Searching for a Way to Live to the End: Decision-Making Process in Patients Considering Participation in Cancer Phase I Clinical Trials

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Patients enrolled in cancer phase I clinical trials have advanced cancer, and no other standard treatments are available for them. Their cancer is end stage; the overall survival time of patients enrolled in a phase I trial is about 5–9 months (Bachelot et al., 2000; Han et al., 2003). Although patients who participated in phase I trials were aware of their option to decline and understood the risk of toxicities (Agrawal et al., 2006), a reason for participation was to obtain a possible health benefit (Agrawal et al., 2006; Cheng et al., 2000; Cox, 2000; Daugherty et al., 1995; Itoh et al., 1997; Meropol et al., 2003; Moore, 2001; Nurgat et al., 2005; Yoder, O’Rourke, Etnyre, Spears, & Brown, 1997). However, the primary objectives of most cancer phase I clinical trials are to evaluate the safety and toxicity of new medicines and to determine the maximum tolerated dose, not to assess therapeutic response. A recent review of cancer phase I trials reported an overall response rate to treatment of 10.6% and an overall toxicity-related death rate of 0.49% (Horstmann et al., 2005).

Wide disparity exists between patients’ expectations and the objectives of studies; therefore, patients who consider participation in a phase I trial should carry out a thoughtful decision-making process. The decision-making process regarding participation in a phase I trial is a situation in which patients with end-stage cancer should assess whether they would be receiving an anticancer treatment with a low response rate and unknown toxicity. Patients who had been invited but declined to participate in phase I trials have chosen to undergo only palliative care. Although carrying out strategies related to successful clinical trial participation is important (Lengacher et al., 2001), nurses should equally support patients who decline phase I trials and choose to undergo only palliative care. Whether or not to participate in a phase I trial is a significant decision that is associated with the patient’s view of end of life. Therefore, supporting patients’ decision making is an important role for nurses.

Few studies have examined the decision-making process of patients considering participation in cancer clinical trials. Schaefer, Ladd, Gergits, and Gyauch (2001)