Presented By: Marcello Venditti, March 3rd, 2010
Reference: The Project ENABLE II Randomized Controlled Trial

Abstract:
Context: There are few randomized controlled trials on the effectiveness of palliative care interventions to improve the care of patients with advanced cancer.

Objective: To determine the effect of a nursing-led intervention on quality of life, symptom intensity, mood, and resource use in patients with advanced cancer.

Design, Setting, and Participants Randomized controlled trial conducted from November 2003 through May 2008 of 322 patients with advanced cancer in a rural, National Cancer Institute-designated comprehensive cancer center in New Hampshire and affiliated outreach clinics and a VA medical center in Vermont.

Interventions: A multicomponent, psychoeducational intervention (Project ENABLE [Educate, Nurture, Advise, Before Life Ends]) conducted by advanced practice nurses consisting of 4 weekly educational sessions and monthly follow-up sessions until death or study completion (n = 161) vs. usual care (n = 161).

Main Outcome Measures: Quality of life was measured by the Functional Assessment of Chronic Illness Therapy for Palliative Care (score range, 0-184). Symptom intensity was measured by the Edmonton Symptom Assessment Scale (score range, 0-900). Mood was measured by the Center for Epidemiological Studies Depression Scale (range, 0-60). These measures were assessed at baseline, 1 month, and every 3 months until death or study completion. Intensity of service was measured as the number of days in the hospital and in the intensive care unit (ICU) and the number of emergency department visits recorded in the electronic medical record.

Results: A total of 322 participants with cancer of the gastrointestinal tract (41%; 67 in the usual care group vs. 66 in the intervention group), lung (36%; 58 vs. 59), genitourinary tract (12%; 20 vs. 19), and breast (10%; 16 vs. 17) were randomized. The estimated treatment effects (intervention minus usual care) for all participants were a mean (SE) of 4.6 (2) for quality of life (P = .02), –27.8 (15) for symptom intensity (P = .06), and –1.8 (0.81) for depressed mood (P = .02). The estimated treatment effects in participants who died during the study were a mean (SE) of 8.6 (3.6) for quality of life (P = .02), –24.2 (20.5) for symptom intensity (P = .24), and –2.7 (1.2) for depressed mood (P = .03). Intensity of service did not differ between the 2 groups.

Conclusion: Compared with participants receiving usual oncology care, those receiving a nurse-led, palliative care–focused intervention addressing physical, psychosocial, and care coordination provided concurrently with oncology care had higher scores for quality of life and mood, but did not have improvements in symptom intensity scores or reduced days in the hospital or ICU or emergency department visits.
Strengths:
- Conducted at a major centre,
- A multi-disciplinary team involvement
- The project focused on important, patient-centered goals such as QoL (by an instrument specifically designed for the palliative population), symptoms intensity, mood and resource use.
- Used stringent statistical definitions – that group differences for QoL and mood scores demonstrated greater than 1 SE (standard error) difference between cohorts.
- The study was also an intention-to-treat analysis.
- Data validates the important role of nursing in end-of-life care.

Weaknesses:
- Limited ethnic and racial representation,
- US health care model, is it universally applicable?
- Several interventions conducted via telephone.
- Finally, is ICU resource use data applicable to our model?
- Resource use data also depended on chart reviews may have missed participants’ use of other health care resources – can comprehensive databases be used to address this?

Relevance to Palliative Care: Palliative patients in a nurse-led, palliative-focused interventions addressing both physical and psycho-social realms have better scores for QoL and mood. Variables such as symptom scores and hospital resource use is not affected by type of specialized nursing care. This study should convince Provincial health authorities nationwide to offer palliative care. True “state of the art of cancer care” should include interdisciplinary attention to supporting physical, psycho-social, and spiritual concerns of our patients and families.