The scores range from 0 to 68. These items consist of the common problems experienced by patients with leukemia, such as fever and bone pain.

Evidence for convergent validity of the general instrument was provided by Cella et al[21] in 1993 using data from 854 patients with various cancer diagnoses compared with the Functional Living Index–Cancer, with a Pearson product moment correlation of 0.79. In 2008, Victorson et al[22] provided evidence of reliability in a study in which 344 reports were reviewed according to predetermined criteria. Of the 344 studies, 78 reported Cronbach's alpha reliability coefficients. They found the FACT–general score reliability to be 0.88 with a range of subscales from 0.71 to 0.83.

Statistical Analysis

The data were analyzed using SAS, version 9.4 (SAS Institute, Cary, NC). The data were screened for outliers and missing data. Descriptive statistics were used to summarize the study participants and study variables. Treatment group comparisons of sociodemographic and clinical variables were completed. The QOL components measured using the FACT-Leu were analyzed using a 2 (treatment) × 2 (time) mixed-design analysis of variance, controlling for any sociodemographic and/or clinical variable that differed by group. The level of significance was set at alpha = 0.05.

Results

Participants

The descriptive statistics summarizing the participant characteristics in the 2 treatment groups for the 73 patients who completed the 1-month post-treatment survey and the P values for test statistics assessing group differences (χ^2 or *t* test) are listed in Table 1. Of the 73 patients, 21 (29%) were women, 70 (96%) were white, and 52 (71%) were married. No significant treatment group differences were found, except for age, which was older for the nonintensive treatment patients. Therefore, age was included as a covariate in the primary analyses.

A total of 89 patients were approached, 88 consented, and 2 patients withdrew consent after signing, noting that the questions were too personal. A total of 86 patients participated in the first QOL measure. However, 10 patients were unable to complete the second QOL measure. Of these 10 patients, 5 each were in the nonintensive and intensive treatment groups, and 3 patients in each group had died before 30 days. Finally, 3 patients were lost to follow-up.

QOL Measures

The descriptive statistics for the 8 measures are listed in Table 2. Mixed-design analysis of variance that included age as a covariate revealed a significant time × treatment group interaction for physical well-being [F(1,70) = 6.12; $P = .016$]. More specifically, the intensive group exhibited a relative increase in physical well-being compared with the nonintensive group when controlling for age. The time × treatment group interaction was marginally significant for the leukemia subscale [F(1,70) = 3.73; $P = .058$] and for social well-being [F(1,70) = 3.68; $P = .059$]. Similar to the changes in physical well-being, the intensive group exhibited a relative increase in the leukemia subscale that was marginally significantly greater than the change exhibited by the nonintensive group. The pattern for social well-being was different. First, a marginally significant main effect was found for treatment group [F(1,70) = 3.04; $P = .085$]. Overall, the intensive group exhibited greater social well-being. Second, the nonintensive group exhibited a relative increase in social well-being such that the difference in the groups was less at the 1-month assessment. The interaction term was not significant for the other 5 FACT-Leu measures.

Discussion

The present study provides QOL data to inform the treatment decisions for patients aged ≥ 60 years with AML and high-risk MDS. Both malignancies are associated with a limited life expectancy, even with treatment. Patients typically ask how the treatment will affect their QOL and want to know what type of side effects they can anticipate. For the main effect, QOL improved in social well-being for both the intensive and the nonintensive treatment groups, with the intensive group averaging a higher score. This could have been related to the social support provided by the health care team, as well as friend and family members, when faced with a life-threatening illness. Physical well-being and the leukemia subscale both improved in the intensive group, perhaps reflecting a more rapid clearance of the leukemia compared with nonintensive treatment, which works more gradually over time.

To the best of our knowledge, the present study is the first to demonstrate that patients aged ≥ 60 years can experience statistically significant improvement in QOL 1 month after completing intensive chemotherapy. Improved QOL was not an anticipated finding and might represent some underlying process that is not obvious, such as hope after completing treatment. It might also reflect improvement in QOL that is relative to how inferior QOL was before treatment. Data were not obtained regarding the treatment response. This would be an important addition in future studies evaluating how QOL differs with various treatment approaches. The subscale analysis revealed that physical well-being and the leukemia subscale improved for the intensive group, suggesting that QOL improvement resulted from treatment and the alleviation of symptoms associated with high-risk MDS and AML. This is important information to share with patients who are concerned that intensive treatment might increase their symptoms and decrease their QOL.

For the nonintensive treatment, QOL remained stable in the leukemia and physical well-being subscales. This is logical because the response to therapy and alleviation of disease-related symptoms requires longer than 1 month for nonintensive treatment. A longer follow-up period of 3 and 6 months would be necessary for a similar response for nonintensive therapy. The nonintensive treatment was given in the outpatient setting. This might also account for the decline in QOL, with the burden of patient care on the patient and family members.

Study Limitations

The primary limitation of the present study was sample size and composition. In addition, our predominantly white, male group limits the generalizability of the findings. The setting was a comprehensive cancer center, with expertise in the management of AML and high-risk MDS. Thus, the findings might differ in a community cancer center.

Implications for Health Care Professionals

Informed health care professionals are critical for the successful treatment of AML and high-risk MDS patients. Patients turn to their health care team for all levels of support, from administration of chemotherapy to holding their hand when crying in fear of what the future brings. The results of our study will help inform decision making because we have provided

pilot data showing that intensive chemotherapy is associated with improved physical QOL and improvement in disease-related symptoms, measured using the leukemia subscale. These results can serve as encouragement that a QOL benefit exists at the end of a 1-month hospitalization associated with intensive treatment.

For the nonintensive group, improved understanding of the patient experience can drive future interventions, such as supportive care team involvement. Key issues for outpatient-based therapy are symptom control and blood count and symptom monitoring for the risk of infection and bleeding. Opportunities exist for education regarding the anticipated length of treatment before seeing a response and helping patients to set realistic expectations. These issues can be addressed holistically with a trained supportive care team.

Conclusion

The present study found that certain aspects of QOL improved at 1 month for patients with AML or high-risk MDS who underwent intense chemotherapy. Without treatment, the disease will progress and cause deterioration in all aspects of QOL. For patients who received nonintensive therapy, the QOL was stable at 1 month. Future studies with larger numbers are recommended to confirm the findings and provide additional clinical information to help patients choose the treatment approach that matches their individual goals.

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References

1. Klepin HD, Rao AV, Pardee TS. Acute myeloid leukemia and myelodysplastic syndromes in older adults. J Clin Oncol 2014; 32:2541–52. [PubMed: 25071138]
2. Merkel D, Filanovsky K, Gafter-Gvili A, et al. Predicting infections in high-risk patients with myelodysplastic syndrome/acute myeloid leukemia treated with azacitidine: a retrospective multicenter study. Am J Hematol 2013; 88: 130–4. [PubMed: 23345248]
3. Sekeres MA, Stone RM, Zahrieh D, et al. Decision-making and quality of life in older adults with acute myeloid leukemia or advanced myelodysplastic syndrome. Leukemia 2004; 18:809–16. [PubMed: 14762444]
4. Zeng Z, Samudio IJ, Munsell M, et al. Inhibition of CXCR4 with the novel RCP168 peptide overcomes stroma-mediated chemoresistance in chronic and acute leukemias. Mol Cancer Ther 2006; 5:3113–21. [PubMed: 17172414]
5. Craig BM, Rollison DE, List AF, Cogle CR. Underreporting of myeloid malignancies by United States cancer registries. Cancer Epidemiol Biomarkers Prev 2012; 21:474–81. [PubMed: 22237987]
6. Ma X, Does M, Raza A, Mayne ST. Myelodysplastic syndromes: incidence and survival in the United States. Cancer 2007; 109:1536–42. [PubMed: 17345612]
7. Greenberg P, Cox C, LeBeau MM, et al. International scoring system for evaluating prognosis in myelodysplastic syndromes. Blood 1997; 89:2079–88. [PubMed: 9058730]
8. National Comprehensive Cancer Network. Myelodysplastic Syndromes, Version 2 2017, Available at:https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed November 20, 2016.

9. National Comprehensive Cancer Network. Acute Myeloid Leukemia, Available at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site. Accessed October 15, 2016.
10. Estey E, Dohner H. Acute myeloid leukaemia. Lancet 2006; 368:1894–907. [PubMed: 17126723]
11. Baron F, Storb R. Hematopoietic cell transplantation after reduced-intensity conditioning for older adults with acute myeloid leukemia in complete remission. Curr Opin Hematol 2007; 14:145–51. [PubMed: 17255792]
12. Erba HP. Prognostic factors in elderly patients with AML and the implications for treatment. Hematol Am Soc Hematol Educ Progr 2007:420–8.
13. Burnett AK, Russell NH, Kell J, et al. European development of clofarabine as treatment for older patients with acute myeloid leukemia considered unsuitable for intensive chemotherapy. J Clin Oncol 2010; 28:2389–95. [PubMed: 20385984]
14. Burnett A, Wetzler M, Lowenberg B. Therapeutic advances in acute myeloid leukemia. J Clin Oncol 2011; 29:487–94. [PubMed: 21220605]
15. Leach M, Kowgier M, Kermalli H, et al. Quality of life (QOL) of older adults with acute myeloid leukemia (AML): effects of treatment and time. Presented at the ASCO Annual Meeting 2006. J Clin Oncol 2006; 24(suppl): 6566.
16. Giralt SA, Horowitz M, Weisdorf D, Cutler C. Review of stem-cell transplantation for myelodysplastic syndromes in older patients in the context of the Decision Memo for Allogeneic Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndrome emanating from the Centers for Medicare and Medicaid Services. J Clin Oncol 2011; 29:566–72. [PubMed: 21220586]
17. Saber W, Horowitz MM. Transplantation for myelodysplastic syndromes: who, when, and which conditioning regimens. ASH Education Book 2016; 2016:478–84.
18. Garcia-Manero G, Fenaux P. Hypomethylating agents and other novel strategies in myelodysplastic syndromes. J Clin Oncol 2011; 29:516–23. [PubMed: 21220589]
19. Estey E Acute myeloid leukemia and myelodysplastic syndromes in older patients. J Clin Oncol 2007; 25:1908–15. [PubMed: 17488990]
20. Earle CC, Landrum MB, Souza JM, Neville BA, Weeks JC, Ayanian JZ. Aggressiveness of cancer care near the end of life: is it a quality-of-care issue? J Clin Oncol 2008; 26:3860–6. [PubMed: 18688053]
21. Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 1993; 11:570–9. [PubMed: 8445433]
22. Victorson D, Barocas J, Song J, Cella D. Reliability across studies from the functional assessment of cancer therapy–general (FACT-G) and its subscales: a reliability generalization. Qual Life Res 2008; 17:1137–46. [PubMed: 18841493]

Clinical Practice Points

- Controversy surrounding optimal treatment in patients 60 years of age and older with AML and high-risk MDS Strategies include supportive care, intensive treatment, and non-intensive regiments.
- Limited research to guide the healthcare team and patients and their families in choosing treatment which align with their goals and value systems.
- This pilot study provided evidence that intensive treatment in patients 60 years of age and older can improve certain aspects of quality of life one month following treatment.
- Quality of life was stable at one month for non-intensive treatment.
- Future research should include supportive care.
- Larger study needed to confirm findings, with inclusion of community cancer centers.
- Quality of life data can help inform patients and the healthcare team in deciding between treatments.

Table 1

Patient Characteristics in Intensive (n = 42) and Nonintensive (n = 31) Groups

Variable	Intensive Group	Nonintensive Group	*P* Value[a]
Gender			.19
Male	27 (64.3)	25 (80.6)	
Female	15 (35.7)	6 (19.4)	
Race			.05
Black/African American	1 (2.4)	0 (0.0)	
Hispanic/Latino	0 (0.0)	1 (3.2)	
White	40 (95.2)	30 (96.8)	
Other	1 (2.4)	0 (0.0)	
Marital status			.28
Married	28 (66.7)	24 (77.4)	
Divorced	7 (16.7)	1 (3.2)	
Widowed	3 (7.1)	5 (16.1)	
Never been married	4 (9.5)	0 (0.0)	
Unmarried couple	0 (0.0)	1 (3.2)	
Age of children in household			.80
No children	36 (94.7)	24 (96.0)	
<5 y	0 (0.0)	1 (4.0)	
5-12 y	1 (2.6)	0 (0.0)	
13-17 y	1 (2.6)	0 (0.0)	
Employment status			.67
Employed full time	7 (17.1)	3 (19.7)	
Employed part time	2 (4.9)	1 (3.2)	
Unemployed	2 (4.9)	0 (0.0)	
Retired	28 (68.3)	25 (80.6)	
Unable to work	2 (4.9)	2 (6.5)	
Income			.21
<$25,000	10 (25.0)	3 (10.0)	
$25,000-$99,999	24 (60.0)	19 (63.3)	
≥$100,000	6 (15.0)	8 (26.7)	
Education			.61
Some high school	5 (12.2)	0 (0.0)	
Completed high school	11 (26.8)	9 (29.0)	
Some college	7 (17.1)	7 (22.6)	
2-y College degree	6 (14.6)	4 (12.9)	
4-y College degree	4 (9.8)	2 (6.5)	
Some graduate work	1 (2.4)	1 (3.2)	

Variable	Intensive Group	Nonintensive Group	*P* Value[a]
Masters or professional degree	5 (12.2)	4 (12.9)	
Advanced graduate work or PhD	2 (4.9)	4 (12.9)	
Attend religious events			.58
More than once per week	2 (4.9)	4 (12.9)	
Once per week	15 (36.6)	9 (29.0)	
Once or twice a month	4 (9.8)	1 (3.2)	
A few times per year	9 (22.0)	9 (29.0)	
Never	11 (26.8)	8 (25.8)	
Age (y)	69.8 ± 6.1	73.4 ± 7.1	.02[b]
Comorbidities	3.1 ± 1.3	3.5 ± 1.8	.26
Global fatigue score	4.2 ± 2.6	3.9 ± 2.1	.61

Data presented as n (%) or mean ± standard deviation.

[a] *P* values for treatment group comparisons (χ^2 or *t* test); for χ^2 tests, all listed levels were used in the analysis; for those analyses with an insufficient sample size to meet formal requirements (eg, race), an additional analysis was performed after collapsing all nonmajority levels into a single group, none of which resulted in a significant group difference.

[b] Statistically significant.

Table 2

Quality of Life Measures for Intensive (n = 42) and Nonintensive (n = 31) Groups

Treatment Group	Patients (n)	At Baseline	At 1 mo
Intensive	42		
Physical well-being		18.0 ± 6.8	20.7 ± 6.1
Social well-being		23.3 ± 3.6	23.4 ± 3.2
Emotional well-being		17.3 ± 5.2	18.9 ± 4.1
Functional well-being		16.5 ± 6.3	14.9 ± 6.8
Leukemia subscale		43.3 ± 11.4	48.8 ± 10.5
FACT-Leukemia, total		118.4 ± 24.9	126.6 ± 22.4
Trial outcome index		77.7 ± 20.5	84.3 ± 19.6
FACT–General, total		75.1 ± 15.4	77.8 ± 14.0
Nonintensive	31		
Physical well-being		21.3 ± 5.0	18.8 ± 5.3
Social well-being		21.4 ± 5.2	22.9 ± 3.7
Emotional well-being		16.0 ± 5.7	17.0 ± 5.0
Functional well-being		15.7 ± 5.5	14.6 ± 5.9
Leukemia subscale		45.9 ± 10.3	45.1 ± 10.0
FACT–Leukemia, total		120.3 ± 24.8	118.4 ± 24.2
Trial outcome index		82.9 ± 18.3	78.5 ± 18.2
FACT–General, total		74.4 ± 16.1	73.3 ± 15.9

Data presented as mean ± standard deviation.

Abbreviation: FACT = Functional Assessment of Cancer Therapy.