Survey of disease and treatment-related symptoms in outpatients with invasive cancer of the breast, prostate, lung, or colon/rectum (E2Z02, the SOAPP study, Abst # 9619)

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Symptom Outcomes and Practice Patterns (SOAPP): E2Z02 Study Team

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eastern cooperative oncology group (ASCO 2009, Abst # 9619)
Abstract

**Background:** The full spectrum and impact of symptoms experienced by ambulatory patients (pts) in medical oncology clinics throughout their care trajectory is poorly understood.

**Methods:** This large prospective study by the Eastern Cooperative Oncology Group (ECOG) enrolled pts with invasive cancer of the breast, prostate, colon/rectum or lung regardless of phase of care or stage of disease. The study was conducted between 3/06 and 5/08 at multiple academic (n=7) and community (n=32) medical oncology clinics. Pre-defined sampling algorithms were used to reduce selection bias. At baseline and again 4 weeks later, pts completed a 25-item measure of symptoms and functional interference (M.D. Anderson Symptom Inventory-ECOG). Patients' providers simultaneously prioritized their symptoms.
**Results:** 3123 patients were enrolled (90% from community clinics) and 3106 were analyzable with 1543 breast (50%), 717 colorectal (23%), 522 lung (17%), and 320 prostate (10%) pts. The most prevalent moderate-to-severe symptoms of the full cohort at baseline (B) and follow-up (F) were: fatigue (B34% to F32%), disturbed sleep (B27% to F21%), drowsiness (B23% to F21%), hair loss (B20% to F19%), pain (B19% to F18%), dry mouth (B19% to F15%), and numbness/tingling (B19% to F18%). At baseline, 40% of the cohort had at least 3 moderate-to-severe symptoms and 40% had this attribute at follow-up. Clinician perception of symptoms was strongly correlated with patient symptom survey results regardless of disease site, race, or ethnicity. Of the 1040 advanced disease pts receiving anti-cancer treatment, half had 2 or more metastatic sites with 77% receiving cytotoxic chemotherapy. Clinicians judged lung cancer patients' symptoms to be the most difficult to manage (p<0.01).
Conclusions: Non-pain symptoms, particularly fatigue and sleep disturbance, are a major source of symptom distress in ambulatory medical oncology practice. Overall, symptom burden remains substantial and difficult to resolve. These data will help guide future interventional studies.
E2Z02, A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer: Prevalence, Severity, and Treatment (SOAPP)

- Outpatient medical oncology clinics
- Patients with a common solid tumor
  - breast, prostate, colorectal, or lung cancer
  - Any point in trajectory of illness

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E2Z02, (SOAPP): Study Conduct

- Study conducted between March 2006 and May 2008
- 7 academic sites and 32 community practices
- Pre-defined sampling algorithms were used to reduce selection bias
Primary Objective

- To describe the prevalence, severity and interference
  - Due to physical and psychological symptoms
  - In patients with common solid tumors
  - Followed on an outpatient basis at ECOG-affiliated academic institutions or community practices (CCOPs)
Hypotheses

- The symptoms rated most severe at baseline and follow-up will include pain, fatigue, and emotional distress.
- Greater than 30% of patients with advanced disease will have at least 3 moderate-to-severe symptoms despite current symptom management efforts.
- Initial Assessments:
  - Patient Forms
  - Clinician Forms

- Follow-up Assessments:
  - Patient Forms
  - Clinician Forms

28-35 Days

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Study Measures: Baseline and 1-Month Follow-up (Day 28-35)

- **Patient-Reported Symptoms**
  - MDASI-ECOG

- **Medications**
  - Current and newly prescribed

- **Consults/Other Maneuvers**
  - Current and newly prescribed or pursued

- **Clinician questionnaire**
  - Prioritize symptoms and estimate degree of difficulty, QOL, etc.
MDASI-ECOG (25 items)

- **13 Core items**
  - Pain, fatigue, nausea, disturbed sleep, being distressed (upset), shortness of breath, difficulty remembering things, lack of appetite, feeling drowsy (sleepy), dry mouth, feeling sad, vomiting, numbness/tingling

- **6 Functional Interference Items**
  - General activity, mood, work, relations with other people, walking, enjoyment of life

- **6 “ECOG” items**
  - Diarrhea, constipation, mouth sores, skin rash, hair loss, coughing
Study CONSORT diagram

3123 Enrolled Patients

3106 Analyzable patients

• 10 in pilot study
• 7 never started study (1 ineligible, 1 coding error, 1 registry cancellation, 1 pt refusal, 3 others)

Academic (N=303)

Community (N=2803)

CCOP (N=2327)

MBCCOP (N=476) *

Breast (N=1196)
Colorectal (N=500)
Prostate (N=217)
Lung (N=411)
Unknown (N=3)

Breast (N=232)
Colorectal (N=122)
Prostate (N=40)
Lung (N=51)
Unknown (N=1)
Disease Distribution

- Breast (50%, 1543)
- Colorectal (23%, 717)
- Lung (17%, 522)
- Prostate (10%, 320)
Overall, 681 (22%) Minority participants
Demographics and Patient Characteristics

Median age 61.3 yrs
PS 0/1 = 92%
Academic sites= 9.8% of enrolled cohort

*Overall, 30% (928 pts) were men
## Symptom Findings (% baseline, % follow-up)

- **Hypothesis:** The symptoms rated most severe at baseline and follow-up will include pain, fatigue, and emotional distress.

- **Our findings were:**
  1. **Fatigue** (34, 32)
  2. **Disturbed Sleep** (27, 21)
  3. **Drowsiness** (22, 21)
What are the priority supportive care needs of your patients after the top 3 symptoms?

- **19% Moderate/Severe**
  - pain
  - numbness/tingling
  - distress
  - dry mouth
  - hair loss*

- **16-17% Moderate/Severe**
  - anorexia/cachexia
  - depression
  - cognitive disturbance

*prevalence of 19.6%
<table>
<thead>
<tr>
<th></th>
<th>Breast</th>
<th>Colorectal</th>
<th>Prostate</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>18</td>
<td>18</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>Numb/T</td>
<td>15</td>
<td>25</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Depress</td>
<td>16</td>
<td>14</td>
<td>14</td>
<td>21</td>
</tr>
</tbody>
</table>

*Symptoms rated >=5 on the numerical rating scale (0-10) were considered in moderate/severe range.

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<table>
<thead>
<tr>
<th>Symptom</th>
<th>Range</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>dyspnea</td>
<td>10-15%</td>
<td>15</td>
</tr>
<tr>
<td>diarrhea</td>
<td>10-15%</td>
<td>11</td>
</tr>
<tr>
<td>constipation</td>
<td>&lt;10%</td>
<td>13</td>
</tr>
<tr>
<td>Coughing</td>
<td>&lt;10%</td>
<td>10</td>
</tr>
<tr>
<td>nausea</td>
<td>&lt;10%</td>
<td>8</td>
</tr>
<tr>
<td>vomiting</td>
<td>&lt;10%</td>
<td>3</td>
</tr>
<tr>
<td>sore mouth</td>
<td>&lt;10%</td>
<td>5</td>
</tr>
<tr>
<td>rash/pruritis</td>
<td>&lt;10%</td>
<td>6</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th></th>
<th>BR</th>
<th>CR</th>
<th>PR</th>
<th>LUNG</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 Sx&gt;\geq7</td>
<td>42</td>
<td>43</td>
<td>37</td>
<td>59</td>
</tr>
<tr>
<td>At least 1 Fx\geq7</td>
<td>21</td>
<td>24</td>
<td>24</td>
<td>37</td>
</tr>
<tr>
<td>% rated “difficult”**</td>
<td>9.2</td>
<td>7.2</td>
<td>7.6</td>
<td>13</td>
</tr>
</tbody>
</table>

**Clinician-judgment about the *degree of difficulty* in caring for the patient’s physical and psychological symptoms (relative to other patients with same stage of disease)
Multiple Difficult Symptoms: A Pervasive Problem

- Hypothesis: Greater than 30% of patients with advanced disease will have at least 3 moderate-to-severe symptoms despite current symptom management efforts
  - At baseline 40% of the cohort had at least 3 moderate to severe symptoms (36% had this attribute at follow-up)

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Clinician perception of symptoms was strongly correlated with patient symptom survey results.

- Spearman Rank correlations 0.85-87
- Regardless of disease site, race, ethnicity

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38% Advanced Disease, 74% Being Treated

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>No Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adv</td>
<td>1040 (34%)</td>
<td>133 (4%)</td>
</tr>
<tr>
<td>Non-Adv</td>
<td>1235 (40%)</td>
<td>684 (22%)</td>
</tr>
</tbody>
</table>

*Notice that there are few patients with advanced disease not receiving cancer treatment in these outpatient oncology clinics.*
### Characteristics of Advanced Disease Patients on Treatment (N=1040)

<table>
<thead>
<tr>
<th>Disease</th>
<th>(%)</th>
<th>PS 0/1</th>
<th>Age</th>
<th>Time from Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>36</td>
<td>86</td>
<td>58</td>
<td>57 mos</td>
</tr>
<tr>
<td>Colorect</td>
<td>29</td>
<td>90</td>
<td>62</td>
<td>19 mos</td>
</tr>
<tr>
<td>Lung</td>
<td>20</td>
<td>80</td>
<td>65</td>
<td>7.6 mos</td>
</tr>
<tr>
<td>Prostate</td>
<td>15</td>
<td>83</td>
<td>73</td>
<td>54 mos</td>
</tr>
</tbody>
</table>

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Conclusions

- Non-pain symptoms, particularly fatigue, sleep disturbance, and drowsiness, are a major source of symptom distress in ambulatory medical oncology practice.

- Overall, symptom burden remains substantial and difficult to resolve.