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Who Needs What? Perceptions of Patients and Caregivers in Oncology Phase 1 Trials

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Abstract

Background: The study design and nature of oncology phase 1 clinical trials create a uniquely vulnerable patient population yet little research has been conducted to identify the added burden these trials create for both cancer patients and their caregiver(s). **Objective:** Examining the perceptions and needs of patients and their caregivers participating in phase 1 oncology clinical trials, the investigators tested the hypothesis that the caregiver will exhibit a higher level of burden and/or distress than the patient. **Method:** A mixed-methods exploratory process utilizing patient and caregiver interviews and quality-of-life questionnaires was used to assess the psychosocial burdens associated with oncology clinical trial participation. A qualitative and quantitative analysis of the responses were 8 performed. **Result:** Both patients and caregivers reported similar themes identifying the burdens and benefits related to phase 1 clinical trial participation. However, the caregivers' expressed burden exceeded that of the patients' validating the study's hypothesis. **Conclusion:** The need for ongoing additional support services for not only the patient but also the caregiver was identified.

Keywords

oncology, patient perspectives/narratives, clinician–patient relationship, caregiving, cancer, patient satisfaction, service excellence, phase 1 clinical trial

Introduction

Phase 1 trials involve newly developed medications or medication combinations that are in the initial stages of being tested in humans. The purposes of these clinical trials include establishing the maximum tolerated dose for the medication(s) and determining the potential toxicities (1). The primary goal of these trials is not measuring the effectiveness of the intervention. They enroll small groups of patients who have advanced cancer for which there is no longer a standard-of-care treatment option available or patients with a type of cancer for which no standard of care treatment exists. Those who enroll in phase 1 trials most often are in the terminal stages of their disease with an expected survival of approximately 5 to 9 months (2). Phase 1 studies often include extended periods of testing over multiple hours and/or consecutive days, numerous laboratory tests and other medical procedures, specimen collections, and may require in-house admissions. There can be treatment delays related to entering the clinical trial such as waiting for treatment cohorts to become available. This can escalate patient and family anxiety as they worry that the patient is going for extended periods of time without treatment to control the cancer's progression. These factors, coupled with the uncertainty of receiving a medical therapy with unknown benefit and toxicities creates a uniquely vulnerable patient population who require additional support and resources from their health-care providers.

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The possibility of not receiving a clinical benefit from the experimental agent(s) is discussed during the clinical trial presentation process and delineated in the clinical trial's informed consent. Despite these alerts, patients will often enroll in phase 1 clinical trials with the expressed hope and/or expectation that the study medication(s) will reduce the size of their tumor, improve symptoms of their cancer, and that they will live longer (3,4). Of note, the historical clinical response rate in phase 1 trials ranged between 4% and 6% with a more recent estimate of 19.8% (5–7).

Researchers examined patients' perceptions of therapeutic benefit in phase 1 clinical trials using an assortment of questionnaires and structured interviews. Perceived benefits included the possibility of controlling or curing their cancer (2,3,7,8–15). Secondary to the potential oncologic benefits, limited research has also been conducted regarding the psychological benefits. These benefits included closer health surveillance; frequent informal interactions with clinical trial staff members; communication that included humor, empathy, and listening; creation of the sense of hope; and providing patients a sense of control over their illness (2,7,8,16,17).

Limited research has been conducted to identify the burden and distress placed upon patients and their caregivers as a result of clinical trial participation. The demands of the additional testing, hospital admissions, problems with parking, long commutes to the medical appointments, completing quality-of-life (QOL) questionnaires, adjusting to changing expectations, adjusting to dealing with the toxic side effects of the medication(s), and coping with the uncertainty of the outcome were all identified as unanticipated burdens at the onset of the clinical trial. These issues were identified as QOL factors that need to be recognized by those involved with the patient and caregiver(s) (16,18,19).

The National Comprehensive Cancer Network, defines distress as "a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment . . . " (20). The incidence of distress ranges up to more than 50% with a possible misclassification rate (false positive/false negative) resulting in a significant number of patients with distress remaining undiagnosed (21–23). Failure to recognize patients in distress and provide adequate intervention can lead to impaired decision-making skills, impaired treatment outcomes, decreased QOL, increased incidences of depression and/or anxiety, increased isolation, increased health-care costs, and spiritual crisis (20,23).

The purpose of this mixed methods study was to explore the experience of cancer patients and their caregivers who participated in a solid tumor oncology phase 1 clinical trial in an academic medical center. The researchers assessed the physical impact, emotional/psychosocial needs, and patient/caregiver perceived needs to improve the clinical experience.

Methods

Recruitment

Patients with a solid tumor and their primary caregiver (spouse/partner, child, sibling, or other designated family member/friend) who enrolled in an oncology phase 1 clinical trial between April 2015 and February 2017 were eligible to participate in this study. The primary caregiver was defined as the person who was routinely responsible for assisting the patient when necessary and accompanied the patient to his/her medical appointments. Both the patient and the caregiver were required to be $\geq$age 18 and consent to be interviewed in order to participate. Table 1 identifies the participants' demographics. A total of 45 patient–caregiver dyads were invited to participate. Forty-one dyads agreed to a formal informed consent presentation; 26 patient–caregiver dyads were recruited.

The primary barrier to enrollment was the patient not meeting the oncology treatment trial eligibility criteria. Other barriers included a sudden decline in the patient's or caregiver's health, the patient did not have an identified primary caregiver, and the patient or caregiver declined to participate. Of those recruited, 7 dyads were unable to complete the second interview due to a decline in the patient's health. Twelve dyads were interviewed at both prespecified time points.

Data Collection

This study utilized a mixed methods design using an exploratory sequential approach to test the hypothesis that the caregiver will exhibit a higher level of burden and/or distress than the patient. The 19 dyads which completed at least one interview and associated QOL tools were included in the final analysis.

Interviews using preestablished open-ended questions were utilized to obtain qualitative data. These interviews were unobtrusively tape recorded, analyzed, coded, and categorized by the research team for emergent themes, similarities, and perceptions. Patients and their caregivers were interviewed independently at the start of the phase 1 trial and at the end of cycle 1 or the end of their therapy. There was no defined length of time for the interview to allow the participants latitude to express their thoughts.

Quality-of-life tools were utilized to obtain quantitative data regarding the patients' and caregivers' perceptions of well-being and burden assessment. The assessment tools were chosen due to similar data points and Likert scales for both patients and caregivers. This provided the opportunity for comparative data analysis utilizing percentages and frequencies to compare and contrast relevant themes, patterns, observations, and perceptions.

Each patient was assessed utilizing:

- the Patient Health Questionnaire—a 9 (PHQ-9)-question questionnaire designed to screen, diagnose, monitor, and measure the severity of depression and

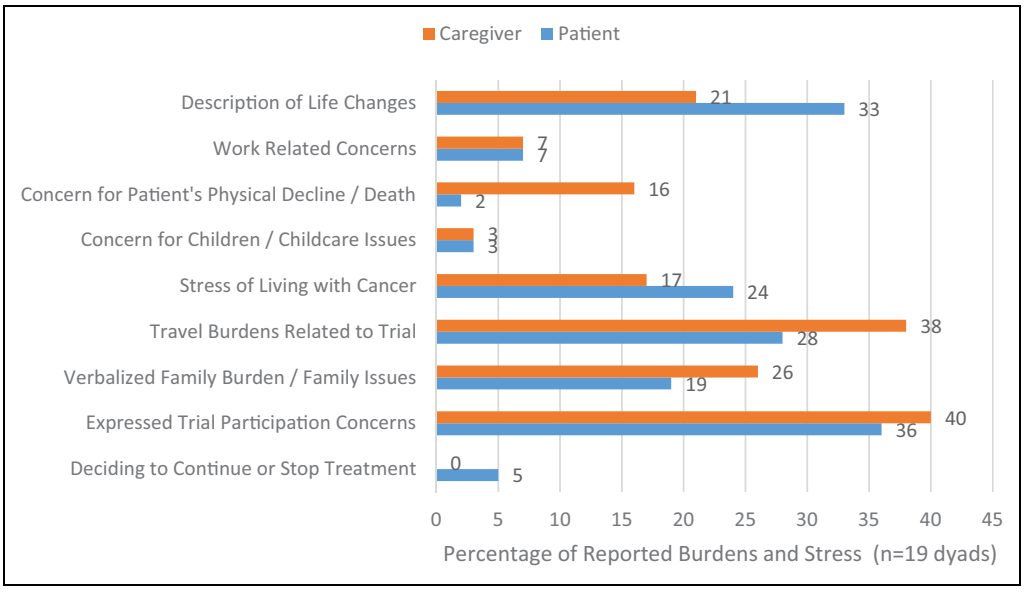

Figure 1. Burden and concerns reported by patients and caregivers (per interviews).

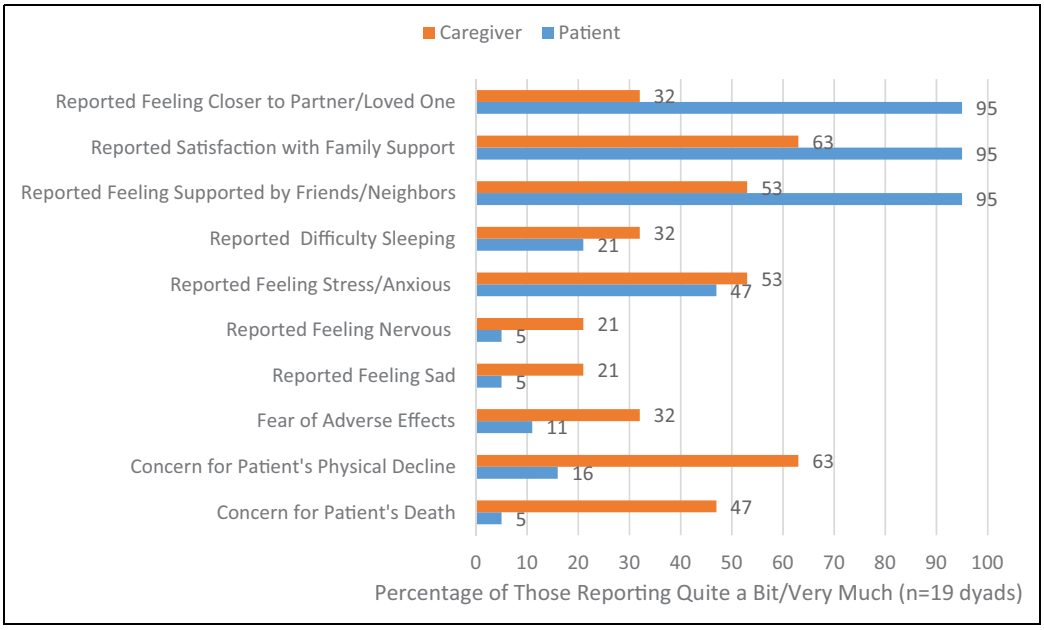

Figure 2. Burden and concerns reported by patients and caregivers (per quality-of-life [QOL] surveys).

the degree to which the depressive symptoms are interfering with a person's ability to conduct activities of daily living (24);

- the Generalized Anxiety Disorder Assessment 7 (GAD-7)—a 7-question questionnaire designed to screen anxiety disorders, panic disorders, social anxiety disorders, and posttraumatic stress disorders (25); and
- the Functional Assessment of Cancer Therapy - general (FACT-G) assessment scales—a 27-question questionnaire, designed to assess physical, social and family, emotional, and functional well-being (26).

Each caregiver was assessed utilizing the Caregiver Quality of Life Index—cancer questionnaire. This 35-question questionnaire assesses the impact of caring for someone with cancer on the caregiver's well-being. The categories assessed include physical, functional, emotional, social, family, spiritual, and financial well-being (27,28).

Results

Both the patients and their caregivers supported the physical and psychological responses as well as the level of burden previously reflected in the literature in relationship to phase 1

trial participation. As Figures 1 and 2 demonstrate, patients and caregivers disclosed the life changes involved when living with cancer and participating in a phase 1 clinical trial. The participants talked about life being turned "upside down" and the need to find "a new normal."

> I'm not sure they know my needs. They always focus on her (the patient). Mostly I am just there – you're a body sitting in a chair. That's what I feel like. (Note 1: Caregiver 11 Initial Interview)

Despite including the patient's caregiver in all of aspects of the patient's clinic visits, caregivers reported feeling they required more support than offered. They voiced the need for the caregiver to be offered the same type of reclining chairs in the treatment rooms, to have full access to support services such as free massages, and open discussions with the medical team. Caregivers recognized the ways in which their daily routines were altered, the financial strain cancer care placed upon their family budgets, the ways in which priorities had to change, and the shift in focus to a day-to-day living. In both the personal interviews and QOL tools, caregivers reported feeling more overwhelmed, sad, fearful, and nervous than patients. Caregivers also reported more concerns that other family members and friends were not offering as much support as they would prefer.

> My needs are the same as hers (the patient) except the treatments. (Note 2: Caregiver 4 Initial Interview)

Despite the perception that the needs of the patient are the same as the needs of the caregiver, caregivers reported more worry, expressed a higher concern regarding the patient's deteriorating physical status, and expressed more fear over the patient's impending death. Compared to the patients, the caregivers reported more difficulties in sleeping and a higher concern for the adverse effects the patient was experiencing as a result of the clinical trial's therapy. Both patients and caregivers commented on the benefit of being able to openly discuss their feelings during the interview portion of this study. Yet fewer spoke about the concerns for the patient's physical decline compared to the concerns reported in the QOL tools.

> Sometimes there's been more care than I like, but hey, more care is better than no care. (Note 3: Patient 22 Initial Interview)
>
> I'm sort of up to my neck in the swamp. So once you are there, there's no reason to complain about it (Note 4: Patient 24 Second Interview)

Comments and concerns regarding what it meant to participate in a phase 1 oncology clinical trial were expressed by approximately half of the participants. They discussed their concerns about the uncertainty of being eligible for the trial, the demands specifically related to the trial, for example, the frequency of visits and the "intimidating" number of pills they were required to take, worrying about the efficacy, and whether the cancer was still growing and spreading. They described the stress related to worrying about computed tomography scan results as they approached each reassessment. One patient and his caregiver each described the "roller coaster ride" of ups and downs experienced while participating in the phase 1 trial. The burden of travel and the high cost for lodging and meals to have tests and treatments done in one central location impacted over a quarter of the participants.

> I'm happy right here (at this facility). I don't need anything more. You only have one shot at this . . . This is serious stuff that requires serious people. (Note 5: Patient 17 Initial Interview)
>
> I love our doctor and nurse practitioner. They ask and care about my family. They know me. (Note 6: Patient 13 Initial Interview)
>
> Our nurse was wonderful and developed good rapport. A relationship with one nurse is important. (Note 7: Patient 2 Initial and Second Interview; Caregiver 2 Second Interview)
>
> Nurses hold patient's hands. (Note 8: Caregiver 13 Initial Interview)

Eighty-one percent of participants talked about the positive experience they shared with the entire medical team which echoes findings in a previous study (16). They found meaning in participating in a clinical trial because they felt special as a result of the attention they received while they were being treated by "expert hands" and receiving what they considered to be the best care possible. They expressed their gratitude to the research staff for the care they received. They spoke about the importance of the personal bond they felt with their medical providers and how that was an essential part of their care. Feeling that the staff were very professional, had a positive outlook, answered their questions and concerns, were friendly and made them laugh, accommodated their unique needs, were compassionate and cared about them, and asked them about their needs all provided a positive impact despite the demands of trial participation.

> You need comfortable waiting rooms with cozy places to sit and lots of light. (Note 9: Caregiver 10 Second Interview; Caregiver 11 Initial Interview; Patient 12 Second Interview; Caregiver 12 Initial and Second Interview; Patient 17 Initial Interview; Caregiver 24 Second Interview)
>
> Everyone should have their own (treatment) room with a door that closes. (Note 10: Patient 19 Initial Interview)
>
> You need to make the treatment room family friendly. My husband (caregiver) should have a reclining chair too. (Note 11: Patient 3 Initial Interview)

As demonstrated in Figure 3, a variety of environmental concerns that impacted the patient/caregiver experience while receiving trial-related care were expressed by 69% of patients and 88% of caregivers. They identified the desire for rooms filled with colors and natural light instead of the sterile white that typically surrounded them. They reported

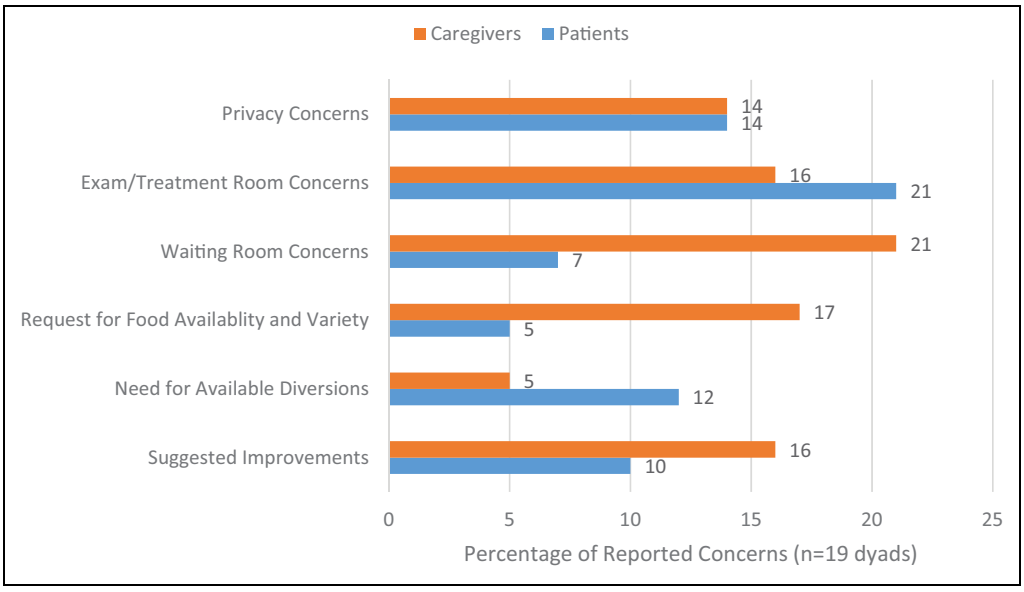

Figure 3. Environmental concerns identified by patients and caregivers (per interviews).

the desire for comfortable seating, private treatment rooms, and a variety of food choices. The ability to have a variety of available diversions (eg, TVs, games, movies, computer access) during their treatment times was also identified by both patients and caregivers.

Discussion

In the literature, the benefits and burdens related to clinical trial participation have been identified and examined from the patient's perspective. Caregiver concerns and burdens have not been studied. The novel research study described here compared and contrasted the perceptions of both patients and their caregivers while participating in an oncology phase 1 clinical trial.

As in previous studies, this study verified patients willingly participate in these types of trials despite the identified burdens. It also supported the results of previous research that the psychological benefits of trial participation outweigh the burdens. Although caregivers reported similar themes related to identifying their burdens and benefits while their loved one participated in the clinical trial, their level of burden exceeded that of the patient's.

> I believe it's harder on the caregiver than on the individual who has cancer. I don't want to tell my wife I'm tired of this when sometimes it is difficult to continue. (Note 12: Patient 10 Initial Interview)

The emotional toll that cancer takes on both patients and their caregivers was identified through both the interviews and QOL assessments used throughout this study. Some level of sadness and nervousness was prevalent among all patient and caregiver participants. However, caregivers identified higher levels of stress related to phase 1 clinical trial participation, family-related burdens, travel requirements, and end-of-life concerns. These findings supported the hypothesis that the caregiver will exhibit a higher level of burden and/or distress as compared to the patient while participating in these trials. Caregivers expressed a higher level of burden in both the interviews and the QOL assessments, but unlike the ongoing assessments for emotional stress used during each clinic visit for patients, the caregivers typically suffered in silence.

Table 1. Sample Characteristics.

Patient Demographics	Mean	SD	Range
Patient's age, (n = 19)	57.58	8.36	39-70
Caregiver's age, (n = 19)	55.63	15.05	24-90
	Male	Female	
Patient's gender, (n = 19)	10	9	
Caregiver's gender, (n = 19)	7	12	
Years of cancer-related treatment	N	%	
0-3	7	37	
4-7	8	42	
>8	4	21	

Limitations

By the nature of this patient population and the expected fluctuations in their physical status, the number of patients meeting the study requirements and/or being physically fit enough to participate in the second interview was limited. A larger population of patients and caregivers would be beneficial to validate these results.

This mixed methods study was done during a transition in treatment options for cancer therapy. The available research is limited and predominantly conducted prior to the

development of the targeted and immunotherapies currently being studied today. These treatments have altered the nature of risk and toxicity profiles.

The available research focused on the phase 1 patient's perceptions of their care and need for support and not the perceptions and needs of the caregivers. The approach of comparing perceptions of patients versus the perceptions of their caregivers is novel and thus needs ongoing research to further understand the unique needs of this population and to develop support systems.

Conclusion

The participants in this mixed methods study supported the physical and psychosocial responses to clinical trial participation reflected in the literature. Eighty-one percent found participating in a phase 1 trial to be a positive experience—one which provided meaning and hope to their life and helped to bridge the transition to hospice care. These patients and their caregivers expressed satisfaction that they had tried everything possible while leaving their legacy of advancing cancer research. Numerous patients and family members expressed their attachment to the phase 1 team members as they found a collegiality during the clinic visits which enhanced their lives.

Every patient and caregiver also experienced at least one significant area of distress and/or burden as a result of the rigorous demands of the phase 1 clinical trial. Caregivers openly expressed their concerns regarding the need to juggle responsibilities with work, medical appointments, and home. Financial concerns related to the high cost of health care, the possible loss of income as the cancer patient faced disability or the end of employment, and fear for the future also added to the caregiver's level of burden. This distress was exacerbated by their unmet expectations of tumor response, addressing end-of-life issues, symptom management as the patient's physical condition deteriorated, and transitioning from active treatment to hospice care.

Both patients and caregivers expressed a need to be heard, to have staff inquire and listen to their fears, concerns, and insecurities. They identified their need to have their burden acknowledged. The need for ongoing additional support services for both patients and their caregivers was validated throughout this study. The need for a comforting and supportive treatment environment, the use of social service consults with ongoing support, palliative medicine consults with ongoing interventions to help with symptom management, the use of psycho-oncology services for additional emotional support, and financial assistance for transportation, housing, and meals in order to accommodate the required clinic visitations were all identified in order to meet the patients' and caregivers' physical, emotional, and psychosocial needs.

Declaration of Conflicting Interests

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