Early advanced directive planning in stage III and IV cancer patients

A. Study Purpose and Rationale

Advanced directives (AD) consist of legal documents which designates a person’s treatment preferences and nominates a health care proxy to make medical decisions on their behalf [1]. The benefit of completing an AD is to help ensure that individuals will receive care that is consistent with their wishes. In a survey of patients seen in an outpatient clinic, 93% expressed interest in AD planning with 70% deciding against life-sustaining therapies when asked to imagine themselves in an incompetent state with a poor prognosis [2]. Despite the overwhelming preference for these discussions, in reality only 18-36% of Americans have a completed AD [1]. In the absence of known preferences, the seriously ill who present to the hospital may receive more aggressive treatment than what they would want. Patients with advanced cancer are only slightly better with 35-40% of cancer patients having completed their AD [3]. Although this may be true, a large retrospective review only showed that 20% of metastatic cancer patients actually had their code status documented in the electronic medical record [4]. If these discussions are being had, they are not being documented consistently.

Discussions of ADs in cancer patients are often occurring during their hospitalization and at the end of life. A large retrospective analysis found that do-not-resuscitate (DNR) orders were often signed on the day of death, with 34% of these orders signed by surrogates [5]. The lack of AD discussions up until the end-of-life may stem from the reluctance of both patients and oncologists to discuss these topics. In a study looking at cancer patients admitted to an oncology inpatient unit, only 23% of patients without ADs prior to admission wished to have these discussions [3]. The most cited reasons in these patients were that AD discussions were not yet necessary and had no added benefit to their current care. Cancer patients maintain optimism about their prognosis, avoiding discussion of possible death and tend to avoid bringing up emotional and social issues regarding their cancer [6]. Similarly, physicians self-report not initiating discussion on these issues, which are crucial in any discussion of ADs.

The absence of AD planning among advanced stage cancer patients may lead to their poor understanding of their disease severity [7]. In a large prospective cohort study, the majority of patients with stage IV lung and colorectal cancers did not understand that the chemotherapy they were receiving was likely not curative. Surprisingly, 40% of patients with advanced cancer were not in full agreement with their cancer diagnosis [8]. In addition to the lack of complete understanding of one’s illness, withholding this discussion may have potential adverse outcomes for cancer patients [9,10]. Early palliative care in patients with metastatic non-small cell lung cancer resulted in less aggressive end-of-life care, improved quality of life scores, and even improved median survival as compared to standard care [9]. Another study showed that patients without advance care planning prior to hematopoietic stem-cell transplantation in hematologic malignancies was associated with increased mortality at 1 year as compared to patients with ADs when adjusted for covariates [10].

Another commonly reported barrier which may result in this divide in communication is the belief that by addressing end-of-life goals, physicians are stripping away a patient’s hope [11]. A study exposed patients to the estimated effect and survival rates of various chemotherapy regimens, and it found that patients remained hopeful despite this knowledge. Therefore the perceived barriers preventing health care providers from discussing AD early in the patients treatment course should be disregarded. Just
initiating the topic for discussion is shown to be powerful; in a randomly-controlled prospective study where advanced stage cancer patients were exposed to videos of code status discussions, 62% of patients without prior code status determination chose DNR for the video patient [12]. Starting these conversations early in the treatment course leaves adequate time for the patient to assign and discuss their goals of care with a surrogate. A retrospective study showed that inpatient’s took on average, 3 separate discussions before completing their AD [13]. A retrospective study in stage IV cancer patients found that first documentation of end-of-life preferences from diagnosis was a median of 33 days [14]. Therefore, having early AD discussions in late stage cancer patient’s can be done soon after diagnosis and ideally should be done early in their treatment.

The purpose of this study is to determine whether early AD discussions by oncologists in newly diagnosed advanced stage cancer patients results in improved compliance with AD completion within 2 months of this conversation. Only newly-diagnosed advance stage cancer patients with stage III or IV disease will be included as oncologists may be reluctant to initiate these discussions with early stage disease.

B. Study Design and Statistical Analysis

The study is a non-blinded, randomized-controlled, prospective study which contains two phases. Medical oncologists from the New York Presbyterian Hospital campuses at Columbia University and Weil Cornell Medical College will be asked to participate in the study. In the first phase of the study, the mean time of AD completion in newly diagnosed stage III and stage IV cancer patients will be determined within the past 6 months for each oncologist. Completion of the an AD is determined by a completed health care proxy which will be determined by the scanned document present in the patient’s medical chart or physician documentation in the patient’s chart. The median time to AD completion will be determined based upon all results from all the participating oncologists.

In the second phase of the study, oncologists will be stratified into two groups: “early AD” and “late AD” based upon their time to AD completion as being below or above the median time of completion for all oncologists, respectively. Therefore to account for differences in baseline practice of AD discussions, these two groups will be analyzed separately. The two groups will be randomize into either discussing AD within 1 month of the patient’s first visit or to the individual oncologist’s standard of care. When AD is discussed, the estimated duration of AD discussion should be recorded in the patient’s medical chart. Patients with completed AD prior to the study will be excluded. Cancer patients referred to oncologists after having been seen another oncologist will be excluded except if that prior oncologist is participating in the study. In that case, the current oncologist will assume his/her standard of care approach to advance care discussion. Additionally, demographic data will be obtained for all patients and will include age, sex, ethnicity, type of cancer, stage of cancer, and performance status (via ECOG score).

The primary outcome is the completion rate for ADs among all patients 2 months or less, or after 2 months from initiation of AD discussion. A T-test will be performed for the mean completion rate in either the 2 month or less group, or greater than 2 month group. My hypothesis is that oncologists randomized to the arm of early AD discussions will show at least a 5% increase in mean AD completion rate. Given the reported mean of 35-40% of advance cancer patients having AD, to show at least a 5% improvement in AD completion powered to 80% with an alpha of <0.05, I will need 34 oncologists in each group and therefore 68 oncologists total. Currently there are 95 oncologists among the two campuses (56 at Weil Cornell Medical College and 39 at Columbia University), which would require participation of at least 72% among all oncologists.

C. Study Procedure
The entire study will take about 1.5 years with about 8 months of subject participation.

D. Study Drugs
N/A.

E. Medical Device
N/A.

F. Study Questionnaires
N/A.

G. Study Subjects
All oncologists who wish to participate will be included. Patients will be excluded if they have a completed AD prior to the study.

H. Recruitment of Subjects
Oncologists will be recruited by email, paper mail, and flyer.

I. Confidentiality of Study Data
All study data will be uniquely coded for each participating oncologist and their patients. Data will be stored in a secure location, accessible only to the investigators.

J. Potential Conflict of Interest
There are no conflicts of interest.

K. Location of the Study
Studies will be conducted at either Columbia University or Weil Cornell Medical College. IRB will be obtained given the investigator is based at Columbia University but part of the study will be conducted at another institution. IRB approval from Weil Cornell Medical College as well.

L. Potential Risks
N/A.

M. Potential Benefits
N/A.

N. Alternative Therapies
N/A.

O. Compensation to Subjects
No compensation will be given to subjects.

P. Costs to Subjects
Subjects will not incur any costs.

Q. Minors as Research Subjects
N/A.

R. Radiation or Radioactive Substances
N/A.
References: