Original Article

Clinical Trial Participation as Part of End-of-Life Cancer Care: Associations With Medical Care and Quality of Life Near Death

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Abstract

Context. Clinical trials are a common therapeutic option for patients with advanced incurable cancer.

Objectives. To examine the associations between trial participation and end-of-life (EOL) outcomes, including aggressive care and quality of life (QOL).

Methods. Coping with Cancer, a multicenter prospective cohort study of patients with metastatic cancer, progressed after at least first-line chemotherapy. Baseline chart review documented clinical trial participation. Baseline interviews assessed psychosocial characteristics and EOL preferences. Caregiver interview and chart review assessed medical care and QOL near death. The primary outcome was aggressive EOL care (ventilation, resuscitation, or intensive care unit admission in last week of life). Propensity score weighting balanced patient characteristics that differed by trial participation, including care preferences and EOL discussion. Propensity score–weighted regression models estimated the effect of trial participation on outcomes.

Results. Of 352 patients followed to death, 37 were enrolled in a clinical trial at baseline. In propensity score–weighted analyses, trial participation was significantly associated with aggressive EOL care (21.6% vs. 12.0%, adjusted odds ratio [AOR] 2.04, 95% confidence interval [CI] 1.00–4.15), late hospice enrollment (51.4% vs. 42.2%, AOR 1.96, 95% CI 1.10–3.50), hospital death (48.6% vs. 25.7%, AOR 2.74, 95% CI 1.37–5.47), intensive care unit death (16.2% vs. 6.3%, AOR 3.53, 95% CI 1.29–9.65), and inferior QOL near death (least squares mean 5.93 vs. 7.69, $P < 0.001$). Controlling for EOL care, trial enrollment was no longer associated with QOL near death ($P = 0.342$).

This study was presented in abstract form as a poster presentation at the 2012 American Society of Clinical Oncology Annual Meeting; Chicago, IL on June 3, 2012.

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Conclusion. Clinical trial participation is associated with aggressive EOL care. Aggressive EOL care appears to explain the association between trial participation and QOL near death. J Pain Symptom Manage 2014;47:1078–1090. © *2014 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.*

Key Words
Palliative care, end-of-life care, clinical trials, cancer

Introduction

For patients with advanced refractory cancer, experimental therapy, particularly on an early-phase clinical trial, is a common therapeutic option.[1] Clinical trials are essential to the process of improving available cancer therapy. Participation, therefore, is strongly encouraged by organizations such as the National Comprehensive Cancer Network, whose guidelines[2] state: "the best management of any cancer patient is in a clinical trial." This position statement underscores the dual research and therapeutic aims of clinical trials. Although the principal purpose of clinical trials is to generate knowledge to improve future therapy,[3] many patients incorrectly believe that the primary purpose of clinical trials is to directly benefit participants.[4] This "therapeutic misconception" threatens the validity of informed consent for cancer clinical trials and has raised substantial controversy about the place of experimental therapy within the care of patients with advanced cancer.[5–8]

Early-phase, and specifically Phase I trials, have prompted the most debate among ethicists and oncology clinicians.[5,8–11] Classic Phase I trials result in very low response rates (in the range of 5–10%),[12,13] and are designed with nontherapeutic primary aims of determining toxicity and the optimal dose for subsequent testing.[13] Unfortunately, most participants misunderstand the purpose of early-phase trials,[14] and enroll anticipating a substantial likelihood of personal benefit, and even cure.[1,8,15–17] Despite the fact that Phase I trials infrequently provide direct benefit to participants and are primarily designed to contribute to scientific knowledge, most patients with advanced cancer enroll in early-phase trials primarily in hopes of personal benefit, rather than for altruistic reasons.[14,18] Nevertheless, several highly successful early-phase trials involving targeted cancer therapies demonstrated that drugs in early development can occasionally provide significant benefit to patient-subjects,[19–21] and support their place within the care of appropriately informed patients.[9]

For patients with very limited life expectancy, the decision to pursue investigational therapy can be particularly difficult.[11] Although many patients are highly motivated to continue disease-directed treatment,[22] national guidelines[23] support balancing this desire with other goals of quality end-of-life (EOL) care including symptom control, avoiding futile interventions, and supporting patients' ability to come to terms with and prepare for death.[24–26] Beyond weighing the odds of disease response and toxicity, the risks and benefits of trial participation on these EOL goals merit consideration.[11] For example, pursuing investigational therapy might help patients feel that they have fought cancer to the best of their ability, and thereby find greater acceptance and peace at EOL. Conversely, trial participation might distract some patients from coming to terms with death and making EOL plans.

Despite an extensive literature devoted to the ethics of early-phase oncology trials,[1,9,16,22] to our knowledge the impact of trial participation on cancer patients' medical care and quality of life (QOL) near death has not been investigated. We sought to examine the relationships between cancer clinical trial participation and goals of quality EOL care including patients' acceptance of terminal illness, advance care planning, use of aggressive medical interventions, and QOL near death.

Methods

Study Sample

Coping with Cancer was a multi-institutional, prospective cohort study of patients with advanced cancer designed to

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