Introduction

The Pain Assessment for Lower Back Symptoms (PAL-S) is a patient-reported outcome (PRO) measure designed to assess the severity, bother, and spontaneous reports of expressed symptoms related to chronic low back pain in adults. It is a 14-item instrument that can be used to evaluate current pain severity, pain disturbance, and the construct validity of pain-related quality of life (QoL) measures.

Methods

The study was conducted in the UK and Germany to support content validity and address the key symptoms of chronic low back pain (CLBP) through qualitative concept elicitation (CE) and cognitive interviews (CI).

Study Design

Qualitative interviews were conducted with patients with low back pain in the UK and Germany to assess the content validity of the PRO measure.

Study Population

Inclusion Criteria

- English-speaking patients
- Subject was eligible if they could read, write, and speak English well enough to understand and complete informed consent form (ICF) and take part in the interview
- Participants in Germany were native German speakers, and their interviews were conducted in German, which was translated into English.

Exclusion Criteria

- Men and female subjects 18 to 50 years of age
- Clinical diagnosis of CLBP of non-malignant origin, with pain present for at least 3 months

The pain level of the patient was rated using the Numerical Rating Scale (NRS), which ranges from 0 to 10, with 0 indicating no pain and 10 indicating the worst possible pain.

Cognitive Interviews

- Determined by number of patient expressions, the most prevalent symptom-related concepts (greater than 6.8% of total) were “Unspontaneous Pain,” “Unspontaneous Pain,” “Hurt,” “Numbness,” and “ache.”

Table 2: Concepts Assessed in PAL-S Items

- The newly-identified instrument, the Pain Assessment for Lower Back Symptoms is a 14-item PRO measure that assesses each concept at the most intense using an 11-point (0-10) numeric rating scale.

Conclusions

- The PAL-S is a 14-item PRO measure intended for use in research and clinical trials to support meaningful pain assessment in low back pain.

Qualitative interviews have provided evidence for content validity.

Cognitive interviews provided evidence that the instructions, items, and response options are comprehensive, easy to complete, and align with key symptom assessments of CLBP that are common in clinical practice.

Future qualitative studies are underway to confirm the measurement properties of the instrument.

Table 1: Participant Demographic and Clinical Characteristics

<table>
<thead>
<tr>
<th>Participant Characteristic</th>
<th>Gender</th>
<th>Age Group</th>
<th>Disease Duration</th>
<th>Pain Intensity (NRS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>30%</td>
<td>40-50</td>
<td>5-10 years</td>
<td>7.5 (5.0-10.0)</td>
</tr>
<tr>
<td>Female</td>
<td>70%</td>
<td>30-40</td>
<td>2-5 years</td>
<td>6.0 (4.0-8.0)</td>
</tr>
</tbody>
</table>

The table above provides the demographic characteristics of the study participants, including gender, age group, disease duration, and pain intensity on a 11-point numeric rating scale (NRS). It highlights the distribution of these characteristics among the study participants, with a majority being female and ranging in age from 30 to 40 years. The disease duration spans from 2 to 5 years, and the pain intensity is reported with a median of 6.0 (4.0-8.0) on the NRS scale.

Conclusion

The Pain Assessment for Lower Back Symptoms (PAL-S) is a validated PRO measure that assesses the severity, bother, and spontaneous reports of expressed symptoms related to chronic low back pain in adults. It is a 14-item instrument that can be used to evaluate current pain severity and disturbance, and it has been developed in accordance with the FDA PAQ Guidance and best practices. Qualitative interviews have provided evidence for content validity, and cognitive interviews have confirmed the comprehensiveness and alignment with key symptom assessments of CLBP. Future qualitative studies are planned to further confirm the measurement properties of the instrument.