Survival of Clinical Trial Subjects vs. Elderly Medicare Patients w/ Extensive Stage Small Cell Lung Cancer Following Treatment with Cisplatin & Etoposide

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Motivation

- Medicare spends billions of dollars annually on chemotherapy drugs for elderly Medicare beneficiaries

- What happens when trial-developed regimens are applied to elderly patients treated in the usual care setting?
Among pts with ES SCLC, compare the survival of trial-treated patients to ambulatory usual care-treated elderly Medicare patients after first-line cisplatin/VP16
Methods

- **Data Sources**
  - Clinical trial data from CALGB Protocol 9732
  - Usual care data from NCI’s SEER-Medicare program

- **Cohort Development**
  - Extensive Stage Small Cell Lung Cancer (ES SCLC)
  - Intent to treat w/ first-line cisplatin/VP16 q 21 days
    - Trial cohort treated w/ first chemotherapy as inpatients or outpatients
    - Usual care cohort treated with first chemotherapy in outpatient setting

- **Variables**
  - Outcome variable is all cause mortality
  - Key predictor variable is patient treatment venue identified (i.e., trial vs. usual care)
  - Covariates age, sex, race, area education
Analytic Approach

- Description of cohort attributes
- Kaplan-Meier survival functions
- Tests of equality of survival functions
# Results

<table>
<thead>
<tr>
<th>Variable (Proportion)</th>
<th>All Aged Trial Cohort N=350</th>
<th>Elderly Usual Care Cohort N=880</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in Years (mean)</td>
<td>61.6</td>
<td>71.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Male</td>
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<td>0.55</td>
<td>0.92</td>
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<tr>
<td>Race</td>
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<td>White</td>
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<td>0.91</td>
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<tr>
<td>Black</td>
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<td>0.05</td>
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</tr>
<tr>
<td>Other</td>
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<td>0.04</td>
<td></td>
</tr>
<tr>
<td>Area College Education</td>
<td>0.21</td>
<td>0.25</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Survival of ES Small Cell Lung Cancer Patients After First-Line CDDP/VP16

Median Survival
- All Aged Trial Patients: 10.2 mos
- Elderly Usual Care Patients: 8.5 mos

Log-rank test p<0.01
# Results

<table>
<thead>
<tr>
<th>Variable (Proportion)</th>
<th>Elderly Trial Cohort N=122</th>
<th>Elderly Usual Care Cohort N=880</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>71.6</td>
<td>71.5</td>
<td>0.76</td>
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<tr>
<td>Male</td>
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<td>White</td>
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</tbody>
</table>
Survival of Elderly ES Small Cell Lung Cancer Patients After First-Line CDDP/VP16

Median Survival
- Elderly Trial Patients: 8.5 mos
- Elderly Usual Care Patients: 8.7 mos

Log-rank test p=0.91
Conclusion

- Clinical trial results over-estimate the survival of elderly Medicare patients treated in the ambulatory usual care setting.
- Subset analyses suggest patient age may mediate the observed survival difference.
- Reporting trial results by patient age may yield more accurate survival estimates for usual care elderly Medicare patients.
Acknowledgements

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