

Supportive Oncology Care at Home Intervention for Patients With Pancreatic Cancer

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QUESTION ASKED: What is the feasibility of delivering a Supportive Oncology Care at Home intervention among patients with pancreatic cancer?

SUMMARY ANSWER: This pilot study demonstrated the feasibility and acceptability of a Supportive Oncology Care at Home intervention. We found high rates of study enrollment, completion of daily assessments, and acceptability reports.

WHAT WE DID: We prospectively enrolled patients with pancreatic cancer from a parent trial of neoadjuvant fluorouracil, leucovorin, oxaliplatin, and irinotecan. The Supportive Oncology Care at Home intervention entailed (1) remote monitoring of patient-reported symptoms, vital signs, and body weight; (2) a hospital-at-home care model; and (3) structured communication with the oncology team. We defined the intervention as feasible if $\geq 60\%$ of patients enrolled in the study and $\geq 60\%$ completed the daily assessments within the first 2 weeks of enrollment.

WHAT WE FOUND: A high proportion of patients enrolled in the study and completed all requested

assessments, with the majority of patients, caregivers, and clinicians finding the intervention acceptable and helpful. In addition, we found high rates of health care use and treatment delays for patients in this study, with lower rates for patients receiving the Supportive Oncology Care at Home intervention than those not receiving the intervention who were in the same parent trial (see Table).

BIAS, CONFOUNDING FACTOR(S): We conducted this work at a single academic institution with limited sociodemographic diversity, which limits the generalizability of our results, and future work will need to further investigate the impact of Supportive Oncology Care at Home in populations with more sociodemographic and geographic diversity.

REAL-LIFE IMPLICATIONS: Findings demonstrate the feasibility and acceptability of a Supportive Oncology Care at Home intervention and support the need for future work to investigate the efficacy of this intervention for decreasing health care use and improving patient outcomes.

ASSOCIATED CONTENT

Protocol

Author affiliations and disclosures are available with the complete article online.

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abstract

PURPOSE We sought to determine the feasibility of delivering a Supportive Oncology Care at Home intervention among patients with pancreatic cancer.

METHODS We prospectively enrolled patients with pancreatic cancer from a parent trial of neoadjuvant fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX). The intervention entailed (1) remote monitoring of patient-reported symptoms, vital signs, and body weight; (2) a hospital-at-home care model; and (3) structured communication with the oncology team. We defined the intervention as feasible if $\geq 60\%$ of patients enrolled in the study and $\geq 60\%$ completed the daily assessments within the first 2-weeks of enrollment. We determined rates of treatment delays, urgent clinic visits, emergency department visits, and hospitalizations among those who did ($n = 20$) and did not ($n = 24$) receive Supportive Oncology Care at Home from the parent trial.

RESULTS From January 2019 to September 2020, we enrolled 80.8% (21/26) of potentially eligible patients. One patient became ineligible following consent because of moving out of state, resulting in 20 participants (median age = 67 years). In the first 2 weeks of enrollment, 65.0% of participants completed all daily assessments. Overall, patients reported 96.1% of daily symptoms, 96.1% of daily vital signs, and 92.5% of weekly body weights. Patients receiving the intervention had lower rates of treatment delays (55.0% v 75.0%), urgent clinic visits (10.0% v 25.0%), and emergency department visits/hospitalizations (45.0% v 62.5%) compared with those not receiving the intervention from the same parent trial.

CONCLUSION Findings demonstrate the feasibility and acceptability of a Supportive Oncology Care at Home intervention. Future work will investigate the efficacy of this intervention for decreasing health care use and improving patient outcomes.

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INTRODUCTION

Increasingly, patients with nonmetastatic pancreatic cancer receive neoadjuvant treatment with the goal of improving resectability and enhancing survival.¹⁻⁵ Neoadjuvant treatment often entails the use of multiagent chemotherapy, which can result in patients experiencing numerous side effects, including nausea, diarrhea, fatigue, fever, neuropathy, and loss of appetite.^{1,6,7} Frequently, patients require hospital admissions to help address uncontrolled cancer symptoms and treatment side effects.^{1,8-10} Specifically, data suggest that approximately one third of patients with pancreatic cancer receiving neoadjuvant fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) require hospital admissions while receiving this

treatment.¹ Therefore, interventions are needed to address symptoms and side effects of neoadjuvant treatment for pancreatic cancer to enhance patient outcomes and prevent excessive health care utilization.

Previous work demonstrates that symptom monitoring interventions can enhance quality of life (QOL), prevent hospitalizations, and increase survival in oncology settings.¹¹⁻¹³ Additionally, studies have shown encouraging results for hospital-at-home interventions, mainly in general medical populations, as a strategy for treating patients in need of inpatient acute care in their homes.¹⁴⁻¹⁶ Hospital-at-home entails the provision of comprehensive medical care, such as vital sign monitoring, clinician home visits, and intravenous therapies, to acutely ill patients in their home.¹⁷⁻²⁰ The

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limited data for hospital-at-home in oncology to date has also included an acute care model,²¹ yet patients with cancer represent a population with persistent supportive care needs meriting longitudinal care. Interventions using symptom monitoring with hospital-at-home care longitudinally hold great promise for improving the overall QOL and care experience of patients with cancer receiving treatment with significant risk of side effects and complications.

We conducted a pilot study of an intervention that entails both symptom monitoring and a longitudinal hospital-at-home care model, called Supportive Oncology Care at Home. We sought to evaluate the feasibility and acceptability of Supportive Oncology Care at Home for patients with pancreatic cancer receiving neoadjuvant FOLFIRINOX. We hypothesized that the majority of patients would enroll in the study, complete their daily assessments, and find the intervention acceptable. Findings from this study will inform future work by allowing us to understand the feasibility and acceptability of a novel model of care seeking to help optimize the care of patients with cancer, enhance their clinical outcomes, and reduce their use of health care services.

METHODS

Study Design and Participants

From January 2019 to September 2020, we enrolled patients at Massachusetts General Hospital (MGH) or Newton-Wellesley Hospital in a single-arm pilot study (ClinicalTrials.gov identifier: [NCT03798769](https://clinicaltrials.gov/ct2/show/study/NCT03798769)). The Dana-Farber/Harvard Cancer Center institutional review board approved the study. Eligible patients were age 18+ years, planning to receive care at MGH or Newton-Wellesley Hospital, residing within 50 miles of MGH, and within 2 weeks of starting treatment on a parent trial that entailed eight cycles of neoadjuvant FOLFIRINOX (ClinicalTrials.gov identifier: [NCT03563248](https://clinicaltrials.gov/ct2/show/study/NCT03563248)). We also enrolled patients' caregivers (family/friend) and oncology clinicians to assess their perceptions of intervention acceptability.

The Supportive Oncology Care at Home Intervention

We developed Supportive Oncology Care at Home with input from oncology and palliative care clinicians. A dedicated, oncology-trained hospital-at-home care team (physicians, advance practice clinicians, and nurses who received study-specific training that entailed didactics and case-based learning [eg, study overview and conduct, pancreatic cancer, chemotherapy, example cases, and caring for patients with cancer]) delivered the intervention in collaboration with the primary oncology team and was available 24 hours a day to provide care, as needed. To initiate care, the hospital-at-home team met with patients in their home to review the services included, perform a physical examination, assess home safety, and educate the patient and caregiver(s) on the use of technology provided (eg, tablet computer, wireless phone, and vital sign

monitoring equipment for patients to self-report their symptoms, vital signs, and body weight via a dedicated online technology platform that supports virtual care, including video visits and patient data transmission). The hospital-at-home care team provided (1) monitoring of patient-reported symptoms, vital signs, and body weight with detailed algorithms for when the team should call the patient to check-in and/or deliver home-based care; (2) clinician home visits for intravenous hydration and medical assessment/management as needed; and (3) regular communication with oncology clinicians to ensure continuity of care. The hospital-at-home team met with a board-certified medical oncologist daily to discuss all patients receiving their care.

Study Measures

Sociodemographic and clinical factors. We obtained information about patients' sociodemographics and clinical factors, including health care utilization (eg, urgent clinic visits, emergency department [ED] visits, and hospitalizations) and cancer treatment-related outcomes (eg, treatment delays and cycles of FOLFIRINOX completed).

Participant-reported outcomes. To monitor patients' symptoms daily, we asked them to complete electronically the revised Edmonton Symptom Assessment System assessing pain, fatigue, drowsiness, nausea, appetite, dyspnea, depression, anxiety, and well-being over the previous 24 hours.^{22,23} We obtained acceptability feedback from patients, caregivers, and oncology clinicians after each patient completed the intervention. Specifically, we asked participants about their perceptions of the helpfulness, convenience, and frequency of the various aspects of the Supportive Oncology Care at Home intervention.

Statistical Analysis

The primary outcome of the study was feasibility. The sample size for the study was based on the feasibility of completing the project during the planned time frame and attaining our feasibility outcome. We defined the intervention as feasible if $\geq 60\%$ of patients enrolled in the study and $\geq 60\%$ completed the daily assessments within the first 2 weeks of enrollment. We explored the use of urgent clinic visits, ED visits, hospitalizations, treatment delays, and cycles of FOLFIRINOX completed among those who received Supportive Oncology Care at Home ($n = 20$) and a comparison group from the parent trial who did not receive the intervention (began parent trial before opening Supportive Oncology Care at Home study) yet resided within 50 miles of MGH ($n = 24$).

RESULTS

Feasibility

We enrolled 80.8% (21/26) of patients approached (Fig 1). One patient became ineligible following consent because of moving out of state, resulting in 20 participants. The sample

median age was 67.29 years, and most were female (60.0%; Table 1). In the first 2 weeks of enrollment, 65.0% (13/20) of participants completed all daily assessments. Overall, in the first 2 weeks of enrollment, participants reported 96.1% of daily symptoms, 96.1% of daily vital signs, and 92.5% of weekly body weights. Each participant generated an average of 2.22 phone calls (range, 0.62-3.77 phone calls), 2.96 e-mails (range, 1.50-5.88 e-mails), and 0.15 home visits (range, 0-0.69 home visits) per week (generally to provide hydration at home to address patients' symptoms). The daily discussions between the hospital-at-home team and medical oncologist lasted an average of 5.08 minutes each day.

Acceptability

Patients, caregivers, and clinicians found the intervention acceptable. More than 90% of patients, caregivers, and clinicians reported the study as helpful, with the majority reporting the helpfulness of having symptoms, vital signs, and body weight monitored. Similarly, the majority of patients, caregivers, and clinicians reported that having symptoms, vital signs, and body weight monitored was convenient. The majority of patients, caregivers, and clinicians also reported that the frequency of the reporting of symptoms, vital signs, and body weight was just right.

Clinical Outcomes

Patients receiving Supportive Oncology Care at Home had lower rates of urgent clinic visits (10.0% v 25.0%), ED visits (40.0% v 58.3%), and hospitalizations (40.0% v 50.0%) compared with those not receiving the intervention who were in the same parent trial (Table 2). Similarly, patients receiving the intervention had lower rates of needing an

TABLE 1. Baseline Characteristics

Characteristic	n = 20
Age, years, median (range)	67.29 (55.84-77.11)
Sex, No. (%)	
Female	12 (60.0)
Male	8 (40.0)
Race, No. (%)	
White	19 (95.0)
Native Hawaiian or Pacific Islander	1 (5.0)
Asian	0 (0.0)
Black	0 (0.0)
Declined to report	0 (0.0)
Relationship status, No. (%)	
Married	18 (90.0)
Widowed	2 (10.0)
Divorced	0 (0.0)
Separated	0 (0.0)
Never married	0 (0.0)
Work status, No. (%)	
Retired	12 (60.0)
Full time	5 (25.0)
Part time	2 (10.0)
Disability	1 (5.0)
ECOG PS, No. (%)	
0	15 (75.0)
1	5 (25.0)

Abbreviation: ECOG PS, Eastern Cooperative Oncology Group performance status.

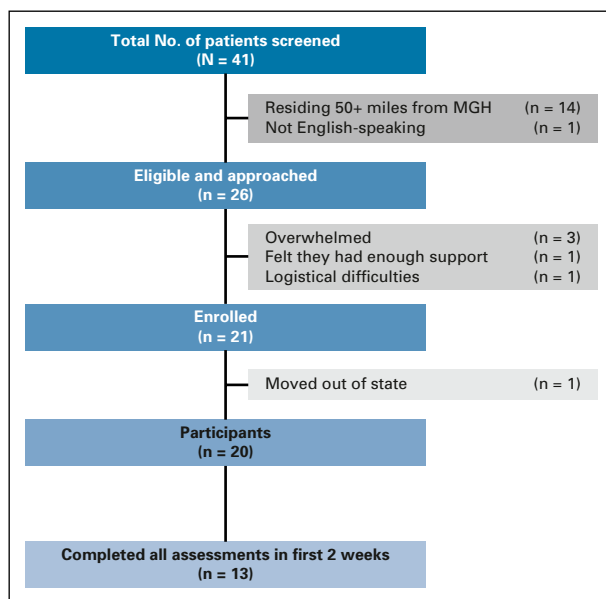


FIG 1. Flow diagram. MGH, Massachusetts General Hospital.

ED visit or hospitalization (45.0% v 62.5%) and a lower percentage of days spent in urgent clinic, ED, or hospital (2.7% v 7.8%). Intervention patients had lower rates of treatment delays (55.0% v 75.0%) and a greater number of planned FOLFIRINOX cycles completed (mean = 7.10 v 6.79) versus those not receiving the intervention.

DISCUSSION

This pilot study demonstrated the feasibility and acceptability of a Supportive Oncology Care at Home intervention, with high rates of study enrollment, completion of daily assessments, and acceptability reports. We enrolled more than 80% of eligible patients, and the majority of participants completed their daily assessments. In addition, patients, caregivers, and clinicians found the intervention highly acceptable on the basis of their perceptions of the helpfulness, convenience, and frequency of the various intervention components. All patients in this study were receiving FOLFIRINOX for nonmetastatic pancreatic cancer, and we found high rates of health care utilization and treatment delays in this population. Collectively, the

TABLE 2. Clinical Outcomes

Outcome	Nonintervention (N = 24)	Intervention (N = 20)
Urgent clinic visits		
Any, No. (%)	6.00 (25.00)	2.00 (10.00)
No. per patient, mean (SD)	0.38 (0.77)	0.15 (0.49)
ED visits		
Any, No. (%)	14.00 (58.30)	8.00 (40.00)
No. per patient, mean (SD)	0.79 (1.06)	0.60 (0.88)
Hospitalizations		
Any, No. (%)	12.00 (50.00)	8.00 (40.00)
No. per patient, mean (SD)	0.88 (1.26)	0.65 (0.99)
ED visit or hospitalization		
Any, No. (%)	15.00 (62.50)	9.00 (45.00)
No. per patient, mean (SD)	1.67 (2.24)	1.25 (1.83)
Percentage of days in hospital/ED		
Mean percent (SD)	7.50 (15.20)	2.60 (4.70)
Percentage of days in hospital/ED/ urgent care		
Mean percent (SD)	7.80 (15.20)	2.70 (4.90)
Treatment delays		
Any, No. (%)	18.00 (75.00)	11.00 (55.00)
No. per patient, mean (SD)	0.92 (0.72)	1.00 (1.03)
FOLFIRINOX cycles		
Completed all planned cycles, No. (%)	19.00 (79.20)	16.00 (80.00)
No. per patient, mean (SD)	6.79 (2.65)	7.10 (1.97)

Abbreviations: ED, emergency department; FOLFIRINOX, fluorouracil, leucovorin, oxaliplatin, and irinotecan; SD, standard deviation.

findings from this work support the need for future efforts to investigate the efficacy of this intervention for decreasing health care use and improving clinical outcomes for patients with pancreatic cancer.

We investigated a novel Supportive Oncology Care at Home intervention, which delivers longitudinal monitoring of patient-reported outcomes coupled with hospital-at-home care. Despite the intensive monitoring required, most patients agreed to enroll in the study and completed their daily assessments. Moreover, we received overwhelmingly positive feedback from patients, caregivers, and clinicians regarding their perceptions of the acceptability of Supportive Oncology Care at Home. Thus, our findings highlight the feasibility of delivering Supportive Oncology Care at Home, an intervention integrating remote monitoring of patient-reported outcomes with longitudinal hospital-at-home care, which holds tremendous potential for enhancing care delivery and outcomes throughout the illness course for patients with cancer.

Importantly, our work highlights the need for interventions to improve clinical outcomes for patients receiving

intensive cancer treatment, such as the population in our study with pancreatic cancer receiving neoadjuvant FOLFIRINOX.^{1,6,8,9} We found that a substantial proportion of patients in our cohort experienced urgent clinic visits, ED visits, hospitalizations, and treatment delays. With the current study design and limited sample size, we cannot comment on the efficacy of the Supportive Oncology Care at Home intervention, but findings from this work support the need to conduct randomized trials in the future to definitively test the impact of this intervention for decreasing health care use and improving patient outcomes. Furthermore, we focused on a specific population of patients with pancreatic cancer receiving neoadjuvant FOLFIRINOX, and thus additional work will need to explore the utility of Supportive Oncology Care at Home in other populations. This model of care holds great promise for helping patients with other types of cancer (eg, head and neck cancer), other treatment paradigms (eg, end-of-life care), and in other geographic areas (eg, rural communities). Therefore, by demonstrating the feasibility and acceptability of a novel Supportive Oncology Care at Home intervention and showing the immense need for this type of intervention for patients with cancer, findings from this study should encourage ongoing efforts to build upon our work and continue striving to enhance the care of patients with cancer.

This study has several important limitations. First, we conducted this work at a single academic institution with limited sociodemographic diversity, which limits the generalizability of our results. Importantly, the lack of diversity limits our ability to comment on the feasibility of this type of care model for patients with different sociodemographic characteristics, and although prior work involving hospital-at-home care has included more diverse samples than our current study,^{14,21} future work will need to investigate the feasibility and efficacy of Supportive Oncology Care at Home in populations with more sociodemographic and geographic diversity. Second, we designed the study to determine feasibility and acceptability, and thus, we have a limited sample size that precludes our ability to test for intervention efficacy. Randomized controlled trials will be needed to demonstrate the efficacy of Supportive Oncology Care at Home for reducing health care utilization, improving clinical outcomes, and enhancing QOL. Finally, we lack data on other potentially important factors, such as patients' educational and economic levels, use of other support services (eg, physical therapy, social work, etc), caregiver support/burden, and health care costs, which we will investigate in future iterations of this work.

In conclusion, in this pilot study, we demonstrated the feasibility and acceptability of Supportive Oncology Care at Home for patients with pancreatic cancer receiving neoadjuvant treatment. A high proportion of patients enrolled in the study and completed all assessments, as requested. Additionally, the majority of patients, caregivers, and

clinicians found the intervention acceptable and helpful. Notably, we found high rates of health care use and treatment delays for patients in this study, albeit lower rates for patients receiving the Supportive Oncology Care at Home intervention than those not receiving the intervention

who were in the same parent trial. Collectively, our findings underscore the importance of efforts like Supportive Oncology Care at Home to more efficiently and effectively monitor and potentially address the care needs of patients with cancer.

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Final approval of manuscript: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Supportive Oncology Care at Home Intervention for Patients With Pancreatic Cancer**

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Leadership: Medically Home

Stock and Other Ownership Interests: Medically Home

Alec C. Kimmelman

Stock and Other Ownership Interests: Vescor Therapeutics, Rafael Pharmaceuticals

Consulting or Advisory Role: Vescor Therapeutics, AbbVie, Deciphera

Patents, Royalties, Other Intellectual Property: Inventor on patents pertaining to Kras-regulated metabolic pathways, redox control pathways in pancreatic

cancer, targeting GOT1 as a therapeutic approach and the autophagic control of iron metabolism, and targeting alanine transport in pancreatic cancer

David Ting

Leadership: PanTher Therapeutics

Stock and Other Ownership Interests: PanTher Therapeutics, ROME Therapeutics, TellBio

Consulting or Advisory Role: ROME Therapeutics, Millipore, Foundation Medicine, Pfizer, NanoString Technologies, Tekla Capital Management, Ikena Oncology

Research Funding: ACD Biotechnie (Inst), PureTech (Inst), Ribon Therapeutics (Inst)

Patents, Royalties, Other Intellectual Property: Patent licensed to Rome Therapeutics by my Institution (Inst); patent license to PanTher Therapeutics (Inst), patent license to TellBio Inc (Inst)

Theodore S. Hong

Stock and Other Ownership Interests: PanTher Therapeutics

Consulting or Advisory Role: Merck, Synthetic Biologics, Novocure, Syndax, Boston Scientific

Research Funding: Taiho Pharmaceutical (Inst), AstraZeneca (Inst), IntraOp (Inst), Tesaro (Inst), Bristol Myers Squibb (Inst), Ipsen (Inst)

Joseph A. Greer

Research Funding: NCCN/AstraZeneca (Inst), Gaido Health/BCG Digital Ventures (Inst), Blue Note Therapeutics (Inst)

Patents, Royalties, Other Intellectual Property: Royalties from Springer Publishing Company for the edited book, *The Massachusetts General Hospital Handbook of Behavioral Medicine*.

David P. Ryan

Stock and Other Ownership Interests: MPM Capital, Acworth Pharmaceuticals, Thrive Earlier Detection Corp, Exact Sciences

Honoraria: UpToDate, Research to Practice

Consulting or Advisory Role: MPM Capital, Oncorus, Gritstone Bio, Maverick Therapeutics, TCR2 Therapeutics, Twentyeight-Seven Therapeutics, Innocrin Pharma

Research Funding: Stand up to Cancer (Inst)

Patents, Royalties, Other Intellectual Property: McGraw Hill Chapter Royalties, Johns Hopkins University Press

Expert Testimony: Boehringer Ingelheim

Other Relationship: TCR2 Therapeutics

Areej El-Jawahri

Consulting or Advisory Role: AIM Specialty Health, Novartis, GlaxoSmithKline, Incyte

No other potential conflicts of interest were reported.