Performance of PROMIS and Legacy Measures Among Advanced Breast Cancer Patients and Their Caregivers

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Background

• A symptom management trial tested reflexology delivered by friend or family caregivers to patients with advanced breast cancer

• Two samples:
  – clinical sample of women with advanced breast cancer
  – general population sample of their caregivers

• The PROMIS Profile-29 was compared to legacy measures of the same or similar conceptual content
Legacy measures

• Medical Outcomes Study Short Form 36 (SF-36)
• Center for Epidemiologic Studies-Depression (CES-D)
• State Anxiety
• Pittsburgh Sleep Symptom Questionnaire-Insomnia (PSSQ_I)
• M. D. Anderson Symptom Inventory (MDASI)
• Completed by both patient and caregiver, with few exceptions
## Correspondence of measures

<table>
<thead>
<tr>
<th>Domain</th>
<th>PROMIS</th>
<th>Legacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>• Physical function Profile 1.0, 4 items</td>
<td>• SF-36 physical function, 10 items</td>
</tr>
<tr>
<td>Pain</td>
<td>• Pain interference Profile 1.0, 4 items</td>
<td>• SF-36 bodily pain, 2 items</td>
</tr>
<tr>
<td></td>
<td>• Pain severity Profile 1.0, 1 item</td>
<td>• MDASI (patient), 1 item</td>
</tr>
<tr>
<td>Fatigue</td>
<td>• Fatigue Profile 1.0, 4 items</td>
<td>• SF-36 vitality, 4 items</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MDASI (patient), 1 item</td>
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<tr>
<td>Sleep</td>
<td>• Sleep disturbance Profile. 1.0 (caregiver), 4 items</td>
<td>• PSSQ_I sleep quality (caregiver), 5 items, PSSQ_I sleep interference (caregiver), 8 items</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MDASI (patient), 1 item, range 0-10</td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>• Depression Profile 1.0, 4 items</td>
<td>• CES-D, 20 items</td>
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<td></td>
<td></td>
<td>• SF-36 mental health, 5 items</td>
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<tr>
<td></td>
<td></td>
<td>• MDASI (patient), 1 item</td>
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<tr>
<td>Anxiety</td>
<td>• Anxiety Profile 1.0 (patient and caregiver), 4 items</td>
<td>• State Anxiety, 20 items</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MDASI (patient), 1 item</td>
</tr>
<tr>
<td>Social role functioning</td>
<td>• Satisfaction with participation in social roles. Profile 1.0, 4 items</td>
<td>• SF-36 social functioning, 2 items</td>
</tr>
<tr>
<td></td>
<td>• Ability to participate in social roles and activities. Short form 2.0 (caregiver), 4 items</td>
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Objective

To compare measures for both members of the patient-caregiver dyads with respect to:

• Length
• Distributions in patient and caregiver samples
• Correlations between pairs of measures of the same or similar construct (concurrent or convergent validity)
• Ability to discriminate patient and caregiver subgroups (known groups validity)
• Ability to discriminate groups with respect to interventions received (responsiveness)
N=256 dyads were recruited from 2 comprehensive cancer centers and 5 community-based oncology settings in the Midwest.

Patients:
- age 21 or older (actual mean=56, SD=11)
- treated with chemotherapy, targeted or hormonal therapy for advanced breast cancer
- had a friend or family caregiver participating with them

Caregivers:
- age 18 or older (actual mean=55, SD=15)
- identified as a caregiver by the patient (55% spouses)
- able and willing to provide the 30-minute reflexology protocol for 4 consecutive weeks
Study procedures

- Baseline telephone interview for patients and caregivers

- Randomization to attention control versus 4 weeks of reflexology delivered to patient by the caregiver

- For intervention dyads, caregivers were trained in standardized 30-minute protocol of stimulating 9 reflexes

- Week 5 (post-intervention) telephone interview, follow up at week 11

- For this report, data from baseline and week 5 interviews were used
Data analyses

- **Distributions**, % at floor (worst), % at ceiling (best), correlations
- **Known groups validity**: comparisons of subgroups according patient’s cancer recurrence and metastasis, treatment type, comorbidity
- **Responsiveness**: intervention effect using two sets of measures. General linear models for outcomes at week 5; trial arm and baseline value were covariates.
- Focus on **consistency of conclusions** and magnitude of the effect sizes for PROMIS and legacy measures
- **Effect size (Cohen’s d)**: difference between subgroup means expressed in the standard deviation units
Results: length

- The SF-36 physical functioning and mental health, legacy measures of sleep, anxiety and depression are longer than the corresponding PROMIS short forms.
- In contrast, legacy measures of the cancer-related symptoms (MDASI) are single items, while PROMIS short forms have 4 items for each symptom.
- The 2-item SF-36 social role functioning is shorter than the PROMIS “Ability to participate in social roles” and “Satisfaction with participation in social roles.”
- The 4-item SF-36 vitality is the same length as the corresponding PROMIS fatigue short form.
Distributions, floor and ceiling effects

- Floor effects were not substantial; ceiling effects were pronounced and greater for caregivers than patients.
- Shorter length was associated with greater percentage of observations at the ceiling.
- Best PROMIS physical function for caregivers 74% v. 43% with the SF-36.
- Lowest depression with PROMIS 34% for patients, 67% with caregivers versus CES-D 3% for patients, 13% with caregivers.
Concurrent and convergent validity

- The majority of the correlations were strong (r=0.6+) or very strong (r=0.8+), with only a few exceptions

- **Moderate correlations**: PROMIS satisfaction with participation in social roles with the SF-36 social functioning (r=0.57 for patients; r=0.44 for caregivers)

- PROMIS depression and severity of distress from MDASI: r=0.58 for patients
Known groups validity

• Similar effect sizes were observed for the differences between known groups, e.g. those with 2+ comorbid conditions v. <2, according to cancer recurrence and treatment type (patients)
• Patients with metastatic v. loco-regional disease:
  - differences in pain with the MDASI single item pain severity rating (d=0.30, p=0.02);
  - SF-36 bodily pain subscale produced smaller effect size (d=.19, p=0.15);
  - even smaller effect sizes were observed using the PROMIS pain interference and severity measures
Responsiveness

- Similar medium effect sizes were seen for reflexology versus attention control groups for pain, fatigue, and anxiety using PROMIS and legacy.
- Post-intervention differences in patient depression were sizable (~ 1/3 of the SD) when assessed by the CES-D and the SF-36 mental health subscale, but not with PROMIS (d=.09). For the MDASI single item distress severity d=0.31.
- The same pattern with similar effect sizes was also seen with caregiver depression.
- Content differences in PROMIS depression item banks and the CES-D have been previously noted.
Conclusions

• Evidence of validity and reduced respondent burden support the use of shorter assessments for symptoms (MDASI, PROMIS) and functioning (PROMIS) in clinical and general populations

• The use of longer instruments such as the CES-D or the SF-36 mental health may have advantages in measuring depression over PROMIS SF-4

• Publicly available transparent scoring for PROMIS Profile-29 and the CES-D