Results: PRs alone reported smaller PRO changes than those PRs with 5% improvement in FVC for dyspnea, pain, and symptom distress. Those with PD alone reported similar change to those with PD and < 5% improvement in FVC. The highest prediction rate (78.4%) was achieved by a combination discriminant of patient-reported dyspnea and FVC; however, combining either two PROs (ie, dyspnea and activity level) or all PROs achieved nearly the same prediction rate (77% and 78%, respectively).

Mean Changes from Baseline and Prediction Rates

<table>
<thead>
<tr>
<th>Item</th>
<th>PR (n=125)</th>
<th>PR and &gt;5% FVC (n=49)</th>
<th>PD (n=120)</th>
<th>PD and &lt;5% FVC (n=50)</th>
<th>Prediction Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspnea</td>
<td>6.4</td>
<td>11.6</td>
<td>-18.8</td>
<td>-21.8</td>
<td>73.1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.5</td>
<td>1.9</td>
<td>-22.0</td>
<td>-22.7</td>
<td>71.3</td>
</tr>
<tr>
<td>Pain</td>
<td>11.1</td>
<td>16.9</td>
<td>-12.3</td>
<td>-15.1</td>
<td>71.0</td>
</tr>
<tr>
<td>Symptom distress</td>
<td>5.8</td>
<td>9.2</td>
<td>-16.5</td>
<td>-16.2</td>
<td>67.3</td>
</tr>
<tr>
<td>Activity level</td>
<td>3.7</td>
<td>1.8</td>
<td>-22.6</td>
<td>-22.5</td>
<td>71.9</td>
</tr>
<tr>
<td>Global quality of life</td>
<td>4.6</td>
<td>1.9</td>
<td>-21.6</td>
<td>-20.4</td>
<td>72.5</td>
</tr>
<tr>
<td>All PROs</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>78.0</td>
</tr>
<tr>
<td>FVC</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>67.2</td>
</tr>
<tr>
<td>Dyspnea/FVC</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>78.4</td>
</tr>
<tr>
<td>Dyspnea/Activity level</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

A. Visual Analogue Scale (0-100 mm) for each PRO item. Positive value indicates improvement.
B. Number of radiological PR+SD correctly classified by discriminant plus number of radiological PD correctly classified by discriminant divided by total sample size; sample sizes are approximately 410 for PROs and 296 for FVC.

Conclusions: Changes in patient-reported LCSS-Meso items correlate with radiological response to therapy. PROs appear to be at least as sensitive in predicting response to therapy as objective measures such as FVC. The LCSS-Meso may serve as an effective, inexpensive, and easy-to-administer alternative to radiological assessment for monitoring response to therapy for MPM. Prospective studies are needed to confirm these findings.

CS-04 Mesothelioma, Wed, 10:30 - 12:15
Exploring alternate methods to monitor therapy in Malignant Pleural Mesothelioma (MPM): comparing Radiological Response with Pulmonary Function Tests (PFTs) and Patient-reported Outcomes (PROs) using the LCSS-Meso Instrument. A study based on 410 patients from the EMPHASIS trial
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Background: Tumor growth in MPM presents technical challenges in measuring tumor volume or response radiographically even when using advanced imaging techniques. Additionally, MPM is highly symptomatic with nearly all patients presenting with three or more symptoms. Of major symptoms, dyspnea is rated by patients as having the greatest severity (Gralla ASCO 2003). Prior analyses indicated that improvement in Forced Vital Capacity (FVC) correlated with improvements in patient-reported dyspnea (Gralla WCLC 2005) and that radiological response correlated with improvements in FVC (Paoletti ASCO 2003). This analysis was undertaken to determine whether dyspnea and other PROs of the 8-item LCSS-Meso and PFTs can enhance or replace radiological evaluation in monitoring response to therapy.

Methods: We analyzed data from 410 patients from the randomized MPM trial of cisplatin ± pemetrexed (Vogelzang JCO 2003). Changes from baseline in PROs and FVC were calculated at the time of response for patients with an investigator-determined radiological major response (PR), at first evidence of at least stable disease (SD) for patients with best response of SD, or at discontinuation for patients with best response of progressive disease (PD). PROs considered are reported in the table. Changes in PROs were summarized by radiological subgroup which were further restricted to patients with or without an FVC improvement of at least 5%. Discriminant analyses were conducted to classify patients into two groups: PR+SD vs PD using changes in PROs and FVC as predictors. Prediction rates from the discriminant analyses were calculated as the number of correctly classified patients divided by total sample size.

<table>
<thead>
<tr>
<th>Median age (range) (years)</th>
<th>P</th>
<th>P+Cis</th>
<th>P+Cb</th>
</tr>
</thead>
<tbody>
<tr>
<td>63.0 (31, 85)</td>
<td>59.5 (26, 77)</td>
<td>61.0 (25, 80)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Karnofsky performance status ≥ 80, % of pts</th>
<th>75.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR, % of pts (95% CI)</td>
<td>74.5</td>
</tr>
<tr>
<td>Disease control rate (responders +SD), % of pts, (95% CI)</td>
<td>50.8 (53.0, 63.0)</td>
</tr>
<tr>
<td>One-year survival rate, % (95% CI)</td>
<td>54.7 (42.6, 66.8)</td>
</tr>
<tr>
<td>Median TTPD (months) (95% CI)</td>
<td>4.9 (4.2, 5.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leukopenia, Gr 3/4, % of pts</th>
<th>13.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia, Gr 3/4, % of pts</td>
<td>15.6</td>
</tr>
<tr>
<td>Thrombocytopenia, Gr 3/4, % of pts</td>
<td>4.9</td>
</tr>
<tr>
<td>Anemia, Gr 3/4, % of pts</td>
<td>9.2</td>
</tr>
</tbody>
</table>

*Approximately 95% of pts in each treatment arm contributed PS data.

CS-05 Mesothelioma, Wed, 10:30 - 12:15
The yield of EUS-FNA in early stage malignant pleural mesothelioma
Tournoy, Kurt1 Burgers, Jacobus A.2 Meerbeeck, Jan v.1 Baas, Paul2
1 University Hospital, Ghent, Belgium 2 Netherlands Cancer Institute, Amsterdam, The Netherlands

Background: Selected patients with limited (cT1-3N0) malignant pleural mesothelioma are being considered for a multimodality therapy with induction chemotherapy followed by extrapleural resection and radiotherapy. Since invasion of the mediastinal lymph nodes is a negative prognostic factor, cervical mediastinoscopy is recommended for staging in these patients. Transesophageal Endoscopic Ultrasound with a linear scanning ultrasound endoscope and real time guided fine needle aspiration (EUS-FNA) enables mediastinal lymph node staging with high accuracy in lung cancer patients.