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SPIRITUALITY IN CANCER PATIENTS ON PHASE 1 CLINICAL TRIALS

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Abstract

Objectives—Patients with cancer who are at a transition to Phase I investigational treatments have been identified as an underserved population with regard to palliative care. This disease transition is often accompanied by spiritual and existential concerns. The study objective was to conduct a secondary analysis of data from a larger study testing a palliative care intervention. This paper reports the findings of this secondary focus on the spiritual needs of this population.

Methods—Patients (n=479) were accrued to this study prior to initiating a Phase I clinical trial with data collected at baseline, and 4, 12, and 24 week follow-up.

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Results—Qualitative data revealed that the transition to Phase I trial participation is a time of balancing hope for extended life with the reality of advancing disease. Quantitative results demonstrated increased spirituality over time in both religious- and non-religious-affiliated patients.

Conclusions—Patients entering Phase I trials have important spiritual needs as they face treatment decisions, advancing disease, and often mortality. Spiritual care should be provided to seriously ill patients as a component of quality care.

Keywords

Cancer; Cancer Patients; Existential concerns; Hope; Investigational Treatments; Oncology; Spirituality; Spiritual Care; Underserved Populations

Background

Spirituality is recognized as one of the 8 essential domains of quality palliative care.¹ A growing body of evidence supports the relationship between spirituality and patient distress, depression, anxiety, and quality of life (QOL)^{2,3,4}. The diagnosis of a serious illness is a critical life event often resulting in reappraisal of religious beliefs, spirituality, and existential concerns.²⁻⁶

National guidelines and extensive literature support the importance of spiritual screening and assessment by clinicians and chaplains, but studies have demonstrated deficiencies in this area.⁸⁻¹⁶ The National Consensus Project (NCP) Guidelines for Quality Palliative Care recommend routine spiritual screening by clinicians and availability of spiritual care providers such as chaplains for more comprehensive assessment and spiritual support.¹ Spiritual assessment and care include a broad spectrum of religious beliefs and practices but spirituality also includes meaning and purpose in life and existential concerns. Attention to spiritual needs is recognized as a shared responsibility of interdisciplinary teams and a part of palliative care.¹⁷⁻²⁷

Transitions in disease trajectories are recognized as stressful times, as in cancer where initial diagnosis, recurrence, or discontinuation of therapies are critical decision points. Another critical juncture is a patient's decision to participate in investigational therapies. These trials are intended for first testing of agents in humans, dose determination, and toxicity monitoring, yet patients often believe they may offer a cure.²⁸⁻²⁹ While new targeted agents and immunotherapies offer reduced toxicities and sometimes prolonged survival, most patients will not realize disease benefit or extended life. The Phase I trial completion often means the end of cancer treatment with high mortality in the months to follow.

This paper describes the spirituality of patients with solid tumors participating in Phase I clinical trials. This population is often underserved by palliative care but is a group clearly facing serious illness, significant QOL concerns, and high symptom burden from progressive disease and treatment toxicity. Previous literature has described the population of patients on Phase I trials as distinct, in that they often remain hopeful for prolonged survival or cure despite advancing disease and having exhausted traditional treatments. Participation in

a Phase 1 trial is also recognized as a point of transition as patients have opted for treatments with unknown outcomes and the completion of the trial often means transition beyond cancer treatment to hospice or end of life care.^{14,28,29} Thus, the investigators believed this population offered a unique opportunity to examine spiritual needs.

Methods

Design

This secondary analysis was conducted on data from a randomized clinical trial funded by the National Cancer Institute to test integration of palliative care for patients beginning a Phase 1 trial. Patients with solid tumors (n=479) were accrued from 2 NCI Comprehensive Cancer Centers with baseline data collected prior to initial Phase I treatment. Patients were randomized to usual care or the palliative care intervention, consisting of comprehensive QOL assessment, interdisciplinary team care planning, and 2 patient/family education sessions. Spirituality was one of four topics covered in the 2 patient teaching sessions with the other topics addressing physical, psychological, and social well-being.

Follow-up evaluation occurred at 4, 12 and 24 weeks. These timepoints were selected to evaluate initial effect of the intervention occurring in weeks 1–3 as well as two follow-up points to assess retained effect of the intervention.

The aim of this secondary analysis was to describe spirituality in the population of patients with solid tumors on Phase 1 trials. The study questions for this analysis were 1) What are subjective descriptors of spirituality in this Phase 1 population? 2) How does spirituality change over time? 3) What is the correlation between spirituality, QOL, and psychological distress? 4) What is the impact of demographic variables on spirituality?

Qualitative Data

Interviews were conducted in a subset of 30 patients included in the larger study sample. The one-time interview was added by the investigators to the original study to ensure inclusion of patients' perspectives. Subjects were selected by convenience sample of those who had completed the intervention stage of the study and were in the follow-up phase. The interviews were conducted at one of the two study sites. The interviews were audio-recorded and transcribed verbatim with content analysis³⁰ completed by the study PI with extensive qualitative research experience and with themes confirmed by other team members. Patients were asked through prompts to share their clinical trial participation experiences and their QOL concerns including physical, psychological, social, and spiritual needs. Data from the responses regarding spiritual needs is included.

Quantitative Data

A demographic data tool and 3 psychosocial and spiritual measures were included in this analysis. The demographic tool was administered at baseline.

FACIT

The FACIT Sp12 spiritual assessment tool is a 12-item survey with items representing 3 subscales of Peace, Meaning, and Faith and an overall score. Patients rate items on a scale of 0 (not at all) to 5 (very much). The FACIT SP12 has been used extensively with documented reliability and validity.¹⁷ For this sample, the cronbach's alpha test of internal consistency was .86 for the total scale and .81–.88 for the subscales.

Distress Scale

The Psychological Distress Scale is a single item asking patients to rate their distress on a scale of 0 (none) to 10 (extreme distress).¹⁸ This tool is included as a measure recommended for clinical practice and research in the NCCN Psychological Distress Guidelines.¹⁸

FACT-G QOL

The FACT-G is a well-established QOL scale consisting of 27 items rated on a 0–4 scale. The tool includes subscales of Physical, Social, Emotional, Functional Well-Being, and overall QOL.¹⁹ The tool was selected as a standard QOL measure applicable to a sample including several solid tumor disease groups.

Statistical Methods

The larger study from which this secondary analysis was conducted was designed as a two-group randomized experiment, powered to detect significant group differences over time. A 336-patient sample size was determined to be sufficient to detect an effect size of 0.25 or greater, with at least 90% power, in the primary outcome measures defined (distress, symptom intensity, symptom interference). Accrual goals were set at 480, to account for 30% attrition at 12 weeks. Patients were expected to be followed for up to 24 weeks, although the 12-week metrics were considered the primary end-point to test the impact of the intervention.

Data Analysis

SAS 9.4® was used to conduct analyses. Data were analyzed according to intent to treat. FACIT-SP12 tool baseline data was used to estimate reliability for this instrument. Change in overall FACIT-SP12 Index and subscale scores was calculated using baseline and week 12 measurements, and a two-sided Wilcoxon signed rank test was used to assess whether paired differences were significantly different than zero.

Mixed model with repeated measures (3 timepoints: baseline, 4, and 12 weeks) was used for prediction of outcome measures. Main effects of demographic variables were also studied, along with interaction of these variables with evaluation time point. Gender, race, education level, marital status, family income, employment status, and enrolling institution were the parameters tested.

Results

Demographic Data

Participant characteristics are presented in Table 1. Patients were predominantly female (56.8%), over age 60, and 30.7% were ethnic minority populations. Religious affiliation included 38.8% Protestant; 29.4% Catholic; 16.5% no affiliation; 5.8% Jewish; 1% Buddhist; 1% Muslim; and 7.3 % other religions.

Qualitative Data

Table 2 presents spirituality themes derived from the content analysis of the interviews. Many patients described their spirituality as an important source of support. Diverse themes included having no interest in spiritual support, being very grateful for spiritual support, acceptance of illness, spiritual struggle, and being spiritual but not religious.

Quantitative Data

Table 3 presents FACIT-SP12 Questionnaire scores for individual questions, subscales, and total index. Each question was scored on a scale of 0 (worst) to 4 (best), with a maximum of 16 points for each subscale and 48 for the overall index. Patients were included if baseline plus one additional time point was collected.

The table includes the individual items, subscales, and the overall spirituality score over time within the experimental and control cohorts, to illustrate the individual aspects of spirituality. Overall, scores for both groups tended to improve over time and the Peace subscale was rated highest followed by Meaning and Faith.

Change in the overall FACIT-SP12 Index and subscale scores were calculated for patients from baseline to week 12, and the Wilcoxon signed rank test was used to assess whether paired differences were significantly different than zero. (Table 4) Results for calculated differences were stratified by Group (experimental vs. control). Mean differences for overall score and subscale for all patients enrolled were all significantly different than 0, regardless of the study arm assignment.

Correlations Between Variables

Spearman correlation coefficients were calculated at each time point, to show the relationship between the overall FACIT-SP12 Index and the distress thermometer score, as well as FACT-G index. (Table 5)

We found the correlation between FACIT-SP12 scores and psychological distress, as well as with FACT-G. FACIT-SP12 index is negatively correlated with distress thermometer (rho: -0.44 to -0.39), and positively correlated with the FACT-G Index (rho: 0.36 to 0.53). Among the four FACT-G subscales, the physical subscale has the lowest correlation with FACIT-SP (rho: 0.14 – 0.30), and the functional subscale has the highest overall correlation coefficients, with values ranging from 0.36 to 0.49 . All significance levels were $<.0001$.

Effects of Demographic Variables

Main effects of demographic variables were studied, along with interaction of these variables with evaluation time point and the intervention, using linear mixed models with repeated measures. There were no significant results to report by demographic groups with regard to the intervention, and the change in spiritual scores over time was not dependent on gender, race, education level, marital status, family income, or employment status.

Comparing Benefit by Religious Affiliation

Mean scores at baseline were higher in those with a religious affiliation than those without. However, both groups demonstrated an increase in FACIT-SP12 scores similarly over time. These effects were tested in a linear mixed model, with a statistically significant difference between the groups as well as over time ($p < .0001$). Overall, there is a marked increase in FACIT scores of patients in this cohort, in both experimental and control arms, and regardless of religious affiliation.

Discussion

This study evaluated spirituality for patients with solid tumors at a critical point, Phase I clinical trial entry. Study findings recognize that spirituality is a key aspect of QOL and a source of support during serious illness and treatment.^{1,2,5} In this sample of 479 patients, only 16.9% indicated no religious affiliation or no response with the remaining 83.1% indicating a religious affiliation. The data also confirmed an increase in FACIT scores regardless of religious affiliation, underscoring the relevance of spiritual care for all patients.

The quantitative and qualitative assessment provided valuable clinical insight across spirituality dimensions to understand the patients' religious and existential concerns. The FACIT tool provided valuable information about various aspects of spirituality. Qualitative data provided patient perspectives and demonstrated the importance of asking patients to describe their spirituality including sources of support as well as concerns.^{8,12,19} Chaplains and community clergy serve as spiritual care specialists and they are supported by all team members involvement in screening for spiritual needs.

The analysis of the quantitative data revealed that spirituality increased over time in both experimental and control groups. This may have been the result of repeated administration of the FACIT tool which means that patients are evaluating their own spirituality across dimensions of peace, meaning, and faith. These 12 items represent a much more comprehensive spiritual screening than exists in most usual initial patient evaluations which ask only a single question about religious affiliation. The tool allowed participants to reflect on items such as feeling peaceful, sense of life purpose, and comfort and strength in faith.

The quantitative data from the FACIT tool is consistent with the qualitative data in Table 2. Participants described the importance of spirituality during this time of advanced cancer. These observations of spirituality and the need for spiritual assessment are consistent with the national palliative care guidelines which also recommended spiritual assessment for all patients with serious illness.¹

Study Limitations

This study was limited to two cancer centers and patients at a specific time in the cancer trajectory, those participating in Phase 1 trials.

Clinical Implications

The study has implications for the growing recognition of spirituality as an important aspect of QOL in serious illness. There is increasing consensus that spiritual care should be integrated in disease-focused care and implemented early in the diagnosis. This study demonstrates the opportunities to improve the support of patients during treatment transitions such as at the time of participating in clinical trials. Improvement in both study arms on the FACIT tool indicates the value of clinicians assessing spiritual needs and patients having opportunities to reflect on their spirituality during serious illness. The data revealed diverse experiences of spirituality and in this population, a need to maintain hope despite the uncertainty of their futures. Spiritual assessment also is important given the increased cultural diversity of the population. Correlations demonstrated a positive relationship between spirituality and domains of QOL and a negative relationship with distress. This data provides insight for clinicians as to the impact of spiritual care on other dimensions of well-being.

Conclusion

Seriously ill patients, including those who continue disease-focused treatments in late stage disease, require care that meets spiritual needs, including religious support as well as existential concerns. Spirituality is an aspect of QOL for religious and non-religious individuals and spiritual care should be part of the usual care for patients on investigational therapies as well as for all patients facing serious illness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Availability Statement

The data that support the findings of this study are available upon request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Table 2.

Patient Perspectives on Spirituality

Theme	Example
Not interested in spiritual support	Do you know, I went to Catholic school for seven years...I went to church every single day and Sundays. but still have a hard time believing that there's a heaven... When you're gone, you're gone- I mean, the heaven thing doesn't...doesn't make a lot of sense...so I don't have a lot of, what's the word, faith. Not on any extreme, but probably not. I mean, I've always been kind of a, I don't want to say scientific-- I'm not a scientist but — I'm kind of more a, you know, 'show me the evidence' kind of person.
Grateful for spiritual support	...we come from a really strong, spiritual background. Not everybody has that, I understand. Our family is very close – are strong Christians, and so we have that, that tie that we're very thankful for Oh, my goodness, a lot. It's helped me have a better relationship with God and to be able to lean into Him for some peace because I didn't have a lot of it when I was going through it. When you're so gravely ill that you rely on people just for the basic necessities, to be able to just day-by-day know that he's there and helping me walk through it. I think too it's helped me bring family members to Jesus, to bring them into going to church and to lean into that. It's been a full circle kind of thing for all of us. I try. I have an amazing pastor and family. I'm a recovering Catholic. Faith has a lot to go over and stuff. One thing that we talked about when we first started – I told Jen when we were sitting in the car after my diagnosis, "I've never considered myself a statistic." I've always felt there was a greater thing that drove me than myself. I've always maintained my faith. Well, I just feel like there's a superior being that is really in charge, and uh, that he's watching over me. Well, actually...I've been very strong in my faith for many years. It just continues. So... this has also given me a real boost knowing that it's not my time to go yet. Got more work to do.
Spiritual struggle	Spiritual wise I think that it just, it teaches me every moment, every day– that I have been blessed in so many ways...There are other people who are so much worse off, and I said, "If you give me the days Lord, I mean, I will find other ways to be more useful to you." I have my ups and downs and I get – I would say on the surface, I'm very – I'm myself, I'm positive, I smile, you know, I'm normal, but then if I have to go any deeper than that, ... try to be mindful and grateful and, and praying, but I also have a lot of anger. I'd say I'm, kind of, in the middle. One of the things I wish was that I was a very devout Christian, a very devout Catholic, a very devout Jew, a very devout Muslim. Those religions help people deal with this. They trust in God; I don't. I'm not an atheist, but I don't think that I can just hand it over. I need more of that. Do I think there's a higher being that's helping me and watching over me? Yes. Do I believe in God? I do. Spiritually, it's kicking my ass because it's saying to me, there's a lesson in this.
Acceptance of illness	I believe everybody has a purpose and, with this it seems like, okay... it's a life-changing disease and, you have a long time to think about, ... what's my purpose with — to me it's a second chance, and, ...what do I want, what do I want to do with that second chance that's going to make it worthwhile...And so all those kind of questions comes up. I haven't got the answers yet but we'll figure it out as we move along.
Spiritual but not religious	Uh, I'm a Catholic. I'm not a, I, to be honest with you, I haven't prayed a single prayer for myself. No, I don't meditate. I accept the faith. I accept that, you know, when it's time to go, it's time to go. And that's what it is It has, but I mean as far as believing there's a higher power that's going to make me better, I have a hard time with that because of all of the people that suffer and don't have any intervention. It seems foolish to expect, well I'll leave it in their hands, [I'll be fine], but I have felt spiritual. I've definitely been feeling a lot... Yeah, I do yoga and walk and garden and trying not to be too stressed.

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Table 3.

FACIT-SP12 Questionnaire Scores

Individual items, subscales, and total score	Groups 1 = Exp 2 = Control	Baseline	Week 4	Week 12	Week 24
		n1=209 n2=217	n1=209 n2=216	n1=158 n2=153	n1=104 n2=106
		Mean±std			
<i>Feel peaceful</i>	1	3.01±1.03	3.30±0.94	3.44±0.98	3.65±0.78
	2	2.99±1.10	3.08±1.00	3.24±0.97	3.55±0.84
<i>Have reason for living</i>	1	3.85±0.51	3.83±0.51	3.82±0.62	3.91±0.35
	2	3.79±0.60	3.69±0.73	3.76±0.63	3.83±0.47
<i>Life is productive</i>	1	3.70±0.67	3.74±0.66	3.77±0.68	3.88±0.40
	2	3.62±0.77	3.65±0.74	3.75±0.57	3.78±0.59
<i>Have trouble with peace of mind †</i>	1	3.26±0.92	3.46±0.82	3.64±0.71	3.81±0.53
	2	3.20±0.96	3.28±0.94	3.44±0.88	3.63±0.72
<i>Feel sense of purpose in life</i>	1	3.52±0.90	3.55±0.88	3.63±0.86	3.78±0.64
	2	3.45±0.92	3.43±0.91	3.52±0.86	3.64±0.77
<i>Able to reach for comfort</i>	1	3.30±0.94	3.38±0.95	3.55±0.86	3.68±0.76
	2	3.20±1.04	3.18±1.04	3.48±0.80	3.52±0.84
<i>Sense of harmony with self</i>	1	3.00±1.05	3.24±1.00	3.48±0.92	3.65±0.76
	2	2.88±1.05	3.04±1.07	3.24±0.94	3.53±0.77
<i>Life lacks meaning and purpose †</i>	1	3.74±0.72	3.72±0.68	3.82±0.58	3.97±0.17
	2	3.64±0.80	3.76±0.59	3.76±0.63	3.79±0.60
<i>Comfort in faith</i>	1	2.71±1.56	2.82±1.53	2.89±1.59	2.97±1.59
	2	2.53±1.60	2.63±1.59	2.69±1.58	2.87±1.67
<i>Strength in faith</i>	1	2.71±1.59	2.82±1.54	2.91±1.57	3.00±1.57
	2	2.53±1.62	2.61±1.59	2.70±1.59	2.87±1.67
<i>Illness strengthened faith</i>	1	2.25±1.66	2.35±1.67	2.43±1.68	2.70±1.68
	2	2.17±1.70	2.29±1.64	2.33±1.68	2.59±1.73
<i>Things will be okay</i>	1	3.02±1.21	3.25±1.08	3.37±1.02	3.67±0.76
	2	2.82±1.24	2.94±1.08	3.00±1.21	3.49±0.92
Peace Subscale	1	13.83±2.42	14.35±2.35	14.66±2.45	15.25±1.70
	2	13.62±2.61	13.71±2.59	14.19±2.30	14.79±2.21
Meaning Subscale	1	13.54±2.92	13.87±3.02	14.47±2.83	15.08±2.15
	2	13.14±3.08	13.42±2.94	14.00±2.51	14.48±2.44
Faith Subscale	1	10.69±5.14	11.23±4.91	11.59±5.12	12.34±4.98
	2	10.05±5.49	10.46±5.28	10.72±5.41	11.82±5.45
FACIT SP12 Index	1	38.06±8.12	39.45±7.99	40.75±8.56	42.67±6.95
	2	36.80±8.70	37.59±8.51	38.93±8.15	41.09±8.07

† these items were reverse-scored

Table 4.

Change in FACIT-SP12 Index and subscales from Baseline to Week 12, Experimental and Control Groups

FACITSP-12 Score	N	Change in Scores BL to 12W		
		Mean (std)	Median (min,max)	p-value *
Peace Subscale	309	0.57 (1.9)	0 (-9, 7)	<.0001
Meaning Subscale	309	0.65 (2.2)	0 (-8, 9)	<.0001
Faith Subscale	307	0.82 (2.6)	0 (-14, 12)	<.0001
Overall FACIT-SP12 Index	307	2.0 (4.9)	1.0 (-28, 21)	<.0001

* p-value is from the Wilcoxon signed rank test statistic

BL=Baseline

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Table 5.

Correlations between Spirituality, Distress, and QOL

<i>Demographic and Results from other Instruments</i>	<i>correlation coefficient with FACIT-SPI2 Index *</i>			
	Baseline	Week 4	Week 12	Week 24
Distress Thermometer	-0.40	-0.43	-0.44	-0.39
FACT-G Index	0.49	0.53	0.46	0.36
<i>Physical Subscale</i>	<i>0.26</i>	<i>0.30</i>	<i>0.20</i>	<i>0.14</i>
<i>Social Subscale</i>	<i>0.35</i>	<i>0.36</i>	<i>0.37</i>	<i>0.29</i>
<i>Emotional Subscale</i>	<i>0.40</i>	<i>0.45</i>	<i>0.40</i>	<i>0.26</i>
<i>Functional Subscale</i>	<i>0.44</i>	<i>0.49</i>	<i>0.42</i>	<i>0.36</i>

* all correlation coefficients were significantly different than 0 (p<0.0001)

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