Original Article

Clinical Decision Support for Symptom Management in Lung Cancer Patients: A Group RCT

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Abstract

Context. Clinical guidelines are available to enhance symptom management during cancer treatment but often are not used in the practice setting. Clinical decision support can facilitate the implementation and adherence to clinical guidelines. and improve the quality of cancer care.

Objectives. Clinical decision support offers an innovative approach to integrate guideline-based symptom management into oncology care. This study evaluated the effect of clinical decision support-based recommendations on clinical management of symptoms and health-related quality of life (HR-QOL) among outpatients with lung cancer.

Methods. Twenty providers and 179 patients were allotted in group randomization to attention control (AC) or Symptom Assessment and Management Intervention (SAMI) arms. SAMI entailed patient-report of symptoms and delivery of recommendations to manage pain, fatigue, dyspnea, depression, and anxiety; AC entailed symptom reporting prior to the visit. Outcomes were collected at baseline, two, four and six-months. Adherence to recommendations was assessed through masked chart review. HR-QOL was measured by the Functional Assessment of Cancer Therapy-Lung questionnaire. Descriptive statistics with linear and logistic regression accounting for the clustering structure of the design and a modified chi-square test were used for analyses.

Results. Median age of patients was 63 years, 58% female, 88% white, and 32% ≤high school education. Significant differences in clinical management were evident in SAMI vs. AC for all target symptoms that passed threshold**.** Patients in SAMI were more likely to receive sustained-release opioids for constant pain, adjuvant medications for neuropathic pain, opioids for dyspnea, stimulants for fatigue and mental health referrals for anxiety. However, there were no statistically significant differences in HR-QOL at any time point.

Conclusion. SAMI improved clinical management for all target symptoms but did not improve patient outcomes. A larger study is warranted to evaluate effectiveness. J Pain Symptom Manage 2022;63:572−580. © *2021 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Symptom management, clinical decision support, nonsmall cell lung cancer, patient-reported outcomes, symptom assessment, depression, anxiety, pain, dyspnea, fatigue health-related quality of life

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Introduction

Eighty percent of lung cancer patients are diagnosed with advanced disease when curative options are no longer available.[1] Fatigue, dyspnea, pain and emotional distress are among their most common symptoms and often present as co-occurring symptoms.[2–4] Sung et al.[5] examined the evolution of symptoms in lung cancer patients and found that, despite advances in treatment, patients with advanced disease continue to experience significant distress; the incidence and type of symptoms has remained unchanged over the past 10 years.

Given that symptom management is a critical part of quality cancer care, patient-reported outcome (PRO) symptom assessment tools have been integrated into routine cancer care. Warrington et al. conducted a systematic review to identify electronic symptom reporting systems and found 41 systems.[6] Systems fell into two main categories: 1) clinician-facing, using PROs to access and monitor symptoms, with alerts when patients report severe symptoms and 2) patient-facing, which track symptoms over time, give tailored education about symptoms, encourage patients to communicate with the health care team, and enable access for them to obtain peer support. These systems have lessened symptom distress, and improved communication and overall survival in cancer patients.[7–9]

Although PROs have become part of routine care, clinicians often need additional support to manage the symptoms revealed by the PROs.[8,10] While there are clinical guidelines for symptom management, they are not consistently used in clinical settings [11–14] A smart algorithm-based clinical decision support (CDS) system can operationalize the guidelines and PROs into clinical recommendations tailored for individual patients.[15,16]

Our Symptom Assessment and Management Intervention (SAMI) CDS is such a system. We previously demonstrated that SAMI was able to deliver patient-specific guideline-based CDS for common symptoms (pain, dyspnea, depression, anxiety, and fatigue) experienced by patients with advanced lung cancer.[16–18] Now, we present the results of a secondary outcomes analysis of SAMI, comparing clinical management of symptoms and health related quality of life (HR-QOL) in the SAMI arm as compared with the attention control (AC) arm. This study extends the literature by integrating CDS for managing multiple symptoms in the outpatient cancer care setting at the point-of-care.

Methods

Study Design and Participants

This study was conducted in a comprehensive cancer center and in a safety-net hospital. Study participants included medical oncologists and nurse practitioners (NPs) and their patients. Eligible patients were English speaking, ≥21 years of age with a diagnosis of stage III or IV nonsmall cell lung cancer, any stage small cell lung cancer, or recurrent lung cancer, who were receiving treatment with chemotherapy or combined treatment. Any patient who needed emergent care or had fewer than monthly visits was excluded. This study was registered in ClinicalTrials.gov (*NCT00852462*). The IRB approved the study and clinicians and patients provided informed consent.

A group randomized clinical trial (RCT) was conducted randomizing medical oncologists into SAMI vs. AC, stratified by clinical site and clinician volume. Patients who agreed to participate were assigned to the same group as their medical oncologist. Because NPs work with multiple physicians any of whom could be assigned to the SAMI group, all participating NPs were assigned to the SAMI group, but they received the SAMI report only when their patient was assigned to SAMI (Fig. 1).

Intervention and Control Conditions

SAMI is a Cloud-based CDS system that collects data from patients and the medical record, processes these data through decision algorithms, and then presents care recommendations at the point-of-care.[17] First, the patient self-reported symptoms are combined with demographic and clinical data either provided by patients or derived from the electronic health record (EHR). The PRO questionnaires selected for use were chosen based on performance in previous studies and the literature.[2,19,20,21–25] Clinical Research Coordinators (CRCs) collected information (drug allergies, cancer treatment, weight, comorbidities, platelet count, serum creatinine, hemoglobin and use of supportive care medications [e.g., opioids]) from the EHR and/or from patients and entered them into the system. Integration of SAMI into the EHR was not supported at the time when the study was conducted.

Next, Web services were utilized to transmit de-identified patient data to a Cloud-based CDS decision engine programmed with symptom management algorithms.[26] Processing the data through the algorithms generated recommendations for symptom management for patients at each visit. The recommendations were returned in less than two seconds and printed as a summary report (Fig. 2). This report showed symptom severity, cancer treatment received, supportive care medications taken, alcohol use, drug allergies, and recommendations, including medication adjustments and referrals. Prior to initiating the intervention, two of the study investigators (M. E. C. and J. L. A.) met with each HCP in the SAMI arm to orient them to the report and answer any questions that they had about the study and study procedures. In addition, we worked with members of the research team who were designated clinical champions (M. S. R. and K. F.) to facilitate seamless

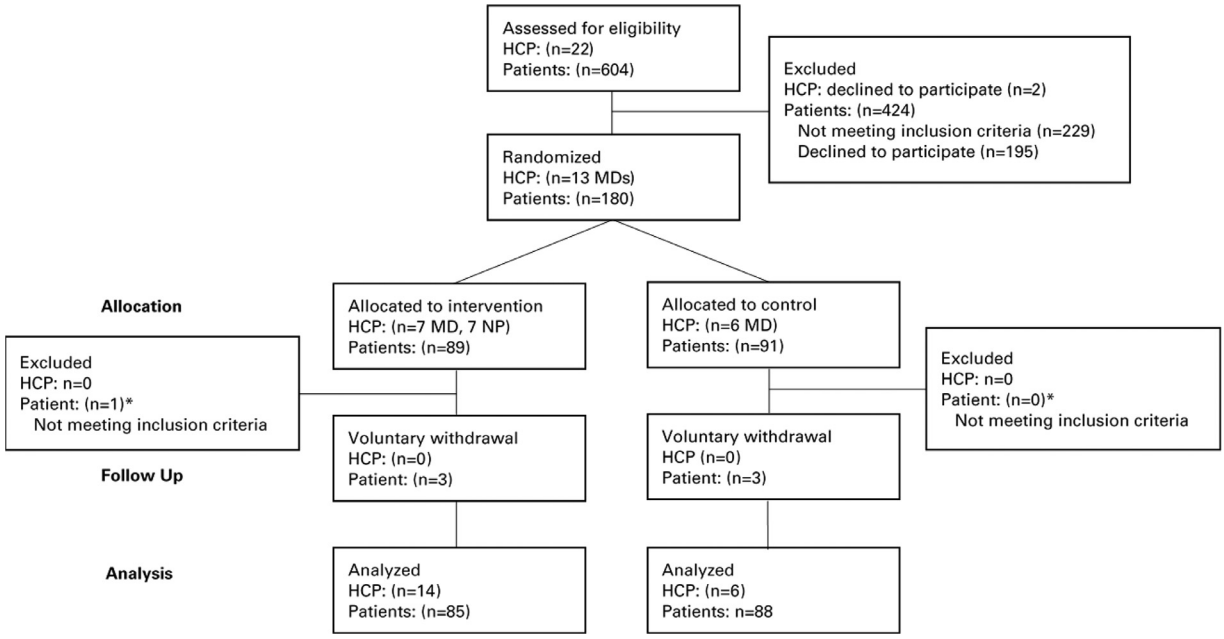

Fig. 1. Consort diagram.

integration of the intervention into the work processes of the clinical setting. Once the study was initiated, CRCs delivered reports to clinicians randomized to SAMI prior to each visit. At entry to the study, SAMI patients received a symptom toolkit, which provided symptom management self-care support.[27]

Patients in AC completed the same questionnaires as did patients in SAMI. These data were processed through the symptom management algorithms to generate patient-tailored care recommendations that could be considered as potential intervention opportunities; however, these recommendations were not communicated to clinicians. At the end of the study, patients in AC also received the symptom toolkit. Patients in both arms of the study received concomitant usual care.

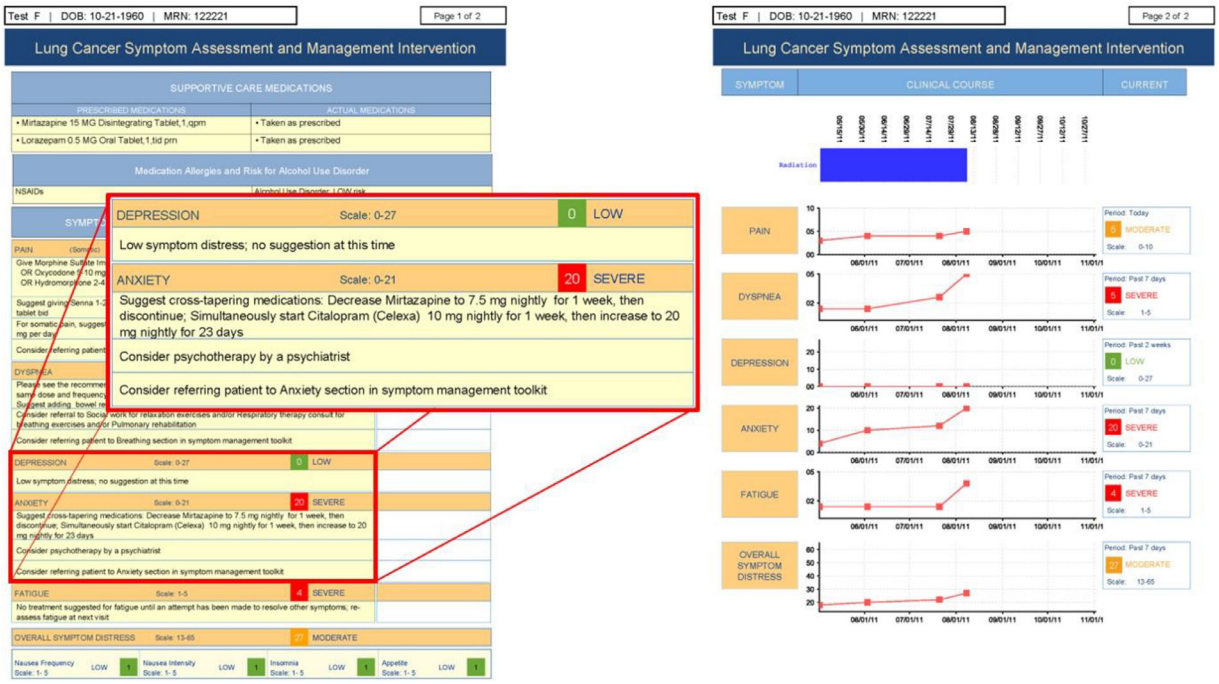

Fig. 2. SAMI report.

Data Collection

Demographic data were collected at baseline. Stage of disease and type of cancer treatment received during the study were obtained through a medical record review. Clinical data collection took place at each on-study clinic visit (used for guideline-based clinical management of symptoms) and study outcome data collection (e.g., HR-QOL) at baseline, two, four, and six months later.

Clinical management of symptoms was assessed at each clinic visit during the study period through a medical chart review by masked CRCs, using a form adapted from a study assessing adherence to pain management guidelines.[28] This form measured use of supportive care medications (opioids, nonsteroidal antiinflammatory agents, laxatives, antidepressants, anticonvulsants, corticosteroids) and referrals (pain, palliative care, psychiatry, social work, and physical therapy services) documented in the medical record at each visit.

HR-QOL was measured with the Trial Outcome Index subscales (TOI). The TOI version of the Functional Assessment of Cancer Therapy questionnaire uses the physical, functional, and lung cancer subscales and was chosen since it was identified as a relevant measure for clinical trials and we wanted to minimize instrument burden among those with advanced disease.[29] Higher scores indicate higher HR-QOL.

Statistical Analyses

To guarantee methodological consistency throughout all the statistical analysis, the descriptive results (reported in Tables 1 and 2) are summarized/compared between AC and SAMI groups using weighted tests that account for the HCP clustering. Patient characteristics were summarized using either standard descriptive statistics or percentages (Table 1), and the balance in baseline characteristics between the two groups were evaluated using weighted (Rao-Scott) chi-squared tests or weighted t-tests for categorical and continuous variables, respectively, accounting for HCP clustering.

The analysis of clinical management utilized only the subset of participants who experienced symptoms passing the predefined threshold for at least one visit. This metric was defined as the percentage of participants who received the recommended clinical management action for their symptom, out of the number of participants with the given symptom passing the predefined threshold for at least one visit. The percentage was then compared between SAMI and AC using a modified (Rao-Scott) chi-square test accounting for HCP clustering (Table 2).

HR-QOL scores (TOI, physical well-being, functional well-being, and lung cancer subscales) were estimated and compared between study groups at each assessment time point using a linear regression model adjusting for baseline scores, and accounting for the HCP clustering structure (Table 3).

Table 1
Patient Characteristics

Characteristic	SAMI	AC	*P*-value (Rao-Scott Chi-square Test)
	N (%)	N (%)	
N	88 (49)	91 (51)	-
Gender			0.06
Male	33 (37)	42 (46)	
Female	55 (62)	49 (54)	
Age, yrs, median (range)	61 (39–81)	64 (38–80)	0.06[a]
Ethnicity			0.49
Hispanic/Latino	5 (6)	3 (3)	
Non-Hispanic/ Latino	83 (94)	88 (97)	
Race			0.94
White/Caucasian	76 (86)	81 (89)	
Other	8 (9)	8 (9)	
Missing	4 (5)	2 (2)	
Marital status			0.52
Single	15 (17)	11 (12)	
Married/ partnered	48 (55)	55 (60)	
Separated/ divorced/ widowed	24 (27)	22 (24)	
Unknown	1 (1)	3 (3)	
Education			0.07
≤High school/ GED	22 (15)	35 (38)	
>High school/ GED	64 (73)	53 (58)	
Unknown	2 (2)	3 (3)	
Work status			0.48
Working	26 (30)	21 (23)	
Not working	61 (69)	68 (75)	
Unknown	1 (1)	2 (2)	

P-values are calculated accounting for clustered design, using the Rao-Scott version of the chi-squared test (or a cluster-adjusted t-test for Age).
[a]cluster-adjusted t-test.

Intracluster correlations (ICC) were estimated using a generalized linear mixed model and are reported in Tables 4 (for grouped symptoms) and 5 (for HR-QOL). Some values for the ICC were not estimated due to the lack of variability of the random effects after controlling for the fixed effects. A complete case analysis was conducted including all participants with available data. No imputation for missing observations was conducted. All the analyses were performed using SAS (version 9.4; SAS Institute, Cary, NC); specifically, we used SAS PROC SURVEYFREQ and SURVEYREG for cross-tabulations of the categorical variables and the modeling of the continuous variables, respectively.

Results

Sample

A total of 13 MDs were randomized to either SAMI (n=7) or AC (n=6), and a total of 7 NP were assigned to

Table 2
Clinical Management of Symptoms

Symptom	Management Action	% Change in Medical Prescribing SAMI vs. AC	No. Pass Threshold (No. With Clinical Management)		*P*-value (Rao-Scott Chi-square Test)
			SAMI	AC	
Moderate-severe pain	Opioid	+7.4	25 (19)	35 (24)	0.51
	Palliative Care Consult	+6.3	25 (3)	35 (2)	0.30
Neurological pain	Neuro Med	+24.7	14 (4)	26 (1)	0.002
Somatic pain	Som Med	+12.0	24 (5)	34 (3)	0.30
Constant pain	Sustained release Opioid	+17.9	17 (8)	24 (7)	0.05
Severe dyspnea	Opioid	+36.7	13 (12)	9 (5)	0.02
	Transfusion	-3.4	13 (1)	9 (1)	0.78
	Referral	-	13 (0)	9 (0)	-
Opioid given	Bowel Med	+3.8	49 (30)	47 (27)	0.72
Moderate-severe depression	Antidepressant	+1.7	12 (5)	10 (4)	0.93
	Psychiatry Referral	+1.7	12 (5)	10 (4)	0.93
Mild depression	Social Work	+10.5	59 (12)	71 (7)	0.08
Moderate-severe anxiety	Anxiolytic	-4.0	14 (8)	18 (11)	0.80
	Psychiatry Referral	+42.1	14 (9)	18 (4)	0.03
Mild anxiety	Benzo Med	+0.4	28 (25)	27 (24)	0.96
	Social Work	-0.8	28 (6)	27 (6)	0.94
Severe fatigue	Stimulant	+24.3	32 (11)	30 (3)	0.002
	PT Consult	-	32 (0)	30 (0)	-
Moderate-severe fatigue	Transfusion	-7.2	57 (3)	56 (7)	0.22
Moderate-severe fatigue +insomnia	Sleep Med	-1.0	30 (9)	29 (9)	0.87

Number of participants with symptom passing the predefined threshold at least one visit (with corresponding number of participants out of the former number who got clinical management of symptom at least one visit). For instance, 25 patients overall for SAMI passed the threshold for moderate-severe pain, and 19 out of those 25 got clinically managed with opioid. Also included: percent difference in clinical management for SAMI vs. AC and corresponding cluster-adjusted *P*-value of the Rao-Scott version of the chi-squared test.

SAMI group. Overall median age for all 20 clinicians was 41 years, 80% white, 40% female, with a median of 11 years of experience in oncology.

A total of 179 patients with lung cancer were group randomized to either SAMI (N=88) or AC (N=91) based on the randomization assignment of their primary oncologist. Patient characteristics were balanced between study groups with the exception of age (P=0.06), gender (P=0.06), and education (P=0.07) where the AC group was slightly older, higher percentage female and less educated (Table 1).

Table 3
HR-QOL Outcomes

Time	Outcome	SAMI vs. AC Estimate (90% CI)	*P*-value
2-month (N=151)	PWB	0.2 (-1.7, 2.0)	0.87
	FWB	0.2 (-1.0, 1.5)	0.74
	LCS	-0.4 (-1.5, 0.7)	0.53
	TOI	-0.03 (-3.8, 3.8)	0.99
4-month (N=131)	PWB	1.6 (0.3, 2.9)	0.05
	FWB	1.2 (-0.09, 2.5)	0.12
	LCS	0.6 (-1.0, 2.2)	0.51
	TOI	3.1 (-0.4, 6.7)	0.14
6-month (N=125)	PWB	0.7 (-1.1, 2.4)	0.51
	FWB	1.9 (-0.2, 4.0)	0.13
	LCS	-0.04 (-1.1, 1.0)	0.95
	TOI	2.4 (-2.0, 6.8)	0.35

PWB = Physical well-being; FWB = Functional well-being; LCS = Lung cancer subscale; TOI = Treatment outcome index.

Clinical Management

Among patients who passed the threshold for pain, anxiety, depression, dyspnea or fatigue severity, significant differences in optimal clinical management of symptoms were identified between the SAMI and AC group participants (Table 2). Patients in the SAMI group compared to AC were more likely to receive adjuvant medications for neuropathic pain (28.6 vs. 3.8%, P=0.002) and sustained-release opioids for constant pain (47.1 vs. 29.2%, P=0.05). Similarly, patients in the SAMI group were more likely to receive a psychiatry referral for moderate-severe anxiety (64.3 vs. 22.2%, P=0.03), opioids for severe dyspnea (92.3 vs. 55.6%, P=0.02) and a stimulant for severe fatigue (34.4 vs. 10%, P=0.002). Social work referrals for mild depression (20.3 vs. 10%, P=0.08) were marginally significant.

Health-Related Quality of Life

HR-QOL did not differ significantly between the groups at any time point.

Patients who have the same HCP have more correlated outcomes (specifically, in the lung cancer subscale and PWB) at six months than they have at either two or four months. FWB and TOI on the other hand, show a more stable, very low, level of intracluster correlation across timepoints.

Table 4
Intracluster Correlation for Symptom Management

Symptom	ICC
Pain	0.11
Dyspnea	0.17
Depression	0.15
Anxiety	0.24
Fatigue	0.14

Discussion

ASCO palliative care guidelines challenged clinicians to integrate palliative care into their standard practice for patients throughout their cancer trajectory.[30] However, partnering with palliative care experts alone will not be sufficient to achieve the goal of purposeful symptom management; there are too few experts, and there will not be enough in the future to meet the demands of an aging population. Innovative models for palliative care delivery, including psychosocial care, are required to meet this demand. Clinician awareness of PROs is not sufficient. Clinicians need patient-specific symptom management recommendations delivered at the point-of-care using CDS.

The results of this study indicate that CDS that is computerized, tailored, and delivered at the point-of-care improved clinical management for all of the target symptoms (pain, anxiety, depression, fatigue and dyspnea). As a result of the recommendations, clinicians prescribed supportive care medications and/or initiated supportive care referrals to address the particular symptom. The results from our study are similar to systematic reviews that examined the effectiveness of CDS in varied populations and found improvement in clinician performance and health care processes.[15,31,32] One study by Lobach et al.[15] examined the relative effectiveness of CDS and found improved processes related to ordering clinical studies (OR:1.72, 95% CI [1.47−2.0]) and prescribing therapies (OR:1.57, 95% CI [1.35−1.82]). In addition, Kawamoto et al. identified features associated with successful systems including; local user involvement, integrating decision support as part of clinician workflow, providing decision support at the time and location of decision-making, and providing specific management suggestions, not just the results of an assessment.[15,18]

Table 5
Intracluster Correlation for HR-QOL Outcomes

Time	Outcome	ICC
2-month	PWB	-
(N=151)	FWB	0.020
	LCS	0.072
	TOI	-
4-month	PWB	0.034
(N=131)	FWB	0.013
	LCS	0.045
	TOI	-
6-month	PWB	0.123
(N=125)	FWB	-
	LCS	0.359
	TOI	0.047

Psychosocial distress screening was mandated by the American College of Surgeons' Commission on Cancer as a requirement for cancer center accreditation in 2015[33] and recommended by ASCO in their 2014 guideline.[12] We adopted these recommendations by screening for depression and anxiety. To operationalize the standardized assessment, we used short, validated questionnaires that had cut points to identify those requiring a referral and/or further treatment.[12,34,35] Previous studies have identified that screening alone is not adequate to improve patient outcomes and reduce health care utilization costs associated with increased distress.[36,37] It is essential to have clear pathways identified for referral and initiation of psychotherapy and/or medication for those who screen positive for high levels of distress.[38] Although SAMI increased the frequency of supportive care referrals for anxiety, there were no differences for the initiation of medications. The initiation of medication for depression has been successful in other settings using algorithm-based CDS. Passik et al.[39] implemented the use of a paper-based algorithm to improve treatment of depression in a routine oncology setting. Results from Passik's et al.[39]study were promising and indicated that pharmacological treatment for depression increased from 7 to 86% of patients who screened positive for depression. Oncologists received more intensive training in the Passik et al.[39] study as compared to our study. It appears that while the use of SAMI to supplement routine psychosocial screening may be a good target for future evaluation, use of implementation strategies such as practice facilitation may be needed to enhance initiation of medications, especially for depression.[40,41]

Standardizing pain management is another important target for intervention. Inadequate pain management has been identified as an issue that contributes significantly to disparities in symptom burden among minority and underserved adults with cancer.[6,7] Patients in the SAMI group were more often prescribed adjuvant medications for neuropathic pain and sustained-release opioids as compared to the AC group. These findings are similar to previous studies that used algorithm-based CDS.[42,43] DuPen et al.[42] conducted one of the first algorithm-based CDS studies in oncology and our findings are similar to their findings such that clinicians in the CDS group prescribed sustained-release opioids and adjuvant medications more often as compared to the AC group. Algorithm-based CDS may provide a strategy to address these disparities and reduce the gap in needless suffering.[32]

Medications were more likely to be initiated for patients who experienced severe fatigue in SAMI as compared to AC. Although exercise is one of the key interventions to mitigate cancer-related fatigue, the recommendations that were embedded within SAMI did not provide clear and specific information to enable clinicians to initiate suggestions for exercise or referral. Future iterations of SAMI will incorporate specific behavioral suggestions for fatigue and insomnia.

There were no significant differences in HR-QOL between the groups at any time point. This finding is similar to a systematic review by Klarenbeek and colleagues[44] that examined the effect of computerized CDS systems on oncology care and found that adherence to clinical practice guidelines improved but there wasn't improvement in patient outcomes. The authors suggest that there was a paucity of studies and that further studies using more rigorous research designs are needed. In our study, it is important to note that a limitation was that the overall level of symptom severity was lower than expected within this group of patients with advanced lung cancer, and as a result the sample sizes for the symptoms that passed threshold were too low to evaluate the effect of SAMI on patient outcomes. Thus, this finding needs to be replicated in a larger study. Jeon et al.[45] suggested that clinical trials seeking to test new psycho-behavioral interventions need to accrue patients who exhibit symptoms that are sufficiently high in order to demonstrate a response to treatment and recommend a symptom severity of >4 on a 10-point Likert scale. Accruing patients whose symptoms fail to reach a pre-specified threshold will result in lower power to detect a statistically significant response. Future studies assessing the impact of SAMI on HR-QOL should include symptoms reaching a predefined threshold for inclusion and/or analyses, rather than offering the trial to all patients, as we did in this trial.

There were several other limitations to our study. First, the study sample was small and drawn from two outpatient thoracic oncology settings. We used a group RCT and randomized physicians and their patients to SAMI or AC to minimize contamination; however, the nurse practitioners enrolled in the study received SAMI reports if their patient was in SAMI, but not if their patient was in AC. Because of this, and the fact that the study was conducted within the same disease center, cross-contamination may have occurred, and may have blunted the effect of the intervention. Future studies should randomize by disease center or cancer center to eliminate risk of contamination and include a larger sample size. Second, although we included a safety-net hospital to recruit a diverse sample of patients, we recruited a smaller number of patients there and our sample was primarily white. Third, we did not integrate the SAMI CDS into the EHR; obtaining clinical data used to generate symptom management recommendations was time intensive and not practical for routine clinical care. Fourth, we used the TOI subscale of the FACT-L to measure HR-QOL in order to minimize participant burden. Although this measure has been recommended to capture the disease-related effects of clinical trials in NSCLC,[29] we noted a significant increase in referrals to mental health providers for anxiety, which was not captured as part of the HR-QOL measure used in this study. More sensitive measures, especially those designed to capture the psychosocial dimension of HR-QOL, should be used in future studies testing the effect of guideline-based CDS of multiple symptoms. Finally, this study targeted those with advanced stage lung cancer receiving treatment in an outpatient setting. Thus, the results pertain to this group of patients. Future studies should be more inclusive and target those with high symptom severity.

Our study was the first group RCT to go beyond making clinicians aware of PROs. Our study extended the literature by determining the feasibility and preliminary efficacy of integrating CDS for managing multiple symptoms that were identified through PRO measurement in the outpatient cancer care setting.[17] Since the completion of this study, advances in measurement and standards for integrating PROs into EHRs will provide new opportunities to integrate our intervention into the EHR. We plan to conduct a study that examines EHR integration of symptom assessment and management algorithms as an implementation strategy to enhance uptake of evidence-based clinical guidelines.

In conclusion, SAMI improved management of all of the target symptoms but did not impact HR-QOL at any time point. This CDS meets a contemporary need to identify and examine varied models of care that integrate PROs and clinical practice guidelines into routine care and enable clinicians to deliver primary palliative care services on a population level to enhance outcomes of care.[46,47] In the future, larger studies are needed that identify effectiveness of CDS and examine strategies to disseminate and scale the intervention, especially among settings that do not have access to palliative care services.

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