

Early Palliative Care in Advanced Lung Cancer

A Qualitative Study

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Background: Early ambulatory palliative care (PC) is an emerging practice, and its key elements have not been defined. We conducted a qualitative analysis of data from a randomized controlled trial that demonstrated improved quality of life, mood, and survival in patients with newly diagnosed metastatic non–small cell lung cancer who received early PC integrated with standard oncologic care vs standard oncologic care alone. Our objectives were to (1) identify key elements of early PC clinic visits, (2) explore the timing of key elements, and (3) compare the content of PC and oncologic visit notes at the critical time points of clinical deterioration and radiographic disease progression.

Methods: We randomly selected 20 patients who received early PC and survived within 4 periods: less than 3 months (n=5), 3 to 6 months (n=5), 6 to 12 months (n=5), and 12 to 24 months (n=5). We performed content analysis on PC and oncologic visit notes from the electronic health records of these patients.

Results: Addressing symptoms and coping were the most prevalent components of the PC clinic visits. Initial vis-

its focused on building relationships and rapport with patients and their families and on illness understanding, including prognostic awareness. Discussions about resuscitation preferences and hospice predominantly occurred during later visits. Comparing PC and oncologic care visits around critical time points, both included discussions about symptoms and illness status; however, PC visits emphasized psychosocial elements, such as coping, whereas oncologic care visits focused on cancer treatment and management of medical complications.

Conclusions: Early PC clinic visits emphasize managing symptoms, strengthening coping, and cultivating illness understanding and prognostic awareness in a responsive and time-sensitive model. During critical clinical time points, PC and oncologic care visits have distinct features that suggest a key role for PC involvement and enable oncologists to focus on cancer treatment and managing medical complications.

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DURING THE LAST DECADE, there has been significant growth of palliative care (PC) services and increasing international awareness of the role of PC for patients with advanced illness and their caregivers.^{1,2} Research has demonstrated that PC is associated with better quality of life and mood, improved symptom control, more appropriate health resource use, increased patient and caregiver satisfaction, health care savings, and possibly even survival.³⁻⁹ The current World Health Organization's definition of PC is "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual."¹⁰ Thus, PC is becoming a more established compo-

nent of cancer care and is poised to provide an integral role in comprehensive cancer care for patients with advanced cancer.

See Invited Commentary at end of article

Currently, many cancer centers have some form of PC services that predominantly consist of inpatient consultative services and acute inpatient units, whereas outpatient PC clinics remain a scarcer entity.² However, accumulating data suggest that early integration of PC in the ambulatory care setting is feasible and can lead to significant improvements in both patient-reported outcomes and several key measures of quality end-of-life care and resource use. Early integration of PC with cancer care also enhances patients' understanding of their illness and prognosis, leads to more timely transitions to hospice care, and decreases chemotherapy use near the end of life.¹¹⁻²³

On the basis of these data, the American Society of Clinical Oncology is advocating for increased PC services in the ambulatory care setting and recommending that all patients with metastatic cancer be offered such services early in their illness.^{24,25} However, more information about the nature and elements of early PC in the ambulatory care setting is necessary to actualize this recommendation.^{15,26-28} The integration of PC with standard oncologic care may have a different emphasis and focus than traditional PC provided as an inpatient or consultative service. Earlier and longer relationships between PC clinicians and patients may allow the time and opportunity to face complex issues, such as treatment decision making and advanced care planning collaboratively, rather than focusing predominately on acute symptom management and imminent death.²⁹

In this study, we sought to determine the salient elements of clinical encounters with PC in the ambulatory care setting by exploring the content of the clinic visits in our randomized study of early integrated PC in patients with metastatic non-small cell lung cancer.⁸ We conducted a qualitative study of clinical documentation from these data to provide a descriptive overview of early integrated PC for cancer. Specifically, our aims were to (1) identify the content and key elements of early PC, (2) explore the variation in these key elements over time, and (3) compare the content of PC and oncologic care encounters at critical clinical time points. This analysis provides one framework for PC clinicians and oncologists to use in developing integrated models of care at their institutions and begins to identify potential mediators of improved patient outcomes and health service use with early PC for examination in further research.

METHODS

OVERALL STUDY DESIGN

We performed a qualitative analysis of clinical documentation from the randomized controlled trial of early PC integrated with standard oncologic care vs standard oncologic care alone in patients with metastatic non-small cell lung cancer.

STUDY PARTICIPANTS

We enrolled 151 patients with newly diagnosed metastatic non-small cell lung cancer from the thoracic oncology clinic at Massachusetts General Hospital in Boston. Eligible patients were within 8 weeks of diagnosis, had an Eastern Cooperative Oncology Group performance status of 0 to 2, and were able to complete questionnaires in English. Participants were randomly assigned in a 1:1 ratio to early PC integrated with standard oncologic care or standard oncologic care alone. Patients assigned to the intervention arm met with a member of the PC team within 3 weeks of enrollment and at least monthly thereafter in the ambulatory care setting until death. Further details are published elsewhere.⁸

General guidelines for the PC visits were based on recommendations from the National Consensus Project for Quality Palliative Care; however, the content of the consultations were not prescribed or scripted.³⁰ The PC clinicians were allowed the flexibility to conduct the visits as deemed appropriate for the individual patient. After each visit, PC clinicians documented the content of the clinical encounter in the electronic health record. This study was approved by the institutional review board of the Dana-Farber/Harvard Cancer Center.

QUALITATIVE STUDY SAMPLE

To ensure representation of patients from varied survival periods, we used a stratified sampling plan. We divided intervention participants (n=77) into 4 groups based on survival times of less than 3 months, 3 to 6 months, 6 to 12 months, and 12 to 24 months; we then randomly selected 5 patients from each survival period. We estimated that a sample size of 20 intervention participants would provide thematic saturation (the point at which no new data emerge) to explore and describe the clinical elements occurring in PC encounters.

QUALITATIVE ANALYSIS

We derived the data set for this analysis by extracting clinical documentation for every PC clinician visit for each patient from the electronic health record. A preliminary thematic scheme was developed after initial reading of the cases by a multidisciplinary team (including expertise from medical oncology, palliative care, psychiatry, and psychology) that involved investigators from the original study team and new investigators. We further refined the thematic scheme through multiple readings of the notes to examine, conceptualize, and categorize themes within each survival period. At biweekly meetings, 3 investigators (J.Y., E.R.P., and A.L.B.) reviewed the clinical documentation, developed a coding scheme, and confirmed that thematic saturation had been reached. The final version of the coding scheme was then reviewed and finalized by the multidisciplinary investigative team. Coding was subsequently performed by one of us (J.Y.) using NVivo 9 qualitative data analysis software (QSR International). To ensure accuracy, both the coding and data interpretation were confirmed through review of the clinical documentation. We then established trustworthiness through analysis of the data in entirety (J.Y.) and independent coding of 25% of the data (A.L.B.).

During the coding process, we added codes and analyzed data across the 4 survival groups according to the illness trajectory, including initial visits (defined as the first and second visits with PC clinicians), middle visit(s) (defined as the numeric median when patients had 10 or fewer visits and median of 3 visits when the patients had more than 10 visits), and final visits (defined as the last 2 visits). We also developed a code for "clinical turning points," referring to either disease progression on radiographic studies or clinical deterioration with increased symptom burden or declining functional status, as documented in the PC visit notes. We did not review primary radiology studies but rather only coded such findings when interpreted by the PC clinician as demonstrating cancer progression. Once a clinical turning point was identified based on the PC visit notes, we subsequently analyzed medical oncologic visit notes from the dates most proximal to the PC documentation. These medical oncologic visit notes were extracted from the electronic health record and coded using a similar coding scheme developed for the PC visit notes.

RESULTS

The demographic and clinical characteristics of the patient cohort for the qualitative analysis were similar to the overall study sample. Specifically, participants had a mean (SD) age of 68.0 (8.6) years (range, 47-84 years), and most were former smokers with a baseline Eastern Cooperative Oncology Group performance status of 1 (**Table 1**).

Table 1. Baseline Characteristics

Characteristic	Value ^a
Age, mean (range), y	68 (47-84)
Female sex	12 (60)
White race	20 (100)
Married	13 (65)
ECOG performance status	
0	6 (30)
1	13 (65)
2	1 (5)
Smoking status	
Never	1 (5)
Ex-smoker	14 (70)
Current	5 (25)
Depression documented	8 (40)

Abbreviation: ECOG, Eastern Cooperative Oncology Group.

^aData are given as number (percentage) of study participants unless otherwise indicated.

ELEMENTS OF AMBULATORY PC VISITS

As listed in **Table 2**, we identified 7 major themes that featured in the clinical documentation of ambulatory PC visits: (1) relationship and rapport building, (2) addressing symptoms, (3) addressing coping, (4) establishing illness understanding, (5) discussing cancer treatments, (6) end-of-life (EOL) planning, and (7) engaging family members. Descriptions of these key elements with supporting quotations are in **Table 3**.

VARIATION OF KEY ELEMENTS OF PC OVER TIME

The PC clinicians emphasized particular elements of care at different phases of the illness trajectory. This pattern differentiated into elements that were frequent during initial or final visits vs present throughout all visits (Table 3). During the initial visits, relationship and rapport building, establishing illness understanding (ie, eliciting patient preferences for information and prognostic awareness), and discussing the effect of cancer treatments (**Figure 1A**) were prominent. Although the specific content varied over time, addressing symptoms, addressing coping, cultivating patients' illness understanding in the form of knowledge of their illness status, and involving and engaging family members were prominent throughout all the visits (Figure 1B). During the final visits, EOL planning, in particular discussion about resuscitation preference and hospice, and discussions about changes to cancer treatment plans and decision making regarding further treatment (Figure 1C) were most prominent. Notably, discussions about specific EOL planning and hospice occurred mostly in the last visits even for patients with longer survival durations and were not prominent in the early phase.

CONTENT OF PC AND ONCOLOGIC CARE VISITS AT CLINICAL TURNING POINTS

We identified 79 clinical turning points based on documentation in PC visit notes. At clinical turning points, the codes for the PC visit notes had a different profile than the

Table 2. Key Elements of Palliative Care Visits

7 Key Elements

- Relationship and rapport building
- Addressing symptoms
 - Symptom assessment and review
 - Symptom management
- Addressing coping
 - Ability to cope
 - Spirituality and faith
 - Emotional status
 - Referral to social work, psychiatry, or psychology
- Establishing illness understanding
 - Information preference
 - Prognostic awareness
 - Current illness status
- Discussing cancer treatments
 - Effect of cancer treatments
 - Decision making about cancer treatment
- End-of-life planning
 - Resuscitation preferences
 - Hospice discussion or referral
 - Practical or personal plans
 - Health care proxy
 - Engaging family members

codes for the medical oncologic visit notes. Coding frequencies for both PC and medical oncologic visit notes emphasized assessing and managing symptoms, reviewing patients' illness understanding, and discussing EOL care plans (**Figure 2**). Of note, 2 additional elements specific to the medical oncology documentation that we observed were discussing plans pertaining to ongoing cancer treatment and assessing and managing medical complications associated with radiographic progression or worsening illness. The PC visits, however, contained elements that focused more on the psychosocial sequelae of worsening disease by addressing how patients were coping with their changing health status, including also the effects on family members. Furthermore, although PC clinicians and oncologists focused on cancer treatments, the PC clinicians tended to emphasize assisting the patient with decision-making regarding therapy and discussing the effect those choices would have on them.

COMMENT

The movement toward greater integration of PC and oncologic care in the ambulatory care setting is gaining momentum. Several randomized controlled studies of PC in the ambulatory care setting have found improvements in patient-reported outcomes, quality of EOL care, and health care resource use. Although these trials may have established the efficacy of PC in ambulatory care settings, the lack of descriptive data on the content and nature of these services impedes the dissemination of early integrated PC. The components of PC provided in the more traditional inpatient setting are already well described in the literature, providing a framework for services focused on the care of hospitalized patients.³¹⁻³⁴ Our analysis sheds light on the clinical components of early integrated PC in the ambulatory care setting, which may serve as a clinically useful foun-

Table 3. Description of Key Elements of Ambulatory PC Clinic Visits Over Time

Timing and Elements of PC Visits	Description	Supporting Quotation(s)
Initial visits		
Relationship and rapport building	Engaged patients in conversations about themselves as a “whole person,” highlighting patients in a “social” context by focusing on topics that were not directly related to the cancer diagnosis or treatment. Topics included details about patients’ families, work- or job-related information, enjoyment activities, and hobbies.	<p>“They made a date out of every session, went out to dinner, the museum or a movie . . . they have a retreat in [Vermont] which they find restful . . .”</p> <p>“Married for 10 years, have known each other for 15 years. Patient has 2 children from a previous marriage with whom they are very close, also has 2 grandchildren.”</p>
Establishing illness understanding: information preference	Elicited how much and what information patients desired. Also established who patients should receive information and who should be involved in decision making.	<p>“She likes the ‘straight story’ and wants to be told everything. She is maintaining hope but reframing what she hopes for . . .”</p> <p>“. . . aware of her illness . . . says the only goal she has is to attend her daughter’s wedding and they are planning to move the date forward, so she does not want to know further information.”</p>
Establishing illness understanding: prognostic awareness	Discussed actual, specific medical prognosis primarily from patients’ perspectives, including their understanding of their prognosis and also their hopes, concerns, and fears associated with this information.	<p>“She understands that her prognosis is 6-12 weeks and has read a lot on the Internet. She would find it helpful to have as much prognostic information as possible so that she can make plans.”</p> <p>“He knows that he will not live to see his 60th birthday, but is hopeful that he’ll live until his 57th or 58th year. He is trying to process how to live with a terminal illness. He appreciates honesty and appreciates that his oncologist was able to tell him the truth about his prognosis.”</p>
Discussing cancer treatment: effect	Discussed the effect of cancer treatments on patients’ lives—how they experienced the reality of experiencing treatment: their hopes, worries, or concerns about starting or getting further treatment, whether treatment was tolerated well or poorly, any specific adverse effects, logistics of getting treatment, and how their lives changed.	<p>“She did not realize how much her body and sense of well-being would be affected by the [chemotherapy] . . . at one point she felt like she wanted to die . . .”</p> <p>“On cycle 2 [carboplatin/ paclitaxel] . . . did well since last cycle . . . anorexia, joint pain and fatigue only lasted a few days after chemo and she felt well for the rest of the time.”</p>
All visits		
Addressing symptoms	Assessed patients’ individual symptoms and also conducted a general symptoms review. Pharmacologic and nonpharmacologic interventions were documented, as well as instructions on how to implement these interventions, what to expect (eg, adverse effects of opioid analgesics), and how to deal with them.	<p>“Her back pain has improved moderately . . . since she underwent radiation therapy . . . she is still having some pain . . . increasing in her right hip and right anterior lateral lower rib . . . consider use of ibuprofen which she found very helpful in the past . . .”</p> <p>“No pain, some shortness of breath with stairs, but goes up and down regularly during the day . . . limited ability to take care of the house/clean.”</p>
Addressing coping	Discussed patients’ ability to cope and their emotions. Initial visits focused on patients’ levels of coping with their diagnosis and treatment implications and how their mood may have been affected by the diagnosis and their current physical state. The notes also referred to patients’ strategies to cope and strategies offered to enhance their ability to cope. Middle visits contained discussions regarding patients’ ongoing level of coping, including review of current concerns and fears and monitoring emotional status and responses to strategies used to improve coping. During final visits, the focus was on patients’ coping associated with deterioration in their clinical status.	<p>“She is struggling to make sense of why she has cancer. She worries that it was diagnosed “too late.” Also feeling a lot of anticipatory anxiety for the next cycle of chemotherapy.”</p> <p>“. . . copes by trying not to think about his diagnosis and focusing on the present. In the last few months has had to work to distract himself to not think about his cancer but this is getting easier for him now.”</p> <p>“We discussed his coping at great length and the disappointing news that his cancer has again spread. He seems to greatly benefit from sharing his fears about his illness and death. He is struggling to figure out when to let go.”</p>

(continued)

ation for developing these services to enhance the care of patients with advanced cancers.

The main elements of PC in our study were consistent with national guidelines for assessing and managing symptoms and psychosocial distress, providing information, and assisting with EOL care planning.^{30,35,36} More important,

we observed that the specific content of the early PC visits varied according to timing along the disease trajectory and clinical events, rather than following a generally prescribed checklist. This novel finding may serve to guide clinicians in providing early PC tailored to specific individual needs, depending on their phase of illness.

Table 3. Description of Key Elements of Ambulatory PC Clinic Visits Over Time (continued)

Timing and Elements of PC Visits	Description	Supporting Quotation(s)
All visits (continued)		
Establishing illness understanding: current illness status	Discussed patients' current illness status in terms of their specific medical situation and any updates. At initial visits, clinicians focused on topics related to diagnosis and management of cancer, including the initial treatment plan and, in some cases, the background of the diagnosis. During middle visits, discussions continued regarding current stage of illness, including scan results, ongoing treatment plans, and any relevant modifications to this. Final visit notes reflected discussions mainly pertaining to disease progression (as diagnosed by imaging studies), deterioration in physical status and any complications present, and discussions about further treatment plans (if any).	"She is eager to speak with thoracic surgery to discuss options for longer-term management of this complication, though is afraid of significant pain associated with chest tube placement." "After about a year on [gefitinib], he has been switched to a second new experimental agent but feels very confident he will get good results."
Engaging family members	Initial visits focused on families' illness understanding, including to what extent they knew about and understood the diagnosis and implications of having cancer for their family member and to their family as a unit. Family members' involvement was also described in terms of their roles as support structures for the patient. Family members' coping with the diagnosis was also documented, as well as strategies to assist with this. Also noted was how the diagnosis created concerns for patients in terms of how they thought their family members may be affected (eg, concerns about burdening their families). Middle visits focused more on patient care and family members' involvement from this aspect, including participating or assisting with medical care and other practical concerns, such as transportation and household chores, but also noted ongoing coping issues. During final visits documentation reflected family members' involvement or influence in medical care and decision making pertaining to treatment or EOL plans and support provided to families as patients approached the end of their illness trajectory.	"He and his fiancée were to get married this month but he doesn't want to burden her. He feels guilty about this." "... reviewed his disease process and his disease trajectory. Discussed his future care needs. Discussed family issues and ability to care for him at their homes. At this point, all families doing as much hands on care as they can or are allowed."
Last visits		
Discussing cancer treatment: decision making	Discussed any changes to cancer treatment plans (stop, break, or change) and the reason for decision and patients' response to this.	"... her disease had progressed through [pemetrexed]. The option of hospice was presented to her and her family and they said they needed to think about it. Their initial feeling was that they wanted to continue active anti-cancer treatments if available ... her mood has been very 'down' since then." "She states radiation has exhausted her ... she is trying this round of treatment and see how she does ... if her quality of life is negatively impacted, she will reconsider her options."
EOL planning	Discussed limitations on life-sustaining treatment, including resuscitation preference and patients' priorities and wishes at the end of life. In discussions about hospice, PC clinicians presented the option of hospice referral, including reasons for hospice. Other aspects of EOL planning, such as discussions about practical (eg, finances and nomination of health care proxy) and personal plans, only featured to a small extent.	"Focus is on maximal comfort, relief of pain and respiratory distress." "We discussed code status and she is clear that she wants to be [DNR]." "Given patient's decline in his quality of life (his current quality of life is not acceptable for him), it is certainly appropriate to arrange hospice services ... patient would like to have these services in place so that he will be able to stay at home."

Abbreviations: DNR, do not resuscitate; EOL, end of life; PC, palliative care.

Our data indicate that PC clinicians focused on establishing relationships with patients and determining their individual needs and preferences for information

early in the illness. In contrast, discussions regarding EOL care planning occurred later in the disease trajectory, often when patients experienced progression of their ill-

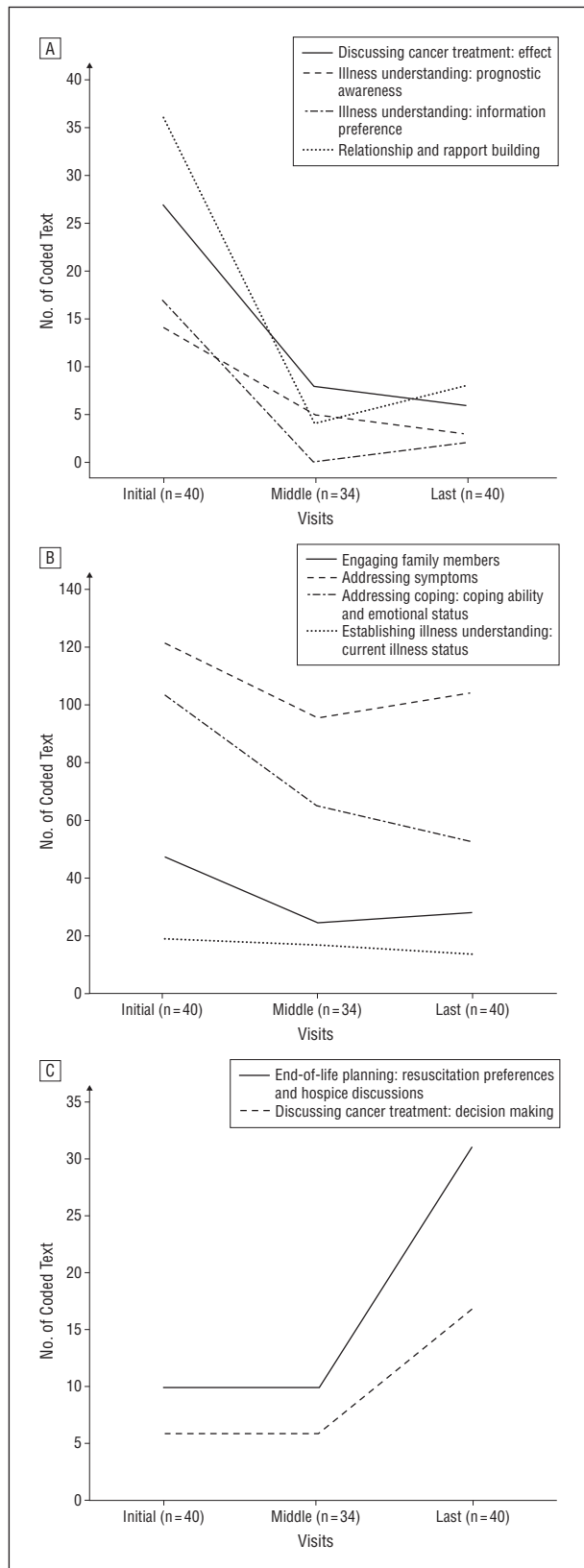


Figure 1. Elements of palliative care (PC) visits over time. A, Elements that feature highly in initial visits. B, Elements that feature throughout all visits. C, Elements that feature highly in last visits. Because of short survival times, some participants only had an initial and final visit.

ness either by symptoms or imaging procedures. Hence, early involvement of PC does not imply a presumed discussion about EOL care and hospice at initial visits. This key finding may allay patient and oncologist concerns that early PC may ask patients and families to discuss and make decisions about EOL care early in the disease process before they are ready to address such challenging topics. Rather, the building blocks of establishing rapport and ascertaining patients' preferences for receiving information seem to form the foundation of the relationship between PC clinicians and patients early in the course of illness.²⁹ Continuity of care and greater familiarity with the patient and family may thus facilitate smoother transitions at later stages of illness when more challenging discussions and decision making about cancer treatments and EOL care are necessary.³⁷⁻⁴³

We also demonstrated pertinent differences in the care provided by PC and oncologic care teams when patients experienced disease progression. Both types of clinicians assessed and managed symptoms and reviewed patients' health status. Although oncologic care visits focused on plans for further cancer treatment and the medical management of acute complications, PC documentation emphasized how patients and family members were coping with their progressive and worsening illness. Interestingly, although oncologic care documentation included specific cancer treatment plans, the PC clinicians noted how these decisions would affect patients' well-being. We hypothesize that PC clinicians may play a role in assisting patients' decisions by helping them review the risks and benefits of pursuing the next line of chemotherapy offered by the oncologist, while also helping them balance the arguments for and against continuing with active cancer treatments. Our previously published analysis found that patients randomized to early, integrated PC were less likely to receive chemotherapy near the EOL compared with those assigned to standard oncologic care.¹⁴

Data suggesting that oncologic care and PC play distinct yet complementary roles in the care of patients with advanced cancers support the national recommendations for early integrated PC in this patient population.^{24,25} Cancer treatment has become more complex with the discovery of genotypic cancer subtypes and the development of targeted therapies. Specifically, at an academic medical center where our study was performed, many patients are enrolled in intensive clinical trials that require considerable time and attention from the oncologist. The results of this qualitative analysis highlight that the expertise from a collaborative and concurrent clinical team, with the necessary skills for managing the psychological, social, and emotional aspects of illness, both enables and provides adequate time for the oncologist to focus on cancer therapy and the medical management of the disease. These findings may have important implications for oncology training as integrated PC and oncologic care becomes a more widely accepted and available practice model.

Alternatively, in care settings with limited access to PC services, another model of integrated care may involve the provision of comprehensive care (including elements of PC that were identified in this study, such as

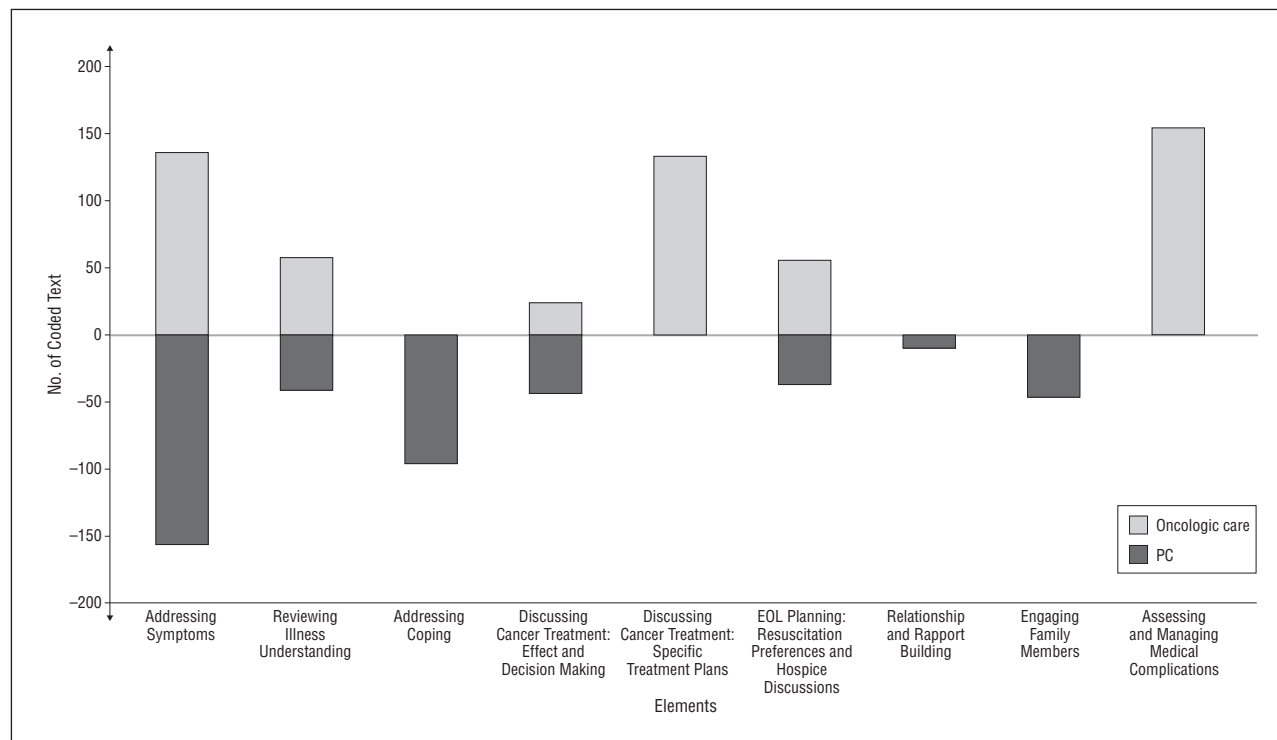


Figure 2. Elements of palliative care (PC) vs oncologic care visits at clinical turning points. EOL indicates end of life.

addressing symptoms, providing assistance with coping, and engaging family members) by the primary oncology team with consultation from PC clinicians in specific circumstances, such as radiographic or symptomatic progression.²⁶ This approach would be similar to the traditional PC model in which PC services are consulted to assist only with the care of complex patients in the ambulatory care setting, which may be more feasible for new PC programs in the community.^{24,44}

Several limitations of this analysis warrant consideration. This study represents a secondary, exploratory analysis to identify the key elements of early integrated PC. Thus, the analysis is significantly limited by the nature of the retrospective data collection and sole reliance on individual PC clinicians' documentation of the encounters. Salient elements of clinical encounters and nonverbal communication that occur between clinicians and patients will not be captured in the written documentation of a clinic note. The written visit note is undoubtedly influenced by the PC clinicians' perceptions of the most important and memorable components of the interaction, which may not entirely reflect the actual encounter with the patient or oncologist. Future research should be conducted with observational methods (eg, recording of clinical encounters using audiotapes or videotapes), expert panels, and quantitative methods to confirm our findings. Despite our failure to record visits prospectively to overcome these limitations, documentation of clinical encounters was reliably available in the electronic health record for every patient visit, and the iterative process we followed confirmed that observations from our sample of clinical notes were representative. In addition, the results should not serve as the definitive approach for outpatient PC. The analysis was based

on a small sample of patients cared for by a single institution's established ambulatory PC team consisting of clinicians who likely provide a similar model of care that may not generalize to the PC practice paradigms in other care settings. Finally, our original study and this analysis consisted almost exclusively of white participants; further work is necessary to ascertain how cultural and racial factors and beliefs influence the nature of PC interactions.

Recent randomized studies of PC in the ambulatory care setting have highlighted the importance of PC in the care and management of patients with advanced cancers. The American Society of Clinical Oncology recently published a provisional statement suggesting that all patients with metastatic cancer or a high symptom burden should be offered PC early in the disease process.²⁵ Currently, clinicians require further knowledge and experience to provide care in this context. Although our data detail a preliminary framework of care provided in our randomized trial, the approach may not be the only or optimal way of providing early integrated PC. Further research is needed not only to determine the generalizability of the benefits of early integrated PC but also to identify the components of the intervention that might be most effective.

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