Special Article

The International Conference on Malignant Bowel Obstruction: A Meeting of the Minds to Advance Palliative Care Research

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Abstract

There is a dearth of well-designed clinical research focusing on palliative care in cancer patients, especially those who are near the end of life. Reasons for this include ethical dilemmas in conducting such trials, communication barriers between specialties, and unclear standards for best care practices. To ensure that patients with incurable illnesses are offered the best available care, it is essential to develop and disseminate research methodologies well suited to this population. Given the multidimensional and culture-dependent nature of the end-of-life experience, it is necessary to adopt an interdisciplinary approach to developing research methods. As a means of initiating the process of palliative clinical research methodology development, malignant bowel obstruction (MBO) was used as a model to develop a research protocol. Although many treatment options for MBO have been proposed, existing literature offers little guidance with regard to algorithms for optimal management. To this end, an international leaders in quality-of-life research, ethnocultural variability, palliative medicine, surgical oncology, gastroenterology, major consortium research, medical ethics, and patient advocacy/cancer survivors was convened in Pasadena, California, on November 12–13, 2004. Participants also represented the broad ethnic and racial perspectives required to develop culturally sensitive research methods. Consensus on methodological approaches was attained through vigorous debate. Using the conference-developed MBO model to implement trials will advance palliative care research. J Pain Symptom Manage 2007;34:S1–S6. *© 2007 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.*

Key Words

Palliative care research, malignant bowel obstruction, quality of life, end-of-life care

The Need for Palliative Care Research

Supportive and palliative care has been recognized as an important component of quality care for all cancer patients, particularly for those with advanced or incurable disease.[1–3] Given an estimated 1,372,910 new patients diagnosed with cancer in the United States in 2005 (excluding non-melanoma skin cancers), and approximately 570,280 cancer-related

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deaths,[4] care for those patients who are near the end of life is an essential aspect of cancer care.[5]

Palliative care is an interdisciplinary team approach to care with a focus on comfort and quality of life rather than prolongation of life or "cure" for a patient and their loved ones. Although many treatments currently exist to manage symptoms and complications of advanced cancer, there continues to be a paucity of well-designed prospective clinical trials examining state-of-the-art practices, impeding the further development of evidence-based guidelines. The absence of an established evidence base in many areas of palliative care is at least due in part to major challenges investigators face in designing palliative care trials. Research challenges include ethical issues in conducting such trials, barriers to collaborative research across specialties, and unclear standards for the types of "best care" practices that should be used as part of such trials.[6,7] Consequently, the young specialty of palliative medicine is struggling to develop an evidence base commensurate with that of other specialties, threatening its credibility within the academic arena. In other words, as stated by Casarett, "As long as the randomized controlled trial is the standard by which effectiveness is judged, the field whose interventions have not been proven by this test is at risk of being relegated to second-class status in the medical hierarchy."[8]

In the absence of a firm evidence-based foundation for clinical practice, care for patients with incurable cancer is frequently based on anecdotal evidence and provider experience. Some treatment opportunities may be delayed or never considered at all, and other nonbeneficial and burdensome interventions may be instituted. Regardless of whether the resulting bias is one of over- or under-treatment, optimal care of patients with advanced illness requires a commitment to base treatment approaches on scientific fact rather than anecdotal experience. The National Cancer Policy Board recently agreed with this viewpoint, noting that research addressing the needs of patients with incurable cancers is severely deficient.[1] Increasing research for this population, however, requires more complete description of the specific methodologic and ethical barriers in the realms of palliative and end-of-life care, as well as expert consensus on approaches to developing research strategies and design.

Dilemmas and Barriers to Palliative Care Research

Palliative care researchers must confront distinctive ethical dilemmas and barriers that extend far beyond those of standard research trials.[9] While ethical issues are not unique to patients facing life's end, they are often magnified in this population and compound the potential ethical issues present in all clinical research trials. These include the vulnerability of the population from which study subjects are recruited, high rates of mental incapacity and emotional distress creating challenges to informed consent, addressing conflicts of interest within the dual roles of the clinician-researcher, the invasiveness and increased frequency of testing relative to standard clinical practice, and questions of scientific value that must balance the benefits and burdens of unproven interventions in a population in whom comfort may be a priority. Ethical concerns specific to palliative research include the difficulty in assessing the risks and benefits of research participation; randomization, especially if there is a "no treatment arm"; and the unstable mental status of patients, with difficulty assessing capacity. Methodological challenges include high rates of loss to follow-up due to physical and mental incapacity and death, the biases introduced by the need for surrogate respondents, and the difficulty of determining appropriate outcomes and methods for assessing those outcomes. Within palliative surgery and other invasive specialty areas, specific concerns include the risks of major morbidity and mortality these treatment approaches entail; patient loss of decision-making capacity and management of life-threatening emergencies in the peri-procedure period; difficulty with equipoise[10] when faced with vastly different treatment options (surgical versus nonsurgical); and the "all-or-nothing" nature of surgery, making irrelevant the idea that a patient should be free to withdraw from a study at any time.

Despite the challenges alluded to above, the effectiveness of palliative interventions must