

## Nurse-led Palliative Care Improves Quality of Life and Mood of Cancer Patients

Bakitas M, Doyle Lyons K, Hegel MT, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: The Project ENABLE II randomized controlled trial. *JAMA* 2009;302:741–9.

### Study Overview

**Objective.** To assess the effect of a nursing-led palliative care intervention on quality of life, symptom intensity, mood, and resource use in patients recently diagnosed with advanced cancer.

**Design.** Randomized controlled trial.

**Setting and participants.** 322 patients with life-limiting cancer (prognosis of approximately 1 year) were enrolled between 2003 and 2007 from 2 primary sites (a rural comprehensive cancer center in New Hampshire and a VA medical center in Vermont). Eligible patients were diagnosed with advanced gastrointestinal tract, lung, genitourinary tract, or breast cancer within the past 8 to 12 weeks. Patients with impaired cognition, Axis I psychiatric disorders, or active substance abuse were excluded. All patients were asked to select a caregiver to participate. Patients and caregivers were randomly assigned to receive either usual care or a telephone-based palliative care intervention which included 4 initial structured educational and problem-solving sessions and at least monthly telephone follow-up sessions conducted by a nurse with palliative care training. Intervention patients and their caregivers were also invited to attend monthly group shared medical appointments led by a palliative care physician and nurse practitioner.

**Main outcome measures.** Participants completed questionnaires at baseline, 1 month, and every 3 months thereafter until death or study completion. Quality of life was measured using the 46-item Functional Assessment of Chronic Illness Therapy for Palliative Care (range 0–184, higher scores indicate better quality of life). Symptom intensity was measured by the Edmonton Symptom Assessment Scale (ESAS; range 0–900, higher scores indicate greater symptom burden). Mood was measured by the 20-item Center for Epidemiological Studies Depression Scale (CES-D; range 0–60, higher scores indicate more depressive symptoms). Data on resource use (days in the hospital, days in the intensive care unit [ICU], emergency department visits) and vital status were collected by chart review.

**Main results.** Of 681 eligible patients, 322 were enrolled and randomly assigned to receive usual care ( $n = 161$ ) or the palliative care intervention ( $n = 161$ ). The groups did not differ at baseline with respect to demographic or clinical characteristics, anticancer treatment, advance directives, palliative care or hospice referral, resource use, quality of life, symptom intensity, or mood. After enrollment, 27 patients in the usual care group and 16 patients in the intervention group dropped out. In longitudinal intention-to-treat analyses, the intervention group had higher quality of life (mean [SE] estimated treatment effect, 4.6 [–2];  $P = 0.02$ ), a trend toward lower symptom intensity (mean, –27.8 [15];  $P = 0.06$ ) and less depressed mood (mean, –1.8 [0.81];  $P = 0.02$ ) as compared with the usual care group. Subset analyses for participants who died during the study revealed a similar pattern of effects with higher quality of life (mean, 8.6 [3.6];  $P = 0.02$ ), no difference in symptom intensity (mean, –24.2 [20.5];  $P = 0.24$ ), and less depressed mood (mean, –2.7 [1.23];  $P = 0.03$ ) in the intervention group. There were no differences between the intervention and usual care groups in number of days in the hospital (6.6 vs. 6.5;  $P = 0.14$ ), number of days in the ICU (0.06 vs. 0.06;  $P > 0.99$ ), or number of emergency department visits (0.86 vs. 0.63;  $P = 0.53$ ).

**Conclusion.** Patients receiving a nurse-led palliative care intervention administered concurrently with anticancer treatment reported higher quality of life and less depressed mood than patients receiving usual care. However, the intervention had minimal effect on symptom intensity and no effect on resource use.

### Commentary

Despite advances in screening and treatment, half of all patients diagnosed with cancer will die from the disease [1]. Most patients dying from cancer experience untreated or undertreated symptoms such as pain, labored breathing, nausea, confusion, and psychological distress [2]. Thus improvements in the scope and quality of palliative care are badly needed, yet the majority of cancer research and treatment continues to focus on attempts to cure [3,4]. Barriers to

improving palliative care for cancer include lack of adequate training for clinicians, the separation of palliative and anti-cancer treatments, inadequate standards and accountability, public misperceptions about palliative care, lack of reliable data, disparities in care by race/ethnicity and socioeconomic status, and low levels of investment in palliative care efforts and research [3].

The Project ENABLE II investigators designed a multifaceted palliative care intervention administered concurrently with anticancer treatment in patients recently diagnosed with advanced disease. In this randomized clinical trial, the telephone-based intervention resulted in improved quality of life and mood, and the magnitude of difference appeared to be both clinically and statistically significant. Effects on symptom intensity were minimal and resource use remained unchanged. The failure of this trial to demonstrate significant effects on symptom intensity may be due to the focus of the intervention on patient activation rather than direct symptom measurement and treatment, or the fact that the overall level of symptom intensity for all participants was low. This study is one of very few well-designed and conducted trials of a palliative care intervention to demonstrate an overall positive and clinically significant effect [5].

Several limitations should be considered in the interpretation of these findings. First, 99% of participants were Caucasian, reflecting the lack of ethnic diversity in the area of rural New England where data were collected. Racial/ethnic disparities in palliative care are well documented [3], and further research is needed to address the acceptability and effectiveness of palliative care interventions in diverse populations. Second, the extent of caregiver involvement in the intervention was not detailed, and there was no measurement of caregiver outcomes such as stress or de-

pression. Third, the authors did not discuss the possibility of changes to usual care over the course of the 5-year study or contamination of the usual care group. Given the evolving state of palliative care and the fact that all participants received care at the same institutions, such changes and contamination seem likely and would be expected to reduce the magnitude of differences. Finally, further work is needed to demonstrate the feasibility and costs of the intervention in clinical settings.

### Applications for Clinical Practice

A multifaceted, nurse-led palliative care intervention appears to improve the quality of life and mood of patients with advanced cancer. This intervention can be administered primarily by telephone and concurrent with anticancer treatment. Further research is needed to evaluate the intervention's effect in diverse patient populations and settings.

—Review by Yael Schenker, MD

### References

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