

Optimizing the Use of TKIs in the Management of Chronic Myelogenous Leukemia

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Abstract

Healthcare providers face multiple barriers when using tyrosine kinase inhibitors to achieve optimal outcomes in the management of patients with chronic myelogenous leukemia, including cost and adherence issues and lack of knowledge of new data. The objective of this study was to evaluate the performance of clinicians on multiple aspects of chronic myelogenous leukemia management and to target any identified proficiency gaps. The results demonstrated the benefits of a serial learning approach as participants who completed multiple activities achieved the greatest clinical performance gains from baseline.

Introduction: The goal of this study was to evaluate the proficiency of clinicians on multiple aspects of chronic myelogenous leukemia (CML) management, and to measure the impact of a multiple-activity educational curriculum on targeting those areas that presented the greatest clinical gaps in practice. **Materials and Methods:** The findings show that before curriculum participation, clinicians demonstrated a high proficiency in their knowledge of first- and second-line therapies. However, they were challenged when asked to apply this knowledge to patient case studies. This clinical gap was then targeted through a multiple-activity educational curriculum platform that allowed participants to engage with nationally recognized CML experts about how to apply the latest clinical research and therapeutic advances to patient management. **Results:** After evaluating these clinicians at the completion of the curriculum, the data showed that the program had successfully improved clinical performance regarding the treatment of patients requiring first-line therapies and treatment intensification in refractory CML (low-intermediate and high Sokal scores). However, participants remained challenged concerning the treatment of patients with intermediate Sokal scores who require treatment intensification after first-line therapy. The results also demonstrate the benefits of serial learning because participants who completed multiple activities achieved the greatest clinical performance gains from baseline. **Conclusion:** The findings demonstrate how a focused and high-engagement educational program, in conjunction with an outcomes methodology that can measure its efficacy, can effectively evaluate and target clinical challenges and provide a model for future educational efforts.

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Introduction

Since the initial association of chronic myelogenous leukemia (CML) with a chromosomal translocation of the c-abl tyrosine kinase gene, much of the focus of CML therapeutics has centered on inhibiting the resultant constitutively active tyrosine kinase activity.¹⁻⁶ Targeting this aberrant gene activity with tyrosine kinase inhibitors (TKI) has now become the first-line treatment of choice after one such inhibitor, imatinib, demonstrated improved disease response when compared with other therapeutic regimens for patients who were

transplant ineligible.⁷⁻¹² Second-generation TKIs have since been developed, and studies show that nilotinib,¹³⁻¹⁵ dasatinib,^{16,17} and bosutinib^{18,19} can offer superior efficacy and more durable responses.

The efficacy of first- and second-generation TKIs in the treatment of CML is now generally accepted because patients who achieve a complete cytogenetic response in 2 years have a life expectancy similar to that of the general population as long as they receive adequate therapy and adhere to the treatment regimen.²⁰ Moreover, there have been no differences in survival measured among different ethnicities, gender, and age groups.²¹ Despite the established efficacy of TKIs in the management of CML and their incorporation into the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines), there remain multiple barriers to their utilization and the achievement of optimal patient outcomes. These include interrelated factors such as the cost of such agents²² and the importance of

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adherence in achieving adequate responses.²³⁻²⁵ Additionally, it is likely that clinicians may not be aware of the most recent safety and efficacy guidelines for mutational and molecular testing, when and whether to switch TKIs, and strategies to improve adherence.

The objective of this study was to evaluate the proficiency and performance of clinicians on multiple aspects of CML management and their use of TKIs and to establish the efficacy of a multiple-activity educational curriculum on targeting any identified proficiency gaps. The findings showed that before curriculum participation clinicians already demonstrated high proficiency in their knowledge of first- and second-line therapies, strategies to promote adherence, and the assessment of whether the disease was resistant or the patient was intolerant to therapy. However, clinical gaps were revealed in their application of this knowledge to patient case studies because low scores were measured on all case-based assessments. These gaps were then targeted through a multiple-activity educational curriculum that allowed participants to engage with nationally recognized CML faculty in discussions about how to apply the latest clinical research and therapeutic advances to improve patient outcomes. After evaluating these clinicians at the completion of the curriculum, the data showed that the program had successfully improved proficiency and performance relating to the treatment of patients requiring first-line therapies and treatment intensification in refractory CML. The findings demonstrate how a focused and high-engagement educational initiative can effectively target clinical challenges, providing a model for how to address those areas in which continued support is needed.

Materials and Methods

A multiple-activity educational curriculum, “Optimizing Management of Chronic Myelogenous Leukemia,” was designed to evaluate the proficiency and performance of clinicians regarding recent therapeutic advances in the treatment of CML. After measuring their initial proficiency (at pre-test) and identifying any potential clinical gaps, clinicians then participated in 1 or 2 educational activities. One of the activities was a “Virtual Grand Rounds”; the second activity was a “Virtual Study Group” that featured 6 live Web events during which faculty were able to engage learners in content-based discussions. Both activities provided participants with the opportunity to interact with nationally recognized CML experts on the most recent clinical research and therapeutic strategies. After participation in the activities, clinicians were re-evaluated (post-test) to assess the efficacy of the program in targeting their clinical gaps.

The evaluation of learners consisted of a variety of question types that focused on specific learning domains: knowledge (fact-based), competence (case-based), confidence (rated on a Likert scale), and performance (assessing specific practice behaviors). All questions presented to the learner in the pre-test section were paired with the identical question in the post-test. Additionally, the performance domain was assessed through a multi-dimensional situation-based repeated-measure (called the RealIndex) that comprehensively addressed the learning objectives of the curriculum. In the RealIndex, participants were presented with a real-life clinical scenario, which was followed by a series of action-based statements that they assessed as either consistent with, or inconsistent with, their current practice approach. The same RealIndex was given in both activities; all other questions were activity-specific. The RealIndex was administered

prior to the first activity of a curriculum (baseline) and following each activity of the curriculum. For each subsequent administration of the RealIndex question, learners were given the opportunity to refine their responses based on their progressive learning. The RealIndex is designed to align the progression of a learner’s RealIndex score from baseline through the multiple activities of a curriculum with the changes that the learner is making in their practice. Reliability analysis (Cronbach alpha) was conducted on the RealIndex to assess the internal consistency of the items in the measure; results indicated a high level of reliability with alpha coefficients ranging from .715 to .838 (on a scale of 0 to 1.0). All data were analyzed using the Statistical Package for Social Sciences version 19.0 (SPSS 19; IBM Corp, Somers, NY). The data were first arrayed using frequencies. Questions were then reported and analyzed for pre-test and post-test comparisons using a matched-pair methodology. Both dependent and independent sample *t* tests were used to assess the differences between the mean evidence-based pre-test and post-test responses of the participants; differences were considered significant at $P \leq .05$. Dependent *t* test calculations were only conducted on matched pairs of participant scores. Analyses of variance were carried out to assess differences among the groups of learners (cohorts).

Results

Participants

A group of 2 cohorts ($n = 15$ from the Montefiore Cancer Center, Bronx, NY; $n = 799$ from a national cohort) participated in this assessment program; 43% ($n = 348$) of these participants identified their profession as physician, 10% ($n = 83$) as physician assistant, 8% ($n = 64$) as nurse practitioner, 7% ($n = 57$) as nurse, and the remaining participants identified health care professions that represented $\leq 5\%$ ($n = 32$) of the total sample. For all analyses in this paper, only those specialists who identified their specialties as oncology (65%, $n = 140$), hematology (10%, $n = 22$), or hematology-oncology (22%, $n = 53$) were evaluated ($N = 215$).

Pre-Curriculum Assessment of Specialists

The initial assessment of clinicians across the multiple learning domains (knowledge, competence, confidence, and performance) showed varying levels of proficiency on different aspects of CML management. Consistently high pre-test scores (92% average) were measured on all knowledge questions that addressed the selection of first-line therapies and the 2014 NCCN Guidelines on first-line therapies. The high scores on these knowledge questions that addressed first-line therapies correlated strongly with the high reported confidence (3.4 on a 5 point Likert scale) of specialists about their ability to choose a TKI for a patient with newly diagnosed chronic-phase CML. In contrast to the high pre-test proficiency demonstrated by the knowledge items on first-line therapies, a notably lower score (52% average) was measured on the case-based question on first-line therapies that presented a real-life clinical vignette and required clinicians to make a decision about the selection and dosage of first-line therapies for the patient presented. Regarding first-line treatment, participants did not consider dasatinib or nilotinib, 2 second-generation TKIs that are approved for first-line use in the latest NCCN Guidelines. Moderately lower scores (83% average) were observed regarding knowledge questions relating to the selection of and 2014 NCCN Guidelines about

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