Background

- Distress is common amongst patients with advanced cancer and is associated with poor outcomes (Kim et al., 2017).
- In other studies, physical symptom burden is associated with worsened survival (Kim et al., 2017).
- Distress may result from other problem types such as family, emotional or practical measures (Ownby, 2019).
- Financial toxicity as a source of distress has received substantial recent attention in the oncology literature (Carrera et al., 2018).  
- Little is known about the causes, prevalence, and clinical impact of distress on patients enrolling onto phase I clinical trials.

Methods

- Validated tools were used for baseline assessments prior to initiation of a phase 1 clinical trial:
  - NCCN Distress Thermometer (shown below)
  - Stressors - NCCN Problem List (shown below)
  - Hospital Anxiety and Depression Scale
  - Anxiety (HADS-A)
  - Depression (HADS-D)
- Pearson’s product moment correlation tested the relationship between distress and HADS-A and HADS-D.
- Spearman’s rank correlation tested the relationship between distress and the NCCN Problem List categories.

Table 1: Patient Characteristics N = 87

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Yes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male: 48%</td>
</tr>
<tr>
<td>Performance</td>
<td>ECOG 0: 28%</td>
</tr>
<tr>
<td>Disease Site</td>
<td>GI: 32%</td>
</tr>
<tr>
<td>Therapy</td>
<td>0-2: 56%</td>
</tr>
<tr>
<td>Presence of Distress</td>
<td>Yes (NCCN DT ≥ 4): 51%</td>
</tr>
<tr>
<td>Presence of Anxiety</td>
<td>Yes (HADS-A ≥ 8): 28%</td>
</tr>
<tr>
<td>Presence of Depression</td>
<td>Yes (HADS-D ≥ 8): 16%</td>
</tr>
<tr>
<td>Grade ≥ 3 toxicity</td>
<td>Yes: 48%</td>
</tr>
</tbody>
</table>

Results

- No significant associations were found between distress and clinical trial outcomes (grade ≥ 3 toxicity, duration on study, hospitalizations, dose reductions, dose interruptions, response rate, disease control rate).
- Top three problems experienced in each category:
  - Practical (treatment decisions, financial, and work/school)
  - Family (partner problems, family health issues, and children problems)
  - Emotional (worry, nervousness, and fears)
  - Physical (pain, sleep problems, and eating problems)

Conclusions

- Baseline distress was prevalent amongst participants in Phase I clinical trials (51%).
- Distress did not negatively impact clinical trial outcomes including toxicity, dose modifications or response rate.
- Emotional, family, practical stressors were associated with higher levels of distress.
- Physical stressors were not associated with higher levels of distress.
- Patients may be better prepared to manage and face physical stressors rather than emotional or practical stressors.
- There may be a lack of support for the emotional, family or practical stressors in patients enrolling on phase 1 trials.

References


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