

Burden and Benefit of Psychosocial Research at the End of Life

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ABSTRACT

Background: The impact of psychosocial research participation has not been examined systematically in palliative care settings. Concerns are often raised regarding the potential for distress among terminally ill patients. This is particularly true when death and dying are the focus of research. Therefore, it is important to understand the specific ways psychosocial research could potentially harm or be helpful to participants.

Objective: To assess the burden and benefits of participation in psychosocial research addressing end-of-life issues among patients receiving inpatient palliative care.

Design: Sixty-eight terminally ill patients with cancer who had an average life expectancy of less than 2 months, were administered a brief self-report questionnaire to assess whether participation in psychosocial research was burdensome and/or beneficial. The specific factors that contributed to their perceptions were also identified.

Results: The majority of patients reported no burden associated with participation (75%) and found the experience as moderately to highly beneficial (68%). Factors most frequently identified as burdensome included the length of the interview (21%), structure of the questionnaires (18%), and difficulty discussing end-of-life issues (12%). Although some patients reported some distress while discussing end-of-life issues (19%), few endorsed a high level of distress (6%). Factors most frequently identified as beneficial were the social interaction (75%), sense of contributing to society (57%), and the opportunity to discuss their illness (47%).

Conclusions: Participants in psychosocial end-of-life research are unlikely to experience significant burden from participation and, in fact, may benefit.

INTRODUCTION

THERE IS AN INCREASING DEMAND for psychosocial research in palliative care in order to provide a higher quality of care at the end of life.¹⁻³ However, ethical concerns regarding the relative risks and benefits of research in vulnerable populations such as the

terminally ill have been raised frequently.²⁻⁹ Research that focuses on end-of-life issues is often considered too burdensome, potentially distressing, or harmful to terminally ill patients.¹⁰ Because of the perceived vulnerability of palliative care patients, hospital Institutional Review Boards (IRBs) may be reluctant to permit psychosocial research, for fear that there are

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minimal benefits and even the potential for harm.^{10,11} These concerns are even more pronounced when research focuses specifically on topics related to death and dying.^{8,12} The World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects¹³ requires that the well-being of human subjects must outweigh scientific interests. Despite this mandate and the growing awareness of the unique ethical issues related to conducting research in a palliative care population, the impact of research participation has not been studied systematically.¹⁰

Palliative care patients are considered a particularly vulnerable population as they often experience pain, suffering, fatigue, and many other physical symptoms, as well as emotional distress.¹⁴ These patients may be more susceptible to coercion to participate in research studies as a result of an increased sense of dependency.¹⁵ Many have argued that because of these vulnerabilities research should be very limited or not be conducted at all at the end of life.^{11,16–18} Kristjanson and colleagues¹⁹ reviewed studies conducted in palliative care settings and found that investigators reported a number of potential risks associated with research participation. These risks included invasion of privacy due to vulnerability or distress, inclusion of overly personal questions, physical stress associated with the completion of interviews, and side effects of interventions.

Despite the potential for adverse reactions to end-of-life research, many researchers have conducted studies with this population in such a way as to successfully minimize harm to participants.^{1,7,17,19} The handful of studies that have solicited feedback on the impact of research participation from palliative care patients have confirmed that the benefits are often equal to or outweigh the risks.^{7,10,17,19,20} Emmanuel et al.¹⁰ found that fewer than 5% of research participants reported a great deal of stress and more than 70% reported no or minimal distress from research participation. In fact, more than 40% of their sample stated that being interviewed about symptoms and death and dying was helpful. Researchers have acknowledged that there are also a number of other potential benefits associated with research participation among terminally ill patients.^{3,8,10,17,19,20} Many study participants have reported experiencing therapeutic effects, such as valuing the companionship and additional attention they received, as well as gaining a sense of satisfaction from helping others.^{19–21} Scarvalone et al.²² reported significant decreases in distress, depression, and anxiety among patients with human immunodeficiency virus (HIV)-related concerns who completed severe combined immunodeficiency (SCID) interviews, suggesting that a well-conducted psychosocial research interview may act as an intervention in itself.³

While prior studies have provided valuable information, a number of important areas remain that warrant exploration. The literature lacks systematic studies specifically conducted in hospice settings with imminently dying patients who are potentially more vulnerable to the risks of research. Additionally, much of this research has been anecdotal in nature¹⁹ and feedback from patients was not elicited by an independent investigator, potentially biasing results. Finally, the specific factors that contribute to a patient's sense of burden or benefit from study participation should be clarified.¹⁰

The purpose of this study was to assess the burden and benefit of participation in research that investigated attitudes toward hastening death, and other symptoms associated with end-of-life suffering among patients receiving palliative care. Our hypothesis was that patients were not only unlikely to experience significant burden but would actually benefit from participation in psychosocial research at the end of life.

METHOD

Participants

Participants were recruited upon admission for end-of-life care to a 200-bed palliative care hospital in New York City. All patients had a diagnosis of end-stage cancer and had a life expectancy of less than 2 months. The participants for the present study were recruited as part of a larger, ongoing study investigating the impact of psychological, physical, and social influences on patient attitudes toward end-of-life care. The study was approved by the IRBs of Calvary Hospital, Memorial Sloan-Kettering Cancer Center, and Fordham University.

All consecutive admissions were evaluated for participation in the larger study. In order to be eligible, patients had to be English speaking and cognitively intact, as determined by a score of 20 or above on the Mini-Mental State Exam (MMSE).²³ Patients were excluded if they were too ill or confused to engage in the screening process. All eligible patients were offered participation in the initial study and provided written informed consent after an explanation of the study's risks and benefits.

Procedures

Participants were interviewed and administered an extensive battery of clinician-rated and self-report measures focusing on depression, hopelessness, desire for hastened death, suicidal ideation, physical symptoms, pain, spiritual well-being and social support (see

Breitbart et al.²⁴ for a summary of the measures used). Because of the poor health of many participants, all interviews were conducted at bedside and all self-report questionnaires were read to the participants by the interviewer. Interviews were conducted by clinical psychologists or psychologists-in-training, all of whom received extensive training in clinical interviewing techniques and issues specific to palliative care populations. Interviews typically required approximately 1 to 2 hours to complete and were conducted over one to three sessions depending on patient preferences or fatigue. It should be noted that the study did offer several potential benefits to participants in regard to facilitating psychosocial treatment. If patients met criteria for depression they were referred for a medication consultation. In addition, if patients reported other significant symptoms such as pain, anxiety, or severe distress, their doctors were informed.

All patients who were enrolled in the larger psychosocial study were approached for this follow-up investigation within 1 week of completion of the initial interview (including any patient who dropped out of the initial study). Patients were unable to participate in this follow-up assessment if they had become too ill, were discharged, or were deceased before the one week follow-up point. The follow-up questionnaire was administered by an independent investigator who had not had previous contact with the subject.

Measures

Burden and benefit. The Benefit and Burden Scale (see Appendix A) is a brief clinician-administered scale designed to measure patient reactions to research participation developed specifically for this study. This scale was based on Kristjanson and colleague's¹⁹ review of the literature, which listed common benefits and burdens of research with palliative care patients, and a number of items that were rooted in anecdotal observations made during the course of our research. This scale was intentionally developed to be brief to minimize any additional burden to the subjects.

The initial question that assesses burden is, "Was participation burdensome to you in any way?" and responses are measured on a five-point Likert scale (0 to 4) with the following response options: "not at all," "a little bit," "somewhat," "quite a bit," and "very much." If this item is endorsed, the follow-up question administered is, "Did you find it was burdensome because . . ." and list six potential reasons study participation may have been a burden (e.g., too ill, the questions were too long, the questions were upsetting) with the option of endorsing multiple items. The sec-

ond question that assesses benefit is, "Was participation beneficial to you in any way?" and responses are measured on the same five-point Likert scale described above. If this item is endorsed, the follow-up question is, "Did you find it was helpful because . . ." and a list of six possible benefits is read to the patients (e.g., helpful to discuss illness, helped to think about topics, facilitated mental health treatment) with the option of endorsing multiple items. There is also an open-ended item for any additional benefits. Patients are also asked if they would participate in the study again and given the opportunity to make additional comments.

Statistical analyses

Frequencies were used to quantify the overall level of patient burden and benefit as well as the proportion of endorsements of specific items on the Burden and Benefit Questionnaire. Correlational analyses were utilized to examine the relationship between overall burden and benefit with demographic and psychosocial variables.

RESULTS

Of 1383 consecutive admissions, approximately 20% met eligibility criteria for the initial study. The remainder of the patients were either severely ill or too cognitively impaired to enter the study. Ninety-seven (7%) subjects agreed to participate in the initial study. Of these 97, only 3 dropped out because they were upset by the questions. The patients who refused to participate indicated the following reasons: did not want to be involved in research, did not want to discuss death and dying, or believed they were too ill. Those subjects who chose to participate were no different than refusers on age, race, and religion. Sixty-eight of the 97 subjects who consented to participate in the initial research study (described above) completed the Benefit and Burden Questionnaire. The remaining 29 subjects were either deceased at the time of follow-up or were too severely physically or cognitively impaired to complete a follow-up questionnaire. No one who was physically able at the time refused to complete the Benefit and Burden Questionnaire. As such, 68 subjects were analyzed. Thirty-nine (57%) were women and 29 (43%) were men. Most of these participants were Caucasian ($n = 47$, 69%), 15 (22%) were black, 4 (6%) were Hispanic, and 2 (3%) were Asian. The average age of the sample was 65 (standard deviation [SD] = 14), and on average the participants lived for 60 days (SD = 54) after admission into the hospital. The mean Karnofsky Performance Rating Scale

(KPRS) of functional ability was 39 ($SD = 7$), indicating a functional level requiring special care and assistance.

Overall, the majority of patients reported that they did not find participation burdensome at all (75%). While a number of patients found the study to be “a little bit” to “somewhat” burdensome (19%), only 4 individuals (6%) reported that participation was “quite a bit” or “very much” burdensome. On the other hand, 18% characterized the experience as highly beneficial (“quite a bit” to “very much”), while most patients found it to be “a little bit” to “somewhat” beneficial (48%), and a quarter of participants reported receiving no benefit (24%).

Factors most frequently identified as burdensome were the length of the interview (21%), the structure of the questionnaires (18%), and difficulty discussing end-of-life issues (12%). Only a few patients felt that they were too ill to participate (9%), that the questions were intrusive (6%), or that the study interfered with other things they wanted to do (4%). The most commonly reported benefits were enjoying the social interaction (75%), feeling a sense of contribution to society (57%), helping to keep them busy (47%) and the therapeutic gains from the opportunity to discuss their illness at length (43%). A significant portion of the sample also stated that the study helped them think about issues they had not necessarily considered or discussed (38%), obtain a referral for treatment for emotional distress (24%), and discuss sensitive issues that they were unable to talk about with others, such as clinicians, family, or clergy (22%). In fact, an overwhelming percentage of patients stated that they would agree to participate again if given the opportunity (77%).

Correlational analyses were used to examine the importance of several potential contributing factors to the experience of burden or benefit. Interestingly, there were no significant associations between patients' overall sense of burden or benefit and the following psychosocial variables: depression (Hamilton Depression Rating Scale), desire for death (Schedule of Attitudes toward Hastened Death), physical functioning (KPRS), cognitive functioning (MMSE), and lifespan (length of stay). In addition, neither burden nor benefit was associated with gender or race. Only age was significantly associated with benefit ($r = -0.34, p < 0.01$), with younger patients reporting a greater sense of gain. Despite the fact that there were only 3 participants who dropped out of the initial study voluntarily, there was a very high correlation between experiencing a sense of burden and drop out ($r = .78, p < 0.001$), suggesting that that severity of burden was an important factor in study retention.

DISCUSSION

This research illuminates a number of important issues related to the burden and benefit of end-of-life research. Most important, these results indicate that conducting psychosocial research can be minimally burdensome to a palliative patient if conducted in a sensitive manner, and in fact, in some cases may be beneficial. Although some patients reported distress discussing end-of-life issues, significantly more patients benefited from the discussion of these topics. Length of the interview was the most frequently reported burden of research participation. In addition, only a small number of patients found it difficult to discuss end-of-life issues or felt they were too ill to participate in spite of the fact that all patients were very close to death. It should also be noted that typical rule outs for good research candidates (i.e., a diagnosis of depression, high desire for death, or poor physical functioning) were not correlated to burden or benefit, indicating that even the most “vulnerable” patients were able to tolerate research participation. Of specific interest to researchers, burden was associated with voluntary drop out, demonstrating that if participation was overly taxing, patients felt able to exercise their right to withdraw. This suggests that even in this vulnerable population patients demonstrate the ability to advocate for themselves and patient autonomy can be preserved.

In fact, a high percentage of subjects reported enjoying the research process as it helped them keep busy and gave them a sense that they were able to continue to contribute to society. These results highlight that research participation offers a unique way to maintain a sense of purpose as these patients approach death. In addition, we believe that participation in psychosocial research has the potential to act as an intervention capable of producing therapeutic gains. Patients in this study had the opportunity to discuss concerns related to their psychological distress at length and processed the difficult topics of death and dying that many had reported were too difficult to discuss with friends or family.

However, it is essential that the following recommendations be considered when working with palliative care populations. Because patients receiving palliative care are a vulnerable population, particular attention should be given to enhancing informed consent. This might include taking extra time to explain the research, clarifying the patient's understanding of the material, and emphasizing the voluntary nature of research. In addition, reminders of the right to withdraw should be repeated throughout the interview, particularly if the patient becomes fatigued, highly symptomatic, or distressed. While we recognize that in some cases patients may be more likely to decline or drop

out as a result of these recommendations, we believe this is a necessary limitation in conducting research in this population and the higher mandate is to protect the patient and minimize burden. The patients who accept and decline, the drop-out rate, and potential selection bias and their potential impact on the research hypotheses should be discussed in the write-up of the research. In designing a study, researchers should attempt to use brief interviews or questionnaires. If lengthier interventions are necessary, it can be helpful to take frequent breaks or divide the interview into several short sessions. Another essential consideration is the importance of establishing a good rapport and working relationship with participants. This can be accomplished by ensuring that interviewers are well trained in sensitivity to end-of-life issues, have an awareness of the vulnerabilities of this population, and have good clinical and interpersonal skills.

There are several limitations to this study. First, the most severely ill patients were not all included in the sample as they could not complete the follow-up interview due to illness or death. Second, despite the use of an independent interviewer, social desirability may have affected results and patients may have been less likely to report their discomforts. Third, self-selection bias may have been an issue with this sample. This sample had previously agreed to participate in the larger study and, as such, had demonstrated that they felt the burden and benefit ratio of research participation was favorable. However, we are only asserting that psychosocial research is more beneficial than burdensome for those patients who would be willing to participate in this type of research. We are not suggesting that this would be the case for all palliative care patients. Finally, and perhaps most important, the investigators of the original study emphasized the importance of training the interviewers, enhancing the informed consent procedure, paying close attention to participant comfort during the interviews, and emphasizing the right to withdraw. Therefore, these results may not be generalizable to other studies that do not stress these aspects of research participation.

CONCLUSION

These results provide more empirical support for the arguments made by other authors who have addressed the challenges for conducting research on death and dying with palliative care patients.^{3,7,10,19,25} Patients are generally open to discussing end-of-life issues and may actually benefit from these discussions. Research can be conducted with terminally ill patients in an ethical manner which minimizes burden, maximizes ben-

efits, maintains autonomy, and allows patients to advocate for themselves.^{7,10,17,19,20}

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Appendix A. Burden and Benefit Questionnaire

Was participation burdensome to you in any way?

Not at all	A little bit	Somewhat	Quite a bit	Very much
0	1	2	3	4

Did you find it was burdensome because:

I was too weak or too ill at times
 The interview was too long/had too many questions
 It interfered with other activities that I wanted to do
 The topics discussed were upsetting to me
 The questions were confusing/difficult to answer/repetitive
 The questions were too personal

Was participation beneficial to you in any way?

Not at all	A little bit	Somewhat	Quite a bit	Very much
0	1	2	3	4

Did you find it was helpful because:

It was helpful or a relief to talk about my illness with someone
 I talked about issues I felt uncomfortable discussing with others
 It helped me think about these topics
 I enjoyed having the company
 It facilitated treatment of my emotional distress
 It helped pass the time/kept my mind busy
 It made me feel good to help others/contribute to society