

**Promoting Advance Care Planning in Patients with Cancer Without Diminishing Hope or Raising Anxiety: an Interactive Computer-Based Decision Aid** Michael Jay Green<sup>1</sup>; Jane R Schubart<sup>1</sup>; Elana Farace<sup>1</sup>; Erik B. Lehman<sup>1</sup>; Megan Whitehead<sup>1</sup>; Benjamin H Levi<sup>1</sup>. <sup>1</sup>Penn State College of Medicine, Hershey, Pennsylvania . (Proposal ID # 11127)

**BACKGROUND:**

Despite agreement that patients with advanced cancer ought to prepare for the future, most do not complete advance directives (AD), and even when they do, physicians often disregard the AD documents at key moments. Among the many reasons for this disregard are concerns that: 1) addressing the topic of advance care planning would diminish patients' hope and raise their anxiety, and 2) lack of knowledge undermines patients' ability to meaningfully complete AD documents that physicians can trust. We developed an interactive computer-based decision aid to help people clarify and articulate their medical treatment preferences in the event they become unable to speak for themselves. The purpose of this study was to determine whether use of the decision aid by patients with advanced cancer would increase their knowledge of advance care planning without diminishing hope or increasing anxiety. The study was sponsored by the American Cancer Society and this in an interim analysis of results.

**METHODS:**

We conducted a randomized controlled trial of advance care planning methods using standard advance directive materials vs. a computer-based decision aid ("Making Your Wishes Known: Planning Your Medical Future"). Patients with advanced cancer (stage 4 disease and life expectancy < 2 years) were recruited from clinics in oncology, surgery, and radiation medicine at a mid-Atlantic academic medical center. Participants were randomly assigned to Control or Intervention Groups, and completed pre/post measures of anxiety (STAI) hope (Herth Hope Index), and knowledge (27 items). Changes in group mean scores from baseline to post-intervention were compared using a repeated measures mixed model adjusted for the baseline measure.

**RESULTS:**

139 individuals were enrolled and 138 completed the protocol (mean age 61 years, range 22-87; 39% female; 96% white; 52% with lung, breast, brain or liver cancer; 84% own their own computer). There were no demographic differences between groups. Baseline anxiety was low in both groups (mean=30 in Control and 29 in Intervention Group, where 20 = low anxiety and 80 = high anxiety), and did not increase significantly after advance care planning. Similarly, hopefulness was high (mean = 41 in both groups, where 12 = low hope and 48 = high hope) and did not diminish after advance care planning. Knowledge scores increased in both groups, but significantly more ( $p < 0.01$ ) in the Intervention Group than the Control Group (13% vs 3%). Finally, participants in the Intervention Group expressed significantly greater mean satisfaction with the advance care planning method than those in the Control Group ( $p = 0.03$ ).

**CONCLUSION:**

In this interim analysis, use of our decision-aid for advance care planning resulted in greater knowledge without increases in anxiety or decreases in hope. These findings counter concerns raised by some physicians about the benefits and risks of advance care planning.

**Glycemic Control and Functional Decline in Frail Elders with Diabetes Mellitus** Celia Yau<sup>1</sup>; Catherine Eng<sup>2</sup>; Irena Stijacic Cenzer<sup>3</sup>; Kathy Rice-Trumble<sup>2</sup>; Sei Lee<sup>3</sup>. <sup>1</sup>University of California, San Francisco and San Francisco VA PRIME Program, San Francisco, California ; <sup>2</sup>On Lok Lifeways, San Francisco, California ; <sup>3</sup>San Francisco VA and University of California, San Francisco, Division of Geriatrics, San Francisco, California . (Proposal ID # 11256)

**BACKGROUND:** The American Geriatric Society (AGS) recommends a Hemoglobin A1c (A1c) less than or equal to 8% for frail elders. Diabetes mellitus has been shown to be a strong risk factor for functional limitations in elders. However, it is unclear whether A1c levels are associated with functional outcomes in the frail elderly.

**METHODS:** We examined the relationship between A1c and 2 year decline in activities of daily living (ADL) in frail, nursing-home eligible elders with diabetes enrolled at On Lok Senior Health between 10/2002 and 12/2008. 1,579 A1c measurements in 367 elders were divided into 4 categories (<7, 7-7.9, 8-8.9, and 9+). At baseline and at 2 year follow-up, nursing or occupational therapy categorized each enrollee's ability to perform 5 ADLs as independent, partially dependent or completely dependent, allowing us to identify elders who had declined in ADLs. We used a population averaged mixed-effects Poisson regression to determine the risk of worsening function across A1c values, accounting for clustering of A1c values by patients and adjusting for age, gender, race/ethnicity, length of time at On Lok, baseline function, hospitalizations, ER visits, and comorbidities. We performed analyses stratified by treatment (insulin versus oral antihyperglycemic agents) to determine whether the A1c-ADL relationship differed across treatments.

**RESULTS:** The mean age was 80 years, and 116 patients (32%) were taking oral antihyperglycemics, and 185 patients (50%) were taking insulin. ADL function declined after 58% of A1c measurements. Lower A1c and insulin use were associated with 2-year functional decline ( $p < 0.001$  and  $p = 0.005$ , respectively). In all subjects, compared to patients with intermediate A1c (7-7.9), there was a trend toward patients with A1c <7 being at higher risk for functional decline ( $p = 0.15$ ) and patients with higher A1c (8-8.9) being at lower risk for functional decline ( $p = 0.03$ ). For elders taking oral medications, A1c <7% was associated with a 20% increase in ADL decline ( $p = 0.04$ ). For elders taking insulin, A1c 8-8.9 and 9+ was associated with 18% and 13% decreases in ADL decline ( $p = 0.006$  and  $0.08$ , respectively).

**CONCLUSION:** Among frail, nursing-home eligible community-living elders, higher A1c levels (>8) is not associated with worse function and may be associated with better function. Our results suggest that the current American Geriatrics Society A1c target of less than or equal to 8% for frail elders may be lower than is necessary to maintain function for this vulnerable population.

**An International, Randomized Non-Inferiority Trial of Outpatient Versus Inpatient Treatment for Pulmonary Embolism** Drahomir Aujesky<sup>1</sup>; Pierre-Marie Roy<sup>2</sup>; Franck Verschuren<sup>3</sup>; Marc Righini<sup>4</sup>; Joseph Osterwalder<sup>5</sup>; Michael Egloff<sup>6</sup>; Bertrand Renaud<sup>7</sup>; Peter Verhamme<sup>8</sup>; Catherine Legall<sup>9</sup>; Olivier Sanchez<sup>10</sup>; Roslyn A. Stone<sup>11</sup>; Nathan Pugh<sup>12</sup>; Alfred Ngako<sup>7</sup>; Jacques Cornuz<sup>13</sup>; Olivier Hugli<sup>14</sup>; Hans-Juerg Beer<sup>6</sup>; Arnaud Perrier<sup>4</sup>; Michael J. Fine<sup>11</sup>; Donald M. Yealy<sup>12</sup>. <sup>1</sup>Bern University Hospital, Bern, N/A ; <sup>2</sup>University of Angers, Angers, N/A ; <sup>3</sup>University of Louvain, Louvain, N/A ; <sup>4</sup>University of Geneva, Geneva, N/A ; <sup>5</sup>Cantonal Hospital of St. Gallen, St. Gallen, N/A ; <sup>6</sup>Cantonal Hospital of Baden, Baden, N/A ; <sup>7</sup>Creteil University Hospital, Creteil, N/A ; <sup>8</sup>University of Leuven, Leuven, N/A ; <sup>9</sup>University of Argenteuil, Argenteuil, N/A ; <sup>10</sup>Hopital Europeen Georges Pompidou, Paris, N/A ; <sup>11</sup>University of Pittsburgh and VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania ; <sup>12</sup>University of Pittsburgh, Pittsburgh, Pennsylvania ; <sup>13</sup>University of Lausanne, Lausanne, N/A . (Proposal ID # 10107)

**BACKGROUND:** Although medical specialty practice guidelines recommend outpatient treatment for selected, hemodynamically stable patients with pulmonary embolism (PE), the outcomes of outpatient management remain unknown. Our aim was to compare the effectiveness and safety of managing low-risk patients with PE in the outpatient versus inpatient setting.

**METHODS:** We conducted an international, randomized non-inferiority trial at 19 emergency departments (EDs) in Europe and the United States. We randomly assigned 344 consecutive patients (02/2007-06/2010) with acute, symptomatic, objectively confirmed PE who were at low risk of death (PE Severity Index risk classes I and II) to initial outpatient versus inpatient treatment with subcutaneous enoxaparin for at least 5 days, followed by oral anticoagulation for at least 90 days. Patients assigned to outpatient treatment received standardized teaching on self-injection with enoxaparin and were discharged from the ED within 24 hours of randomization. Patients assigned to receive inpatient treatment were admitted to the hospital, with their readiness for hospital discharge autonomously determined by their treating physicians. The primary outcome was symptomatic, objectively confirmed, recurrent venous thromboembolism (VTE) within 90 days; secondary outcomes were 90-day mortality, major bleeding at 14 and 90 days, and medical resource utilization (i.e., hospital bed-days). We compared the percentages of outpatients and inpatients that experienced recurrent VTE, death, and major bleeding. Non-inferiority was defined a priori as an exact upper 95% confidence interval (CI) limit of less than 4% for the difference. We analyzed data according to the intention-to-treat principle.

**RESULTS:** Overall, 1 (0.6%) of 171 patients randomized to outpatient care and 0 of 168 patients randomized to inpatient care developed recurrent VTE within 90 days ( $P=0.001$ ; 95% upper CI limit=2.7%). Only 1 (0.6%) patient in each treatment arm died within 90 days ( $P=0.005$ ; 95% upper CI limit=2.1%). Within 14 days, 2 (1.2%) outpatients and 0 inpatients had major bleeding ( $P=0.001$ ; 95% upper CI limit=3.6%). Collectively, these results support non-inferiority for recurrent VTE, mortality, and major bleeding. Within 90 days, 1 additional outpatient developed major bleeding, totaling 3 (1.8%) outpatients and 0 inpatients with this outcome ( $P=0.086$ ; 95% upper CI limit=4.5%); although the 95% upper CI limit slightly exceeds our non-inferiority threshold, this third bleeding episode occurred on day 50 and was not temporally related to the initial use of enoxaparin or randomization to outpatient treatment. Outpatients had a significantly shorter length of stay than inpatients (0.5 vs 3.9 days;  $P<0.001$ ).

**CONCLUSION:** In low-risk patients defined using the PE Severity Index, outpatient treatment with low-molecular-weight heparin is feasible, is not less effective or safe than inpatient treatment, and provides a substantial reduction in health care resource use.